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THE CASE OF SULFA AND THE SWINE SUBSECTOR

presented by

Carol S. Kramer

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Doctor of Philosophy degree in Agricultural Economics

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AN ECONOMIC ANALYSIS OF FOOD SAFETY REGULATION: THE CASE OF SULFA AND THE SWINE SUBSECTOR

By

Carol S. Kramer

G 117705

A DISSERTATION

Submitted to
Michigan State University
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ABSTRACT

AN ECONOMIC ANALYSIS OF FOOD SAFETY REGULATION:
THE CASE OF SULFA AND THE SWINE SUBSECTOR

By

Carol S. Kramer

This research analyzes the economics of food safety regulation emphasizing the case of sulfa contamination in swine. Since 1973, illegal sulfa drug residues have been found in 4 to 15 percent of sampled swine. Sulfa use, contamination, and regulation affect a variety of food system participants.

The research identifies and analyzes diverse policy approaches to residue problems in livestock; 1) a drug ban; 2) increased residue tolerance levels; 3) combined research, educational, compliance efforts; 4) regulation directed at the feed industry, including proposed "Second Generation" policies; 5) altered inspection and livestock marketing rules, including in-plant chemical screening and animal identification systems.

Policy impacts on firm decision-making and food system performance are examined. Emphasized are changes in consumer exposure to illegal residues, public program costs, and economic impacts for consumers and other subsector participants. To examine economic impacts of food safety regulations, an analytical model of firm decision-making throughout the swine subsector was developed.

Factors considered include market and firm structure, major economic interests in sulfa, and interactions between participants.

Four principal industries are involved in the sulfa case: animal health, commercial feed, swine and meat packing. Their economic interests include sulfa as a revenue-producing product, an input, a contaminant. Decision-making in regulatory agencies, where sulfa is primarily a policy problem, was also examined.

Data collection involved 108 interviews with a purposively selected sample of management and staff within animal health, feed, swine and meat packing industries, federal and state regulatory agencies and universities.

Research conclusions indicate that relative efficacy and economic impacts of alternative regulatory policies depend upon: policy objectives, elimination versus control of contaminants; placement of regulatory controls within the subsector; structure of the regulated industry and policy design (scope, technologies employed, financing methods). Annual public program costs are negligible for a drug ban or tolerance increase. They range between $4 million for research-education-inspection efforts to over $8 billion for comprehensive plant-site screening of live hogs. A ban would effectively eliminate consumer exposure to illegal residues. Residue control is attainable combining information and compliance activities with sulfa granulation. A systems approach to food safety regulatory design is recommended.

To the marathon runners in my life:
Kramers, Benedicts, Newmans--Mark,
Amanda and Peter--Jim Shaffer, Clark
Burbee, Helyn Marshall.

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For errors of fact, emphasis or analysis, I must steadfastly claim credit.

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CHAPTER I

INTRODUCTION

This research presents a case study of an important U.S. food safety regulatory issue: the presence of illegal sulfa residues in swine and pork products. Two sulfa compounds, sulfamethazine and sulfathiazole, are widely used in U.S. swine production for purposes of disease prevention and treatment, enhancement of feed efficiency and growth acceleration.

While their value in production is widely appreciated, so recently has been the frequent occurrence of illegal sulfa residues in pork consumed by humans. Since the United States Department of Agriculture began monitoring for chemical residues in 1973, sulfonamides[1] in swine tissue have presented the most persistent residue problem of any encountered so far--with violative levels consistently found in from 4 to 15 percent of all sampled swine.

This research consists of an economic analysis of several regulatory procedures which have been proposed to resolve food safety problems of the type characterized by sulfa residues in meat. In order to assess impacts of alternative regulatory programs upon food system performance, it is first necessary to understand, describe and analyze the manner in which firms within the food system make economic decisions under status quo

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[1]The sulfonamides are a class of sulphur-containing compounds.

conditions. Subsequently, the modifying effects which various forms of regulation exert upon economic decision-making can be assessed. Modeling firm decision-making permits the explicit consideration of factors which influence the degree of compliance engendered by different regulations and the costs, effectiveness and distributional impacts of food safety regulations in attaining policy goals.

Especially critical to the analysis of food safety policy problems is an adequate understanding of the role of uncertainty and imperfect markets as these affect the several food system participants. Additionally, a familiarity with the body of laws and regulations presently shaping food safety performance facilitates identification of policy changes capable of improving current performance.

1.1 Background and Problem Situation

Ever since the early 1900s, the objective of providing a safe food supply has been a public policy focus in the U.S. With the passage in 1906 and 1907 of the Pure Food and the Meat Inspection Acts, legislators signalled their intent that the market place for food items should not be characterized by a philosophy of caveat emptor where unwholesome, adulterated, misbranded or deceptively packaged products unfairly compete with safe and accurately labeled products due to the inability of consumers to distinguish a difference.

Food safety regulation in the U.S., then, reflects a policy response to actual or potentially unsatisfactory performance of various markets within the food system. Throughout the twentieth century, legislative

and administrative actions have modified and elaborated the earlier laws in response to changing conditions. (For major developments, see Figure 1.1.)

Developments within and outside of the food system in recent decades have altered many aspects of the food safety problem. Of particular relevance to this study is the exponential growth in societal uses of chemical technology; in the food system for improvements in production, processing and packaging; outside the food system for a myriad of other purposes. Rapid growth and seemingly ubiquitous use of chemical products have created difficulties with respect to the design, implementation and enforcement of food safety regulation. Uncertainty associated with the human health and environmental impacts of chemical exposure both pervades and distinguishes policy problems in this area.

It is the nature of uncertainty that society is continually forced to reevaluate many of its most powerful technologies. The latter half of this century has repeatedly demonstrated the inherently complex and ambivalent nature of chemical technology in its many manifestations as growing knowledge proves that technology in application is never neutral nor costless, although frequently providing important benefits.

Frequently a dichotomy can be observed between those bearing costs imposed by use of a chemical technology and those enjoying benefits. The economic term "externality" refers to economic costs or benefits produced in the course of economic activity but neglected in market accounts. This dichotomy between those enjoying benefits and assuming costs complicates social determination of property rights. Additionally,

1890	Meat Inspection Act (for Exported Pork)
1906	Publication of The Jungle (Sinclair Lewis)
1906	Pure Food Act
1907	Federal Meat Inspection Act
1927	Food, Drug and Insecticide Administration created within USDA
1930	Food, Drug and Insecticide Administration name changed to Food and Drug Administration
1937	Case of Elixir Sulfanilamide
1938	Federal Food, Drug and Cosmetic Act
1940	Food and Drug Administration transferred to Federal Security Agency
1953	Federal Security Agency became the Department of Health, Education and Welfare
1957	Poultry Products Inspection Act (effective January 1, 1959)
1958	Food Additives Amendments to FFDCA
1962	Animal Drug Amendments (DES Proviso)
1967	Wholesome Meat Act (replaced 1907 Meat Inspection Act)

FIGURE 1.1. FOOD LAW AND MAJOR EVENTS

a characteristic cycle has been remarked[1] in which a lag frequently occurs between initial appreciation of technological benefits and later awareness of potential costs. As a result, the technology becomes securely installed in the society in its first bloom of success--with all that this implies in the matter of fostering a loyal clientele. When public concern regarding dangers begins to grow over time, it is then discovered that the policy situation has grown vastly more complex and controversial than originally perceived. Controversy stems from the many economic, political, legal, scientific, and other social investments sunk in the technology.

In general, new technologies create new patterns of external effects--both costs and benefits--beyond the dictates of current accounting procedures and disturbing the equilibrium of control in the current institutional context. In the wake of new technologies, economic actors find rational the attempt to install "protective institutions" in order to capture technological benefits and avoid costs.[2] A premise of this research is that the demand for administrative food safety regulation can in large measure be understood as the demand for protective institutions on the part of diverse interest groups. This study specifically concerns the body of law setting limits on societal exposure to animal drug residues in meat.

---

[1] James D. Shaffer, "On Institutional Obsolescence and Innovation--Background for Professional Dialogue and Public Policy," American Journal of Agricultural Economics, May, 1969, pp. 245-267.

[2] Ibid.

1.1.1 Problems Related to the Use of Animal Drugs in Meat Production

Producers employ a variety of animal drugs in livestock production for assorted purposes. The antibacterials, including antibiotics, have become an integral part of livestock production in the past thirty years, particularly in conjunction with large-scale closed confinement practices. Their value when used at subtherapeutic levels in feed lies in generally well-documented contributions to improved rates of gain and feed-efficiency and as disease preventives.

In recent years concern has risen regarding potentially detrimental public health consequences of widespread subtherapeutic feeding of antibacterials in livestock.[1] Of principal concern is the presence of drug residues in meat consumed by humans. Drug residues may have deleterious human health effects of three basic types: 1) residues or metabolites of certain drugs known or suspected to be carcinogenic, mutagenic or teratogenic may themselves be carcinogenic, mutagenic or teratogenic; 2) certain drug residues may trigger dangerous allergic reactions in sensitized persons; 3) a third concern is the development and transfer of antibacterial resistance from livestock to man.

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[1] U.S. Congress, Office of Technology Assessment (OTA), Drugs in Livestock Feed, Volume I: Technical Report (Washington, DC: Government Printing Office, 1979), pp. 1-67; Kenny S. Crump, "Estimating Human Risks From Drug Feed Additives," Louisiana Technical University, unpublished background paper commissioned by OTA, 1979; Richard P. Novick, "Transmission of Bacterial Pathogens From Animals to Man With Special Reference to Antibiotic Resistance," Public Health Research Institute, City of New York, unpublished paper commissioned by OTA, 1979; "Report by the Antibiotics in Animal Feeds Subcommittee (AAFS) to the National Advisory Food and Drug Committee (NAFDC)," unpublished paper, January 3, 1977; U.S. General Accounting Office, Need To Establish Safety and Effectiveness of Antibiotics Used in Animal Feeds HRO-77-81 (Washington, DC: Government Printing Office, June 27, 1977), pp. 1-53.

Resistance properties could compromise performance of one or more drugs of choice in human disease treatments, potentially resulting in a serious epidemic.

The public health issues surrounding establishment of food safety regulations affording socially acceptable levels of risk with respect to carcinogens, allergens, or agents contributing to an antibacterial-resistant gene pool and appearing in food are complex in the extreme. Nevertheless, by necessity policy makers daily make determinations of safety based on imperfect knowledge and in the face of constantly changing information. Although the correlation is imprecise, to a degree the level of public health protection achieved is a function of the policy chosen.

It is characteristic of animal drug regulation in this case, and chemical additive and residue regulation more generally, that seldom can clearcut links from low level chemical exposure to human health effects be demonstrated. Regulators must rely upon indirect evidence, principally of three types: laboratory studies of microorganisms (the Ames test for cancer is an example) which are suggestive of human disease; laboratory tests of animals; epidemiological data wherein human populations exposed to particular unique chemical influences are contrasted with control groups not exposed. Further complicating judgment are such factors as the differing susceptibilities to stress of different sub-populations, unknown interactions between chemicals, effects of metabolites, and the length of time over which adverse effects may develop.

Uncertainties regarding the impacts of exposure to low-level drug residuestranslate into uncertain assumptions in the statistical models

used for extrapolation of the results of high dosage, low population animal studies to the human population, or epidemiological studies to the general population.[1]

In effect, acknowledging the degree of uncertainty in this public health area, the intent of amendments to the Food, Drug and Cosmetic Act has been to alter the traditional burden of proof in the case of additives, animal drugs and other chemicals from one which presumed safety until evidence (generated by a regulatory agency) demonstrated otherwise to one which presumes danger and prohibits use until safety data are supplied by industry for approval.

1.1.2 Potential Problems Associated with Sulfa Residues

The current status of sulfa drugs, particularly sulfamethazine, with respect to these three general health risks--allergic reactions in sensitized humans; potential carcinogenic response; and development of resistance to antibacterials now used in humans for medical therapy--is unclear and a matter of considerable recent controversy. The case illustrates how an old drug can be caught up in a new problem. The FDA established conditions of use for sulfa drugs based on the state of knowledge at the time. Conditions of use include permitted dosage, tolerance levels (the maximum amount of drug residue permissible), and a withdrawal time to enable the animal to deplete the drug from its system. Improvements in assay methodology imply increased sensitivity

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[1]See OTA, Drugs in Livestock Feed, pp. 46-53.

to residues and, thus, the capacity to detect increasingly low levels of contamination--creating the appearance if not the reality of greater contamination frequency. In response to user and producer requests for a higher tolerance level, the Food and Drug Administration has taken the policy position that currently available data are insufficient to justify the agency raising current tolerance levels. The agency's greatest concern is possible carcinogenicity.[1] The contribution of sulfamethazine or the other sulfonamides to a resistant gene pool in animals or man and the impacts of resistance are highly speculative. As in the case of other antibiotics, resistance research needs are vast and potentially very difficult. It is known that a certain degree of resistance to sulfa compounds develops among certain strains of microorganisms.[2]

Industry argues not only that subtherapeutic use of sulfamethazine in livestock is safe, but that current tolerance levels should be raised, in effect, to legitimize some of the low level residues now occurring in pork. It is argued that a 40 year history of human use of various sulfa drugs (at therapeutic levels much higher than current violative residues) has presented no known adverse effects.

Industry also argues that current tolerance levels provide several times the requisite protection against allergic reactions attributable to ingestion of meat. Industry disputes any sulfamethazine links with cancer.

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[1] Interview with Dr. Neal Littlefield, National Center for Toxicological Research, Pine Bluff, Arkansas, March 9, 1981.

[2] One veterinarian interviewed stated that it is well known certain strains of Bronchiseptica (which cause atrophic rhinitis in hogs) have developed resistance to sulfa drugs. Interview with Dr. Lowell Breeden, Department of Veterinary Medicine, Kansas State University, Manhattan, Kansas, November, 1980.

It contends that such low levels of residues as are present in meat, along with any reasonable consumption rates of pork (including pork organs), can have no significant effect on sulfa resistance in humans.

1.1.3 Sulfa Violation Rates 1973-1980

The United States Department of Agriculture began sampling for sulfonamides in the early 1970s as a part of its residue monitoring program.[1] Food Additive Amendments of 1958 and Animal Drug Amendments of 1962 had contributed to increased concern over possible misuse of these substances.

Sampling clearly indicated excessive sulfonamide residues in swine. The percentage of sampled hogs with residues in excess of the FDA tolerance level of .1 ppm in muscle, kidney or liver tissues was: 9.97 in 1974; 11.56 in 1975; 9.44 in 1976; 9.4 in the first six months of 1977 and from July, 1977 through February, 1980 residue rates ranged as shown in Figure 1.2.

In all, residue rates have dropped from a high of approximately 15 percent in September, 1977 to 4 percent reported for the month of March, 1981.

Analysis of the geographical incidence of sulfa violation rates indicated that from an essentially uniform distribution over all inspection sites, violation rates dropped in most swine producing regions of the country--with the exception of portions of the South, particularly the states of Florida and Georgia (see Figure 1.3).

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[1]Discussed in Chapter II.

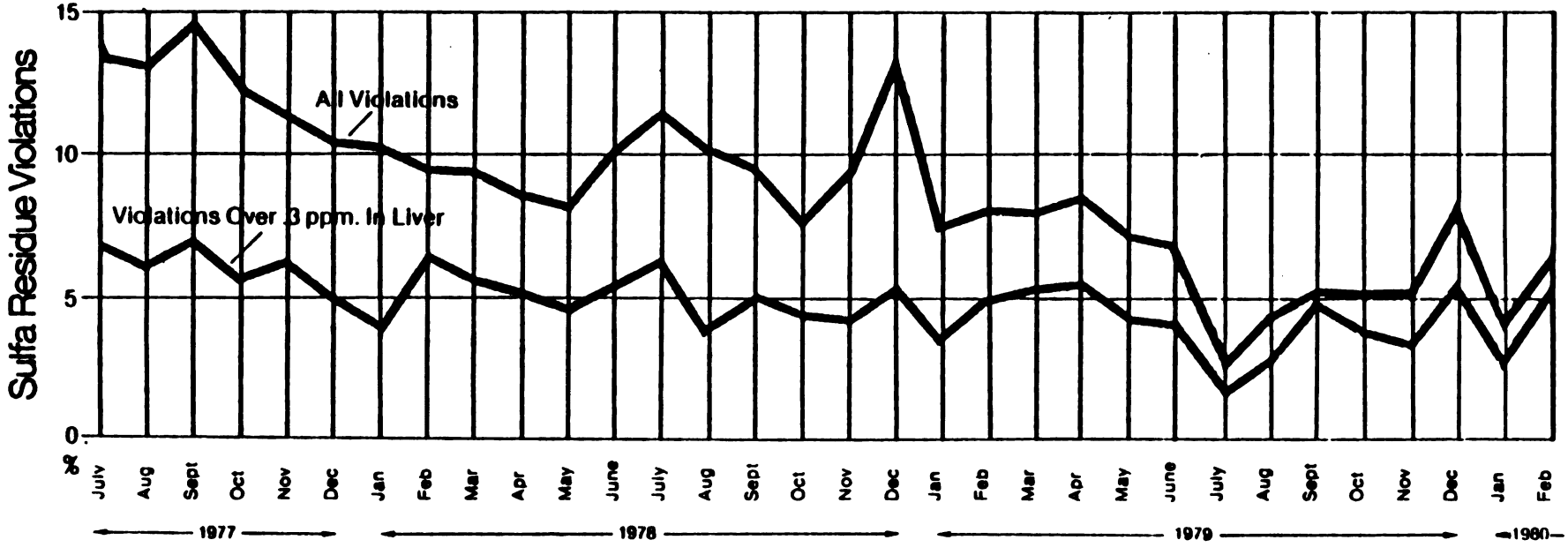
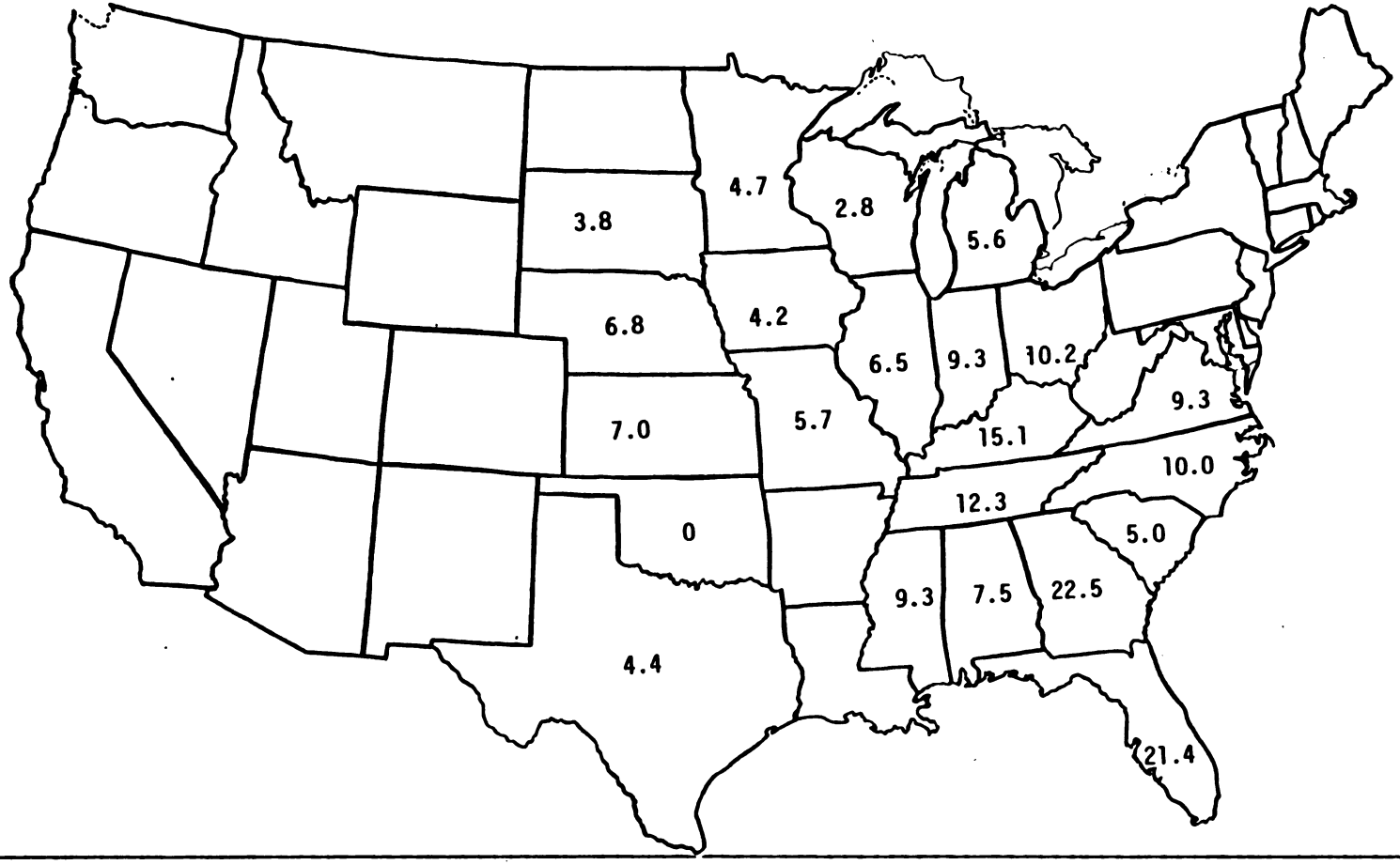


FIGURE 1.2. SULFA RESIDUE VIOLATION RATES



Source: Data Collected by USDA Sulfa Task Force

FIGURE 1.3. GEOGRAPHICAL INCIDENCE OF SULFA RESIDUE VIOLATION RATES (1979)

1.1.4 Sources of the Problem

Initially, the primary cause of the sulfa residue problem was believed to be swine producer failure to comply with withdrawal requirements. However, recent research sponsored by USDA has revealed four principal sources of sulfa contamination in swine tissue:[1]

1) contaminated "non-medicated" feed, either farm or commercially mixed;

2) contaminated manure packs or other environmental sources;

3) premature marketing of medicated swine;

4) over-medication.

Contaminated swine at the packing plant can result from exposure of hogs to minute quantities of sulfa in feed, on farms or in marketing channels as well as failure to follow label instructions, including withdrawal times. In order to appreciate the severity of the problem it is helpful to understand something about the physical amounts involved. As little as 1/2 teaspoon of sulfa per ton of feed during withdrawal periods may produce test results in excess of established tolerance levels.

One FDA spokesman attempted to assign priorities to problem causes.[2] He estimated that 54 percent of violations were due to

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[1] Research conducted under aegis of the Sulfa Task Force and reported in U.S. Department of Agriculture, "Results of USDA-Producer Cooperative Field Study on the Sulfa Problem," by Robert D. Brown, APHIS, USDA, 1979.

[2] Robert C. Wetherell, Jr., Associate Commissioner for Legislative Affairs, FDA, USDHEW, in a personal letter to J.B. Cordaro, Group Manager, Food Group, Office of Technology Assessment, U.S. Congress cited in U.S. Congress, OTA, Drugs in Livestock Feed, Volume 1, Technical Report (Washington, DC: Government Printing Office, June 1979), p. 21.

contaminated withdrawal feed, 26 percent to failure on the part of swine producers to observe the withdrawal period, 12 percent to feeding or feed mixing errors and 9 percent from miscellaneous causes. Due to the impossibility of accurately ascertaining the actual cause of a violation, however, (particularly when 30-40 percent of hogs marketed cannot be traced back to the original producer) such quantitative estimates are necessarily highly speculative.

1.2 Problem Statement and Scope of Research

Performance of the food system with respect to sulfa and other animal drugs has not been considered satisfactory. In recent years government, consumers, and producers have been confronted with a situation where illegal sulfa residues consistently enter the human food supply in pork products. Evidence suggests that problems with sulfa drugs may be symptomatic of numerous other drug and chemical residue problems. The law mandates that regulators ensure adequate food safety.

This research systematically identifies and analyzes regulatory proposals potentially applicable to the sulfa case and to other cases of residue problems. A broad range of proposals originating from a variety of sources has been identified. In part, proposals reflect varying problem definitions, philosophies, judgments as to problem causes and evaluations of program efficiency and cost.

Proposals analyzed and evaluated in this study include:

1) a ban or restriction of the use of sulfa drugs at subtherapeutic levels in swine feed;

2) increasing the legal tolerance level for sulfa drugs in swine carcasses;

3) the procedures undertaken by the Sulfa Task Force;

4) measures to reduce sulfa residues in commercial feed;

5) alterations in swine inspection and marketing rules to reduce sulfa contamination.

In order to analyze policy impacts, it is necessary to understand the portions of the food system in which the problem lies and the currently operative regulatory structure.

Out of the identification and understanding of relevant participant groups grows an understanding of participants' economic interests in sulfa and the impacts on these interests of alternative regulatory formats. The specification of regulatory performance variables of relevance to the participants then follows.

At the most fundamental level this research seeks to contribute to public understanding of ways in which technological change, uncertainty, and society's political-economic institutions interact to affect property rights, and to identification of policy measures through which food system performance in the area of food safety and animal drug use can be improved.

1.3 Research Objectives

1) Identification of that set of policies most relevant for analysis within the context of the sulfa residue problem.

2) Identification of pertinent groups of swine subsector food system participants (extending to relevant input suppliers, meat packers and consumers); their food system performance goals; and major interests in the sulfa case; in order to model decision-making

with respect to sulfa drugs and alternative food safety regulatory policies.

3) Conceptualization, prediction and systematic display of linkages between alternative regulatory policies, behavior, and patterns of costs and benefits affecting various participant groups.

4) Evaluation of proposed policies in light of impacts upon participant behavior and system performance.

1.4 Research Procedures

The research method incorporated iterative use of the procedures listed below.

1) Identification of a range of policy scenarios in conjunction with policy makers within USDA and FDA and university specialists using exploratory interviews and the literature of food system regulation.

2) Development of an analytical framework linking institutional, behavioral and performance variables which explicitly facilitates assessment of economic impacts of food safety regulations upon different participant groups, upon public program costs and policy impacts on consumer exposure to sulfa.

3) Identification of relevant participants in the sulfa case and development of a research issues interview schedule. Subsequent interviewing of approximately 100 individuals.

4) Analysis of policy proposals combining results of extensive research interviews regarding firm decision-making and the conceptual research model in order to diagnose probable economic and behavioral impacts of alternative forms of food safety regulation.

1.5 Overview of the Conceptual Model Underlying Research

The conceptual model underlying any research suggests relationships between variables of import and establishes bounds to the analysis. For this reason, a brief description of the basic model underlying the study may be useful in acquainting the reader with the analysis to be used.

The research identifies three categories of variables in the analytical system: institutional, decision-making and performance variables. These variables are interdependent but for purposes of analysis may be specified at alternative times as independent or dependent.

As stated in slightly different language above, a major goal of the research is to understand the interaction between administrative regulation in the food safety area and ultimate performance of the food system. Regulations form a class of institutional variables. They influence food system performance by providing incentives or disincentives for particular individual or organizational actions. Thus, the link between regulation and performance is forged through impacts on organizational decision-making.

The overall food system is viewed within an evolutionary institutions, decision-making, performance framework. Man's environment is conceived to be prominently characterized by scarcity, interdependence, uncertainty, and varying degrees of power. Within the context of the environment exist the institutions of the political economy in general and the food system more specifically.

Institutions refer to collective rules which shape and interrelate individuals' behavior by influencing individual opportunity sets including property rights. Decision-making of individuals and of groups is reflected in satisficing strategies employed individually and in the aggregate. Decision-making strategies shape performance. Performance, broadly conceived, constitutes the sum total of system outcomes. System outcomes relay back upon institutions and subsequent decisions in an evolutionary process.

The food system consists of various participants who seek to influence institutions within the system and to exert influence on food system performance. Performance goals for the food system comprise the various goals of system participants. One formulation of food system goals offered by Shaffer[1] identifies system goals in a broad and comprehensive manner which recognizes the interdependent interests of broad classes of participants. Specific participants' goals within the food system are naturally more particularistic than the set of goals presented by Shaffer.

The conceptual approach utilized here shares features with industrial organization frameworks employed by authors Scherer and Bain which relate structure, conduct and performance variables within an industry. However, it also differs significantly in scope, focus and intent. As for scope, a subsectoral perspective is chosen in order to examine the changing nature and impacts of a food safety problem as it reappears in various value-added stages of input purchasing, production and

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[1]See Figure 1.4.

1) To assure an abundant and reliable supply of safe and nutritionally adequate food at economical prices.

2) To facilitate and promote the production and distribution of those combinations of foods and related services which best reflect the preferences of consumers and the real relative costs of production.

3) To create incentives for increased productivity in each activity of the total system.

4) To provide productive and rewarding employment opportunities in the system.

5) To distribute the rewards of the system fairly and equitably, especially the consequences of government policies and programs.

6) To discourage uneconomic uses and spoilation of natural resources and environment.

7) To encourage socially desirable population settlement patterns.

8) To encourage a sense of belonging and effectiveness among participants in the system.

Source: James D. Shaffer, Department of Agricultural Economics, Michigan State University

FIGURE 1.4. PERFORMANCE DIMENSIONS FOR THE FOOD SYSTEM

marketing. Secondly, system performance is evaluated chiefly in terms of performance variables relating to food safety and economic impacts of food safety regulation, upon various participants.

A subsectoral approach is particularly appropriate for the analysis of food safety problems and associated regulation for two reasons:

1) it permits explicit consideration of the vertical stages through which an animal drug or other chemical flows thereby suggesting diverse participant interests in the substance (as product, input, contaminant or combination);

2) it also facilitates explicit consideration of alternative control points toward which public policy measures may be directed to improve system performance.

1.6 The Extended Swine Subsector

Examination of the case of sulfa drugs--manufactured by pharmaceutical companies, mixed in livestock feeds, fed to swine--affords an interesting panorama of some important features and interrelationships of the extended swine subsector (see Figure 1.5). This section provides a brief introduction to that group of four industries most involved in the sulfa case--the animal health industry, the commercial feed industry, the swine and the meatpacking industries. For purposes of convenience they are labeled simply the extended swine subsector.

1.6.1 The Animal Health Industry

The animal health industry which manufactures sulfa and sulfa combination drugs produces three distinct product groups:

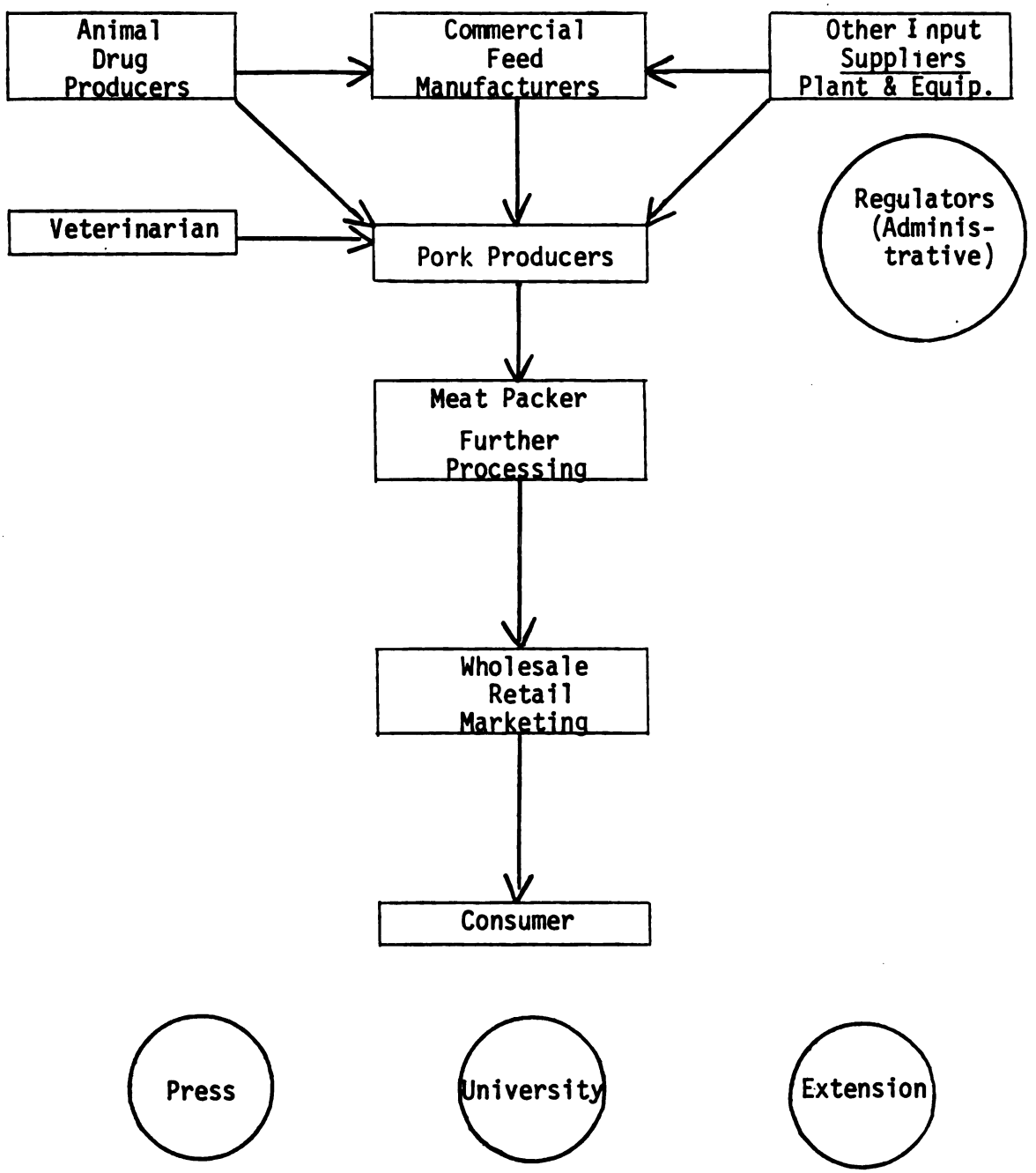


FIGURE 1.5. THE EXTENDED SWINE SUBSECTOR

1) Biologicals - vaccines which originate in living organisms and are utilized to prevent infectious disease.

2) Pharmaceuticals - drugs and other chemical compounds employed by veterinarians to prevent, treat or control disease.

3) Feed additives - drugs and other chemical compounds added to feeds for growth promotion, improvement of feed efficiency, reduction of disease.

Sulfamethazine is used both as a feed additive and a pharmaceutical.

The animal health industry had sales of $1.5 billion to the livestock and poultry industries in 1978. A breakdown of sales shown in Table 1.1 indicates the predominance of feed additives and shows the secondary economic importance of pharmaceuticals.

Domestic antibiotic production increased from .39 million kg to 11.66 million kg from 1950 to 1978, an increase of 2974 percent. Table 1.2 indicates the dramatic increase in non-medicinal use of antibiotics. In 1951, 84 percent of total antibiotic production was used for medicinal purposes; by 1978, the percentage had shrunk to 52 percent with the major share of the remaining 48 percent going into feed additives. Figure 1.6 indicates that the average price of antibiotics used for non-medical purposes fell steadily over the 20-year period ending in 1971 from approximately $200 per kg to approximately $20 per kg. Since that time, average prices of antibiotics have been rising, in part reflecting inflationary conditions.[1]

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[1]Virgil W. Hays, "Effectiveness of Feed Additive Usage of Antibacterial Agents in Swine and Poultry Production," unpublished paper commissioned by the Office of Technology Assessment, 1978, p. 26.

TABLE 1.1. ANIMAL HEALTH INDUSTRY PRODUCT SALES ($1,000,000)

Products	1976	1977	1978
Feed Additives:	$ 775.8	$ 807.6	$ 989.5
Biologicals:	88.0	91.8	105.9
Pharmaceuticals:	291.9	308.4	375.8
TOTALS:	$1,155.7	$1,207.8	$1,471.2

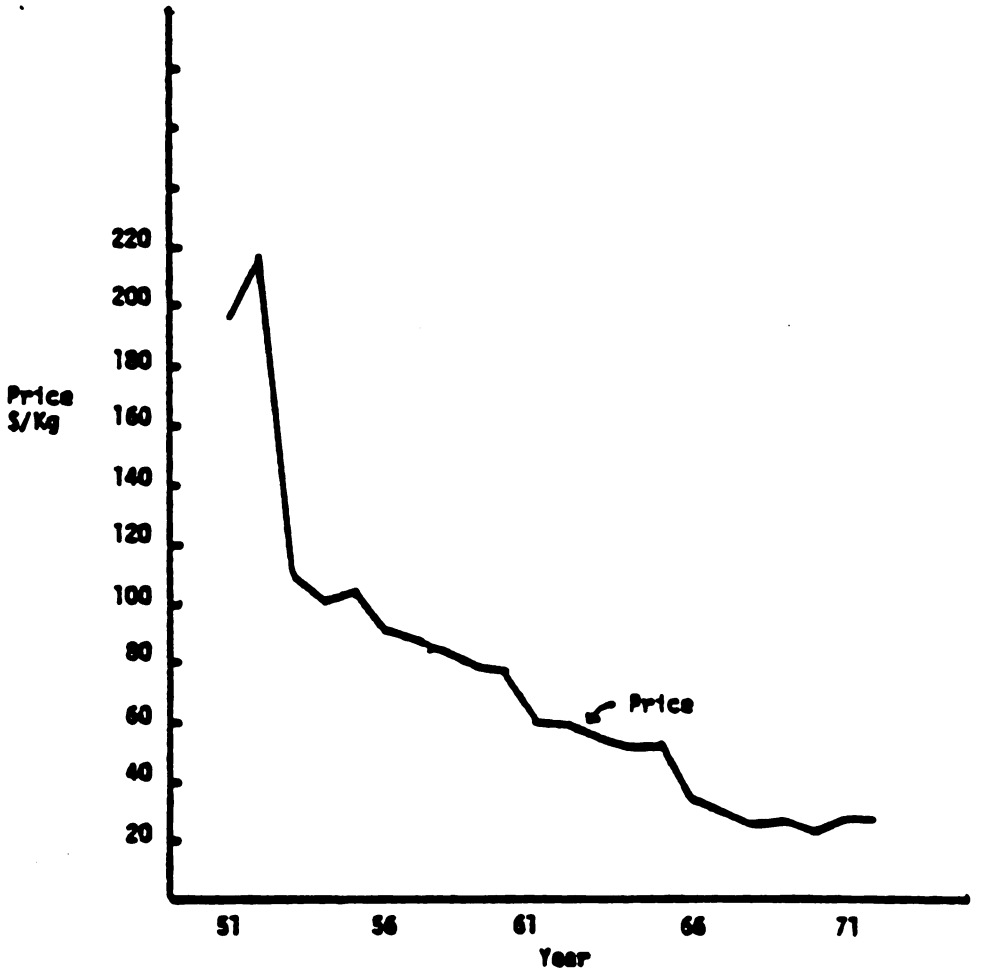
Source: Animal Health Institute, Market Survey Information, Feedstuffs, October 29, 1979.

TABLE 1.2. ANTIBIOTIC PRODUCTION AND USE FROM 1950 TO 1978 (millions of kg)[a]

Year	Total	Medicinal Use in Humans & Animals	Used in Animal Feed & Other
1978	11.66	6.08	5.58
1977	10.48	6.35	4.58
1976	9.30	4.72	4.54
1975	8.30	4.26	4.04
1974	9.30	5.99	3.36
1973	9.43	5.72	3.72
1972	7.53	4.45	3.08
1971	8.12	4.90	3.22
1970	7.67	4.35	3.31
1969	5.99	3.36	2.63
1968	4.67	2.72	1.95
1967	4.29	2.36	1.91
1966	4.40	2.45	1.91
1965	3.40	2.13	1.27
1964	2.95	1.77	1.18
1963	3.04	1.91	1.13
1962	2.86	1.81	1.04
1961	2.31	1.50	0.82
1960	2.13	1.36	0.77
1959	1.68	1.04	0.64
1958	1.59	1.18	0.41
1957	1.47	1.08	0.39
1956	1.24	0.89	0.35
1955	0.95	0.71	0.24
1954	1.05	0.83	0.22
1953	0.94	0.74	0.20
1952	0.79	0.67	0.12
1951	0.69	0.58	0.11
1950	0.39	0.39	Mentioned, but no figure

[a]Values exclude production of sulfonamides.

Source: U.S. International Trade Commission Reports (1951-1979).



Source: Virgil W. Hays, "Effectiveness of Feed Additive Usage of Antibacterial Agents in Swine and Poultry Production," 1978.

FIGURE 1.6. UNIT PRICE OF ANTIBIOTICS FOR NONMEDICINAL USES

In the animal health feed additive market, the sulfa drugs comprise a significant share of sales. In the swine feed additive market, particularly, the four companies producing the three major sulfa combination drugs furnish approximately 70 percent of total sales.[1]

1.6.2 The Formula Feed Industry

The formula feed industry purchases feed additives from the animal health industry for inclusion in feed articles of various types.

The feed industry is the largest agricultural input supplier, producing a variety of products and composed of a diversity of firms in terms of major activity, size and degree of diversification. Figure 1.7 provides a good representation of formula feed industry structure.

The industry produces four major kinds of feed articles distinguished by protein content and other features of composition:[2]

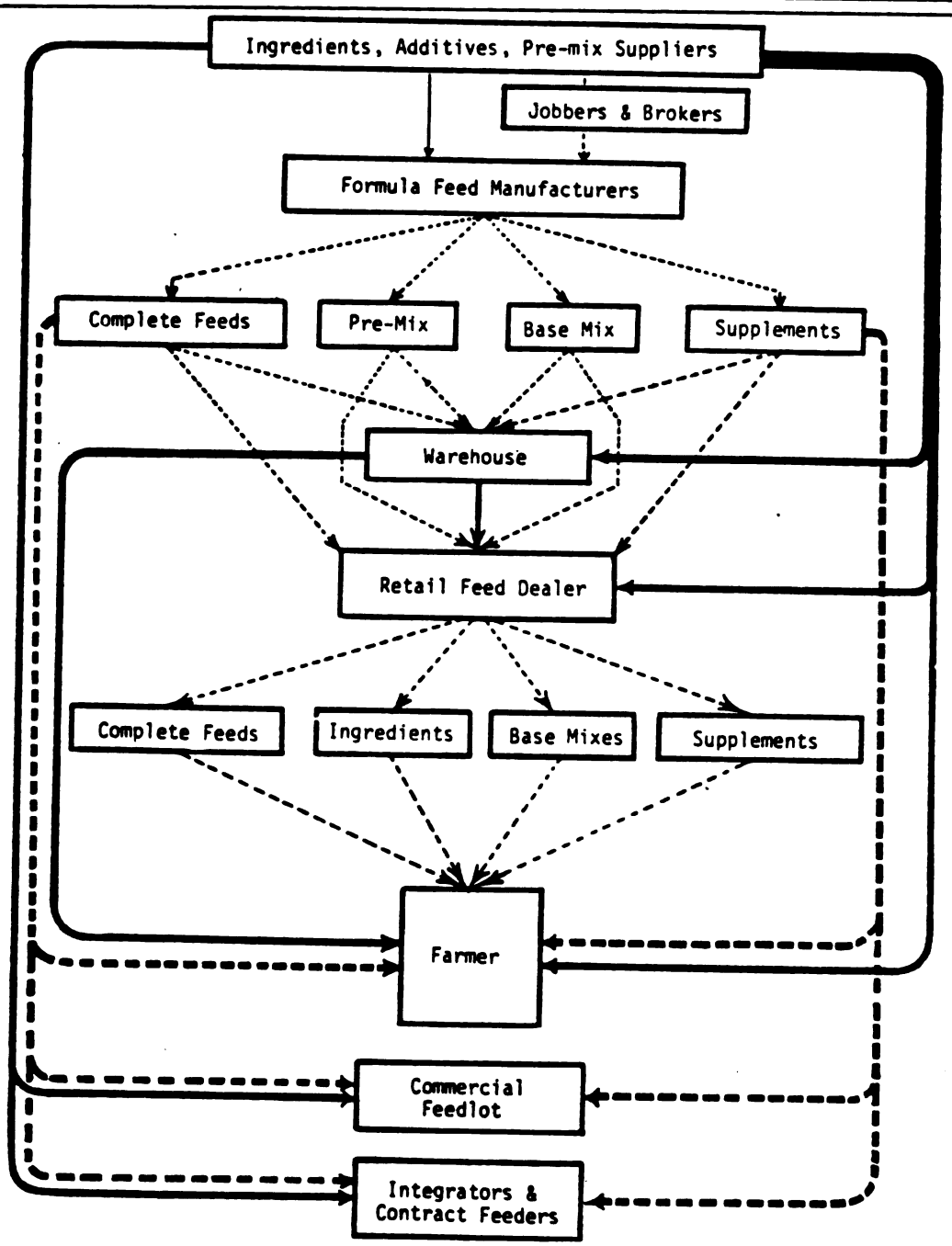
1) Feed premix - contains trace minerals, vitamins and, frequently, drugs with a diluent. It must be further diluted before feeding and is mixed at a rate of between 5-100 pounds per ton of complete feed.

2) Base-mix or super concentrate - contains minerals, vitamins and other minor ingredients--but omits major protein source (commonly soybean meal)--and is mixed at a rate of between 50 and 300 pounds with grain and soybean meal to make one ton of complete feed (protein content 5-20 percent).

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[1] Interview with Bob Holmes, Product Group Manager, Marketing Sales/Production, Doanes Agricultural Services, Market Research. St. Louis, April 15, 1981.

[2] Robert W. Schoeff, "The Formula Feed Industry," Feed Manufacturing Technology, Harry B. Pfost and Diane Pickering, eds. (Arlington, VA: Feed Production Council, American Feed Manufacturers Associates, 1976), pp. 1-18.



Source: Robert W. Schoeff, "The Formula Feed Industry." Feed Manufacturing Technology.

FIGURE 1.7. MARKET STRUCTURE OF THE FORMULA FEED INDUSTRY

3) Supplement or concentrate - adds protein source to above ingredient to attain over-all protein content of 30-70 percent. While supplements may be further diluted, they need not be. Supplements (or concentrates) may comprise anywhere from 10 to 50 percent of a ton of complete feed.

4) Complete feed - contains all necessary ingredients for livestock diets.

Some confusion in terminology exists due to the use by the Food and Drug Administration of the terms "premix," "concentrates," and "supplements" in reference to degree of drug concentration while industry use refers to nutrient contents. The FDA is currently introducing new terminology to eliminate confusion in this area.

Commercial feeds are also classified by livestock class and by form: 1) meal (or mash); 2) pellets (including cubes); 3) blocks; 4) liquid. Additionally, feeds may be sold in bulk or bagged form.

In reference to industry structure, the FDA counts approximately 12,000 feed mills on the basis of figures generated from annual feed mill registrations required of all establishments mixing feed. Of this number, approximately 1,000 companies in the U.S. manufacture feed "from the ground up," that is, beginning with primary ingredients. These companies generally supply state, regional or even national market areas. Approximately 10,000 feed mills are "country elevators" or dealers, usually having a custom mixing operation.[1]

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[1] Interview with Chuck Klinger, Director of Regulatory Compliance, Central Soya, Ft. Wayne, August 14, 1980.

The third significant group of firms consists of integrators, members of livestock industries who manufacture their own feed. The dairy and swine industries represent the best over-all markets for the feed industry. Dairy feeders generally demand complete feed while the swine industry, with substantial integration from the bottom up, has a substantial demand for concentrates.

1.6.3 The Swine Industry

Traditionally comprised of small to medium producers, the swine industry today continues a transition of the past 30 years toward concentration of an increasing share of production in larger units. The median point in the distribution of annual sales of slaughter hogs still falls within a sales class ranging from 500 to 999 head per annum. However, the number of farms selling hogs has decreased markedly from a 1950 count of 2.1 million units to a 1978 total of 453,000. Estimates for 1978 indicate that the average number of hogs per operation nationwide was 95; in the 14 major hog producing states, it was 128.[1] In the decade 1964 to 1974, percentage of sales from farms producing less than 200 head nearly halved (from 46 to 24 percent of total sales) while that from larger farms (with 1000 or more annual sales) increased share from 7 to 25 percent of total sales.[2] The growing importance of larger

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[1] "The Pork Industry, The Mortgage Lifter: A Story of Lard to Lean," Feedstuffs, October 29, 1979, pp. 134-142.

[2] U.S. Department of Agriculture, Economics, Statistics, and Cooperatives Service, Structural Characteristics of the U.S. Hog Production Industry, Agricultural Economic Report No. 415 by Roy N. Van Arsdall (Washington, DC: Government Printing Office, 1978).

units is expected to continue. Rhodes et al. estimate that 1,340 large volume producers, nationally, defined as marketing over 5,000 hogs annually, sold 11.2 million hogs and pigs in 1977 for an average sales rate of 8,358 per operation.[1]

The report identified important trends among the largest hog producing firms in the latter 1970s including 1) rapid growth in the size of some of the larger existing units in 1975; 2) entry of new operations into the industry; 3) growth in the number of specialized farrowing houses; 4) an increase in corporate organization among large units; 5) an indication from survey respondents that approximately 10 percent were part of an agribusiness operation, primarily feed companies but also including meat packing operations, poultry firms and others.

The predominant enterprise type within the hog industry remains the farrow-to-finish operation in which sows are bred to produce baby pigs that are then fed out to market weights of 220 to 240 pounds. Specialized feeder pig production and feeder pig finishing operations appear to be growing in significance, however, especially among some of the larger size classes of firms. Feeder pigs are typically raised to a weight of 40 to 60 pounds before sale to finishing operations. The relative contribution of the three types of operations to adjusted gross farm sales contributed by hog sales is: feeder pig production, 37 percent; farrow-to-finish operations, 52 percent; and feeder finishing operations, 40 percent.

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[1]V. James Rhodes, Calvin Stemme, Glenn Grimes, Large and Medium Volume Hog Producers: A National Survey (Columbia, MO: University of Missouri Agricultural Experiment Station, 1979), pp. 1-43.

[2]USDA, Structural Characteristics of the U.S. Hog Production Industry.

Geographically, hog production has remained fairly stable with approximately 80 percent of total live weight production occurring in the North Central states, primarily Iowa and Illinois (see Figure 1.8).

The swine industry, then, is characterized by pronounced trends toward larger, more specialized operations although the current importance of medium sized farrow-to-finish operations cannot be discounted. The major regional locus of hog production remains the Corn Belt and the predominant type of operation combines grain and livestock enterprises. More recent areas of growth, especially in feeder pig production, include the Southeast and the Southwestern regions.

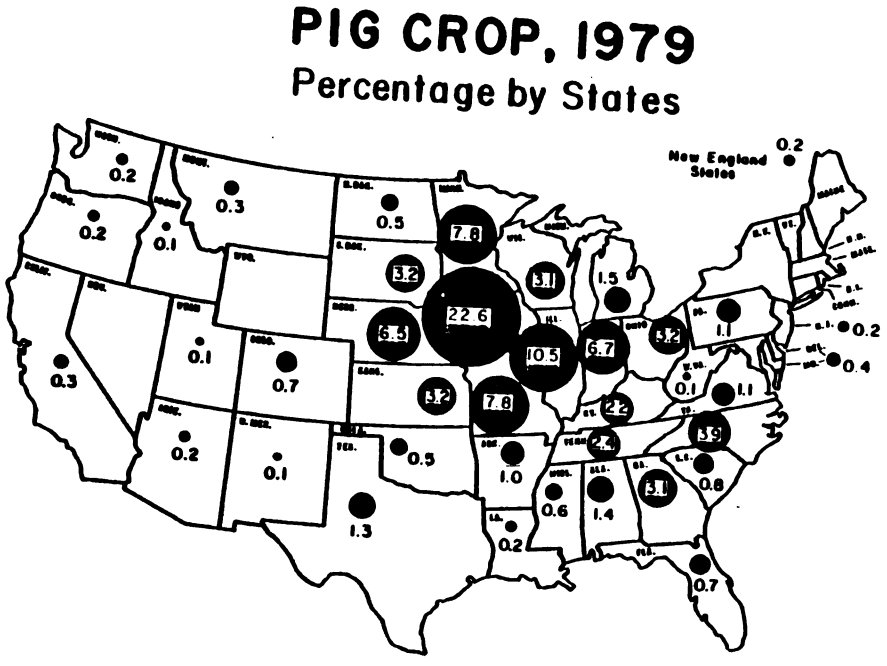
1.6.4 Hog Slaughter and Marketing

Hog slaughter in the U.S. generally follows production patterns.[1] Figure 1.9 indicates the distribution of hog slaughter by state; Iowa accounts for approximately one-fifth of production and one-quarter of slaughter.

The wholesale market for fresh and frozen pork is national while markets for processed meats are more localized according to local brands. In general, marketing changes in the hog industry have meant the declining importance of terminal markets and the growing importance of direct marketing. Direct marketing accounted for nearly 70 percent of hogs sold in the 1970s.

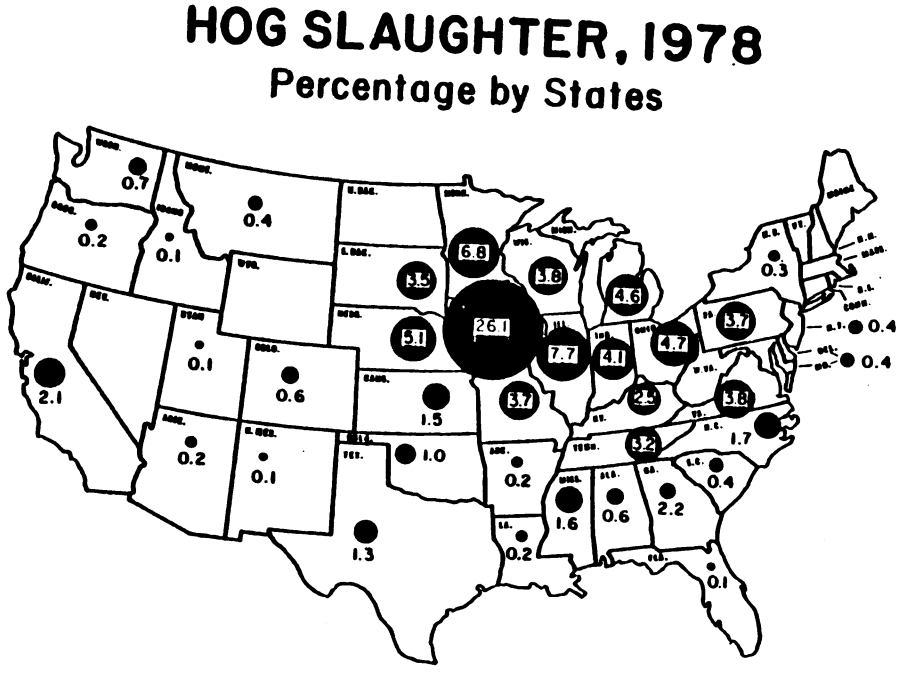
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[1]This description draws upon Gerald Engelman, U.S. Department of Agriculture, Agricultural Marketing Service, "Changes in Livestock Marketing in the United States and Prospects for the Future," Statement to the 1980 Annual Outlook Conference, Agriculture Canada, Ottawa, Ontario, December 8, 1980.



Source: USDA, Meat Animals, April, 1980
U.S. Total - 102,771,000 Head

FIGURE 1.8. PIG CROP, 1979 (Percentage by States)



Source: USDA, Packers and Stockyards Resume, December 28, 1979.
U.S. Total, 73,776,000 Head

FIGURE 1.9. HOG SLAUGHTER, 1978 (Percentage by States)

Because most livestock are slaughtered close to feeding points, market competition depends on marketing alternatives within the local area. These are limited in many locales. Two-thirds of all slaughter occurs in the 14 largest hog slaughtering states. In these states, weighted average market shares at the four-firm level were 71 percent in 1969 and 76 percent in 1978. In many respects the market for slaughter hogs is imperfectly competitive, limited by lack of swine producer access to multiple buyers and characterized in some cases by monopsonistic price-making.[1]

1.7 Sampling Plan and Characteristics of the Sample

This research describes and evaluates impacts of animal drug food safety regulations upon members of the diverse industries briefly described above, that is, animal health, commercial feed, swine and meat packing industries. The regulations, additionally, represent the mixed product of both the Food and Drug Administration and the United States Department of Agriculture. Bounds for the analysis were provided by the factual developments of the sulfa case and the conceptual framework underlying the research.

As the intent of the research was to identify, understand and analyze interrelationships between food safety regulations (both existing and proposed) and market performance throughout a complex system involving multiple industries, the diversity of participant groups and their interrelationships along with time and resource

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[1] Ibid.

constraints, argued against meaningful and effective use of probability sampling techniques and in support of a data gathering procedure which purposively selected participants for interviews on the basis of individual characteristics and the nature of participant involvement in the sulfa case.[1]

1.7.1 Sampling Procedure

The sampling procedure involved the following steps:

1) identification of participant groups most intimately involved in the sulfa case on the basis of exploratory interviews and secondary information;

2) identification of important organizational attributes of subsets within participant groups on the basis of review of literature, and expert opinion of individuals within industries, university and government in order to appreciate the diversity and the prevalence of various attributes;

3) selection of individual participants for personal interviews on the basis of their participant group affiliations and individual production characteristics in an attempt to appropriately reflect the diversity of the system and its constituent members;

4) development of research schedules and conduct of interviews using a combination of open-ended and closed-ended interview questions with members of important groups;

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[1]Such an approach must necessarily sacrifice use of statistical testing procedures and results; what is gained, however, is breadth of scope and an understanding of complex interrelationships which is valuable in exploratory research.

5) utilization of an iterative reassessment procedure whereby information regarding important additional sources of information was periodically incorporated into the sampling plan.

1.7.2 Characteristics of the Sample

Approximately 100 persons were interviewed in the course of this research. A roster of persons interviewed is included in the Appendix along with date of interviews. Here the total sample is described in order to afford a clearer understanding of sample characteristics.

Initial identification of participant groups led to a categorization of membership according to industry, regulatory agency, other government agency and university. Groups within which interviews were conducted and the number of interviews in each are identified in Table 1.3.

In the animal health industry, representatives from all major pharmaceutical firms manufacturing sulfa combination swine feed additives were interviewed as well as representatives of some competitors. Sulfa additive producers are headquartered in four different states although competing in national markets. In addition, officials of the Animal Health Institute, the primary industry trade association, were interviewed.

In the commercial feed industry representatives of a variety of enterprise types, ownership forms, geographical locations, firm sizes and worker roles were represented in the interview sample. Sample attributes of feed industry participants are summarized in Table 1.4. In addition, contact was made and/or in-depth interviews were conducted

TABLE 1.3. INTERVIEW SUBJECTS: AFFILIATION AND NUMBER

Type of Enterprise, Agency, Institution	No. of People Interviewed	No. of Firms	No. of Trade Associations
Industry			
Animal Health	9	5	1
Commercial Feed	20	11	
U.S.	18		1
Canada	2		1
Swine	20	19	2
Meat Packers, Buyers First Handlers	6	5	1
Insurance (Product Liability)	1	1	
Market Research	2	2	
Government			
Food and Drug Administration	6		
U.S. Department of Agriculture	22		
Other	7		
University			
Extension Swine Specialists	5		
Animal Science/Animal Husbandry	3		
Veterinary Medicine	3		
Grain Science and Industry	4		
Agricultural Economics	10		
Biochemistry	1		
TOTAL	108*	43	6

*Excluding Dual Affiliation

TABLE 1.4. SAMPLE ATTRIBUTES: FEED INDUSTRY PARTICIPANTS INTERVIEWED

ORGANIZATIONAL CHARACTERISTICS	FEED INSTITUTION								
	Amer. Feed Manu. Assn.	Cent. Soya	F.S. Growmark	Hamilton Coop	IN Fm. Bureau	Kent Feeds	MI Fm. Bureau	Moormans	Purina
TRADE ASSOCIATION	*								
COOPERATIVE[a]			*	*	*		*		
CORPORATION		*				*		*	*
INTERVIEWEE POS. QUALITY CONTROL		*		*	*	*		*	
SALES		*					*		*
MANAGEMENT	*	*	*	*			*		*
PRODUCTION							*		
INTERVIEWEE(S) LOCALE AT HEADQUARTERS		*	*		*		*	*	
LOCAL PLANT		*					*		*
GEOGRAPHICAL LOCATION COMPANY HDQTRS.	Wash. DC	Ft. Wayne IN	Bloom-ington IL	Hamilton MI	Ind. IN	Mus-catine IA	Lans. MI	Quincy IL.	St. Louis MO

[a]or associated with Cooperative

with officials of the American Feed Manufacturers Association, the primary industry trade group, with industry experts in universities, government and the press. The researcher additionally attended a two-week feed manufacturing short course in Manhattan, Kansas at a session jointly sponsored by the American Feed Manufacturers Association and Kansas State University's Department of Grain Science and Industry.

Swine industry persons interviewed included numerous producers primarily in Michigan, with some in Kansas and Illinois. Different size operations were sought as well as a variety of crop, livestock enterprise combinations. The sample included a mixture of producers, some recommended by Extension specialists as "good managers," some described as mediocre and others not referred by Extension. Members of the Michigan and Kansas Pork Producers' Councils were interviewed along with Cooperative Extension Service swine veterinarians and swine specialists. At the Federal level, persons within USDA involved in swine research and producer educational activities were also consulted.

Representatives of swine marketing and slaughter operations were interviewed including managers of Michigan Livestock Exchange, a Michigan auction market, and various personnel at Frederick-Harrods of Detroit, a large Michigan slaughter house, and Farmer Peets of Chesaning, Michigan. The former president of the American Meat Institute, who was administrator during much of the period of the sulfa case and is currently Deputy Secretary of Agriculture, was also interviewed.

Finally, a variety of governmental personnel involved in regulatory and non-regulatory activities contributed insights to this research.

These persons worked within the U.S. Department of Agriculture and the Food and Drug Administration primarily at the Federal level and within the Michigan or Kansas Departments of Agriculture at the State level.

Governmental and regulatory personnel are identified by agency in Table 1.5.

1.8 Plan for Presentation of the Research

The research is presented in six chapters. Chapter I provides introductory material, research objectives and procedures, and an overview of the conceptual framework, sampling procedures and sample characteristics.

Chapter II delineates important aspects of the legal framework within which animal drug and food safety regulatory policies evolve.

Chapter III develops the conceptual basis for the research. The chapter includes a critical review of four major analytical formats: benefit-cost, risk-benefit, cost-effectiveness, and impact analysis. A combination of cost-effectiveness and impact analysis is judged most useful for purposes of this research. Included in the impact analysis is the explicit consideration of ways in which food safety regulations influence firm decision-making and, ultimately, market and subsector performance. The chapter concludes with the identification of performance variables of import in assessing food safety regulatory impacts and a transition to Chapter IV.

Chapter IV presents empirical analysis of firm economic interests in sulfa drugs, standard operating procedures respecting animal drugs and the means by which current food safety regulations (including the

TABLE 1.5. GOVERNMENTAL PERSONNEL INTERVIEWED

Agency and Branch	Number Interviewed		
Food and Drug Administration	6		
Bureau of Veterinary Medicine		4	
Bureau of Foods		1	
Office of Planning and Evaluation		1	
National Center for Toxicological Research	1		
U.S. Department of Agriculture	22		
Food, Safety, Quality Service (FSQS)		12	
Located in Washington			7
Meat Inspection in State			5
Animal Plant Health Inspection Service (APHIS)		1	
Science, Education Administration (SEA)		3	
Economics, Statistics Cooperative Service (ESCS)		2	
Economic Research Service		1	
Secretary's Office		1	
Office of Program Planning and Budget Evaluation		1	
Office of Legislative Affairs		1	
U.S. Congress Office of Technology Assessment	1		
U.S. International Trade Commission	1		
Agriculture: Canada	1		
Health and Welfare: Canada	1		
Michigan Department of Agriculture	2		
TOTAL	35		

Sulfa Task Force program described below) influence economic decisions. Out of the empirical analysis comes a number of conclusions useful for purposes of analyzing some alternative regulatory options presented in Chapter V.

Chapter V develops and analyzes five policy options or scenarios (listed above) ranging from a ban of sulfa feed additives to an increase in tolerance levels. Economic impacts upon major industries, public program costs and program impacts upon the probable exposure of consumers to sulfa residues in pork are assessed.

Chapter VI presents research conclusions, policy recommendations and additional research needs.

CHAPTER II

SULFA DRUGS AND THE FOOD SAFETY INSTITUTIONAL STRUCTURE

Chapter II introduces the sulfa drugs responsible for this research and describes the manner in which they are regulated within the food system. Information regarding physical properties of the sulfonamides is minimized in the body of the text; the reader interested in more technical information is referred to Appendix A. For information on the contribution of sulfonamide feed additives to feed efficiency, growth promotion and disease prevention, see Chapter V, Section 1.

2.1 Sulfa Drugs

Sulfa drugs have been used for a variety of medical purposes for the past 40-45 years. In the late 1940s and early 1950s, discoveries of growth promoting characteristics of subtherapeutic dosages of a number of antibacterials, including the sulfa drugs, led ultimately to their currently widespread utilization in livestock production. Antibacterials are used for three purposes: 1) disease prevention; 2) growth promotion; and 3) improved feed efficiency.

Two sulfa compounds, sulfamethazine and sulfathiazole, are now cleared by the FDA for use in swine rations.[1] While the drugs are

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[1] In approved combination with selected antibiotics. For approved claims see Appendix A.

close substitutes, some significant differences exist. Sulfamethazine reaches a higher blood level than sulfathiazole; sulfathiazole depletes more rapidly from a hog's system.[1] Whereas electrostaticity of sulfamethazine in powder form has been a major source of cross-contamination problems in feed mills (due to sulfamethazine carryover from one batch of feed to another), sulfathiazole does not appear to exhibit the same degree of electrostaticity.

The major implications of these features for the sulfa case are that sulfamethazine is much more extensively used than sulfathiazole but is also much more likely to cause residue problems due to its greater electrostaticity and its slower depletion characteristics.

2.2 The Food Safety Institutional Structure

This section explores major provisions of the Federal Food, Drug, and Cosmetic Act providing the Food and Drug Administration (FDA) with legal responsibility for regulation of animal drugs, commercial feeds and the presence of contaminants in food. Legal background is followed by a discussion of some of the issues in property rights associated with various categorizations under the law. Finally, legal status of sulfamethazine, past, present and future, is examined. The section also examines the Wholesome Meat Act of 1967 directing the United States Department of Agriculture (USDA) to safeguard the nation's meat supply.[2] Provisions of the act with special relevance

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[1]For further discussion see Appendix A. The differences in drug action are claimed by many to make sulfamethazine more effective in combatting infection.

[2]This act replaced the 1907 Meat Inspection Act.

to the sulfa case include the requirement that USDA monitor meat for chemical residues. Residue monitoring activities of the USDA are examined below.

Initial passage of national food safety legislation in the United States occurred in 1906 and 1907 with approval of the Pure Food and Drug Act and the Meat Inspection Act. Championed by Dr. Harvey W. Wiley, a social activist head of the Bureau of Chemistry in the Department of Agriculture, a coalition of social reformers, muckraking journalists,[1] professional and trade organizations and President Theodore Roosevelt actively supported the bill (President Roosevelt after reading and confirming the accuracy of Sinclair's novel, The Jungle).

The early laws were weak when compared to the currently applicable body of food and drug law; the drug provisions were restricted principally to prohibitions against misbranding, specifically, false and misleading labeling claims. In cases of dispute, the burden rested with the government to prove, after the fact, that a preparation was unsafe or ineffectual and that fraud had been intended.[2] The Pure Food and Drug Act prohibited adulteration of food in the federal

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[1]Upton Sinclair's graphic description of unsanitary conditions prevailing in Chicago slaughterhouses (The Jungle, 1905) led to a 25% drop in meat consumption in the following year. Harrison Wellford, Sowing the Wind (Toronto: Bantam Books, 1971) p. 4.

[2]A 1912 modification of the misbranding provision added the requirement that the government demonstrate fraudulent intent. Paul J. Quirk, "Food and Drug Administration," The Politics of Regulation, ed. James Q. Wilson (New York: Basic Books, 1980) p. 194.

territories and interstate distribution of fraudulent or unhealthy products. The Meat Inspection Act of 1907 legitimized the first federal inspection of meat marketed in interstate commerce.

In 1927 a separate law enforcement agency, the Food, Drug and Insecticide Administration, was created within the USDA; this became the Food and Drug Administration in 1931. In 1940 the FDA migrated from the Department of Agriculture to the Federal Health Security Agency which in 1953 became the Department of Health, Education and Welfare and most recently, the Department of Health and Human Services. An interesting outgrowth of this ongoing process of reorganization is that, with the major exception of meat, meat products and poultry inspection, principal responsibility for food safety now resides within an agency dedicated exclusively to the protection of public health. Through the years, spokesmen for the agency, including former FDA commissioner Donald Kennedy, have voiced the conviction that the agency's legal mandate does not permit the consideration of economic costs or benefits associated with agency policies promulgated to protect the public health. Stated Kennedy in 1977, "Our laws in this area, I think, are clear in not permitting us to balance economic gain to sectors of the economy against health risks to a population at large."[1] More recently, pressures have increased to modify the FDA's stance on consideration of economic factors.

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[1]Donald Kennedy, Commissioner, FDA, Public Health Service, Department of Health, Education and Welfare, "Statements on the Use of Antibiotics in Animal Feed" in Food Safety and Quality: Use of Antibiotics in Animal Feed, Part II. Hearings before the Subcommittee on Agriculture, Nutrition and Forestry (Wash., DC: U.S. Government Printing Office, September 21 and 22, 1977).

2.2.1 The Federal Food, Drug and Cosmetic Act (FFDCA)

In 1938, the current foundation of food safety legislation was passed in the form of the Federal Food, Drug, and Cosmetic Act. Ironically, a sulfa drug provided the impetus for 1938 passage of the entire Food, Drug and Cosmetic Act, strengthened from earlier versions of the bill. In 1937, Elixir Sulfanilamide (sulfanilamide is the parent drug from which sulfamethazine and a host of other sulfonamides were originally synthesized) was rushed onto the market without prior safety testing, resulting in the death of more than 100 persons due to the toxicity of the solvent in which the sulfa drug was suspended. The case generated immense support for drug reform which was incorporated into the then-pending bill.[1]

The act contains provisions relating to food and animal feed, to human and animal drugs, and defines conditions of contamination of food by drugs and other substances.

Regarding food, drugs, devices or cosmetics, the act prohibits the introduction or receipt of adulterated or misbranded products. The act also provides the FDA with the power to inspect products, records and premises of food and drug establishments to establish compliance with the law. Among other powers, the FDA is given the authority to establish tolerance levels for various classes of contaminants. The act also establishes Food and Drug Administration authority to mandate acceptable safety testing prior to granting a

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[1]Quirk, "Food and Drug Administration."

company the license to market a drug. It also enables the FDA to require a drug's withdrawal from the market if evidence indicates lack of safety.

In 1958, 1960, 1962 and 1967, important amendments modified the Food and Drug Act with important implications for animal drug regulation. The 1958 Food Additive Amendment[1] currently represents one of the two major sections of the Federal Food, Drug and Cosmetic Act providing the FDA with authority over substances added to animal feed and animal drugs;[2] the second major section is Section 5.2 concerning new animal drugs.[3]

2.2.1.1 The 1958 Food Additives Amendment

The 1958 Food Additives Amendment defines "food additives" as any substance which in its intended use. . .

> results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. . .if such substance is not generally recognized, . .to be safe under the conditions of intended use.[4]

The FFDCA defines a food to include: 1) articles used for food or drink for man or other animals; 2) chewing gum; 3) articles used

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[1] 21 U.S.C. 301 Et. Seq.

[2] U.S. Congress, Office of Technology Assessment, Drugs in Livestock Feed, Volume I (Washington, DC: U.S. Government Printing Office, June 1979).

[3] 21 U.S.C. 360.

[4] 21 U.S.C. 321 (a).

as components of any such article.[1] The 1958 amendment provides that any substance added to food must be proven safe by the manufacturer to FDA before the product can be legally sold. Thus, this portion of the law accomplishes for food additives what the strengthened Food, Drug and Cosmetic Act did for prescription drugs in 1939 in the area of shifting the burden of proof from the government (ex post facto) to private industry through requirements of pre-market testing. Hence, the amendment formally legitimizes the role of chemical technology in the production and processing of food, provided that chemicals and any residues are proven safe at the expected levels of human exposure.

As indicated, the law initially defines a food additive as any substance which may become, directly or indirectly, a component of any food, or affect the characteristics of any food. Included here are intended additives, natural and synthetic additives, other foods, elements of packaging which may migrate and become part of food and some varieties of incidental additives which may "reasonably" be expected to become a part of food.

The law narrows the impact of the amendment to a degree by defining exemptions. Not included under the definition of food additives are those substances accidentally entering or becoming part of a food article. Accidental additives include environmental contaminants, and some cleaning solutions; these may be permitted in food under Section 406 despite classification as poisonous or deleterious substances

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[1]This section benefits from and in some statements paraphrases an exposition of the Delaney Amendment by Donald H. Mackaman. "Food and the Law: The Delaney Controversy," Milling and Baking News, January 2, 1979, p. 27.

provided occurrence is below specified tolerance or action levels. A second exemption from food additive status involves those substances which were sanctioned by either USDA or FDA prior to the enactment of the food additive amendments (September 6, 1958).

Those substances "generally recognized as safe" (called GRAS) make up a third category of exemption from the food additive amendment. No complete list of GRAS substances exists; however, the category includes two groups. Some fall under a grandfather clause which accords GRAS status to those substances commonly used in food prior to January 1, 1958 with no perceptible problem. GRAS substances not grandfathered into the category require expert evaluation of existing scientific records for confirmation of safety.

Pesticide chemicals contaminating raw agricultural products do not conform to the meaning or intent of the food additive amendment, and are exempted, falling under general adulteration portions of the act unless occurring in quantities below tolerances set, in this case, by the Environmental Protection Agency.

The 1958 Food Additive Amendment has become notorious for containing the Delaney Clause which states, "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in men or animals." This specific clause applies only to food additives, not to substances exempted from food additive status. In 1960 when a color additive amendment was added to the law, the Delaney Clause was restated for color additives in much the same manner.

2.2.1.2 The Drug Amendments of 1962

The FFDCA treats new animal drugs separately from food additives and in the same manner as human drugs in many respects. The 1962 drug amendments added to previously established safety requirements a requirement that drugs be proven effective as well. In addition to evidence demonstrating safety and efficacy, the law requires that an application for FDA market approval include descriptions of manufacturing, processing and packaging procedures (including quality controls), proposed labeling and the proposed tolerance, withdrawal period or other conditions of use along with other information.[1]

The section establishing grounds for refusal of an animal drug application contains yet another restatement of a Delaney Clause although with a modification this time: a drug inducing cancer but intended for use in animals may be approved

> . . .if the Secretary finds that, under the condition of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animal for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulation[2]. . .) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals. . . .[3]

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[1] 21 U.S.C. 360 (b).

[2] The inclusion of the clause by Congress enables the FDA to exercise some flexibility regarding low-level carcinogens by specification of the sensitivity of method to be used in the test. The clause does not mandate use of the most sensitive assay method at any point in time.

[3] 21 U.S.C. 360 (b) (d) (1).

In the case of animal drugs which are not carcinogenic, the FDA is given the authority to establish tolerance levels for any residues which might remain in meats and withdrawal periods mandating the number of days the drug must be withdrawn from an animal prior to slaughter.

A tolerance level is the maximum level of a drug (or other substance) legally present in the tissues (organ and muscle) at slaughter. Establishment of tolerances for residual drugs recognizes one of two things: the fact that depletion from the animal's system may be incomplete at time of slaughter so that any residual quantity must be determined safe; or that the level of sensitivity of the official tissue residue method may place a floor under detectable levels of drugs. FDA distinguishes between what it calls "negligible" and "finite" tolerance levels. Negligible tolerances are set on the basis of evidence generated in acute 90-day toxicity studies in small animals. "Finite" tolerances are based upon results of longer term lifespan studies. In the case of rats, the lifespan may be 2-3 years. If a 90-day, rather than a lifetime, toxicity study provides the experimental data for risk assessment, a 2000-fold safety factor is applied. Experimental results from a lifetime study, considered relatively more certain, necessitate a lower 100-fold safety margin.[1] Another difference in the application of negligible vis a vis finite tolerances is that the former generally requires that a withdrawal period

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[1] Interview with Dr. Catherine Carnavale, Bureau of Veterinary Medicine, FDA, Rockville, Maryland, September 18, 1979.

be set in order to reduce potential residues below the lower tolerances required.[1]

Once some of the legal parameters characterizing animal drug and food additive regulation are understood, it becomes apparent that different patterns of costs and benefits result from a substance gaining a particular categorization under the law. For example, once a substance is declared a food additive, unless exempted as GRAS or prior sanctioned, it cannot be permitted for use in foods in any amount if shown to pose any carcinogenic risk in animals or man. If a substance can win GRAS status, especially if grandfathered into the GRAS category, then no safety data need be submitted for FDA approval.[2] Such a categorization can represent a substantial cost savings, even economic survival, to companies wishing to produce or utilize the substance.

Controversy in the latter 1970s over nitrites and nitrates used in curing meats illustrates the battleground the Federal Food, Drug and Cosmetic Act can provide for warring interest groups. The use of nitrites in red meats as a preservative was sanctioned prior to the Food Additive Amendment of 1958 thus exempting them from provisions of the Food Additive Amendment, in general, (requiring pre-market

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[1] Interview with Carnavale, FDA; Office of Technology Assessment, Drugs in Livestock Feed, p. 46.

[2] Recall no complete list of GRAS substances exists.

safety evidence) and the Delaney Amendment regarding carcinogens, in particular. Nitrite and nitrate use as a preservative in fish, pet food and possibly poultry had no prior sanction.[1] Given a prior sanction, the burden of proof falls to the government to demonstrate by competent scientific evidence that a substance is poisonous or deleterious and injurious to health. With no prior sanction, a substance may be classified as a food additive, necessitating a ban in the event of evidence of carcinogenicity.

Consumer advocates attempted to have nitrites banned from the market. They argued that although use of nitrites as a preservative had been prior sanctioned in red meats, its use to fix color had not.

They attempted (unsuccessfully) to have nitrites classified as color additives, thus subjecting them to Delaney and premarket safety provisions of the color additives amendments of 1960.[2] Ultimately, however, the fate of nitrites appeared to hinge less on the Court's interpretation of their legal status than on the validity of the experimental evidence used by the FDA and USDA as a basis for initiating a gradual phase-out of nitrite use.[3] The case does demonstrate,

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[1]Mackaman, "Food and the Law." In 1925 USDA published regulations permitting 200 ppm nitrite or nitrate in finished meat products, A. Estes Reynolds and Sharon O. Kennedy, "History of Facts Behind Nitrite Issue," Michigan Farmer, February 3, 1979, pp. 51-2.

[2]21 U.S.C. 376.

[3]The Massachusetts Institute of Technology study upon which FDA and USDA based initial policy actions. "FDA Ripped for Handling of Nitrite Data: Congressional Probe Finds Agency Failed to Follow Own Scientific Review Procedures," National Hog Farmer, October 15, 1979, p. 9.

however, the economic interests of various groups in having a particular substance fall under a given legal designation which carries with it assorted patterns of costs and benefits as a property right.

2.2.1.3 Legal Status of Sulfamethazine

What about sulfamethazine? Unfortunately, an understanding of the major provisions of food and drug law in this area does not provide a sufficient basis for determination of either the legal status or the probable economic ramifications of legal status in individual cases.

Sulfamethazine is considered an old or "not new" drug having been in use since the 1940s. Legally sulfamethazine can only be fed to swine at sub-therapeutic levels in combination with chlortetracycline and penicillin or with tylosin. Sulfathiazole is permitted only in combination with chlortetracycline and penicillin. Finally, sulfamethazine has also been cleared for use in cattle in combination with chlortetracycline (AS-700).

Five certifiable antibiotics--chlortetracycline, penicillin, streptomycin, bacitracin and chloramphenicol--and their certifiable combinations are currently exempted by administrative fiat from regulatory requirements applicable to new animal drugs.[1] This means that use of combination drugs such as ASP-250 (chlortetracycline:sulfamethazine:penicillin) and CSP-250 (chlortetracycline:sulfathiazole:penicillin) does not require a new animal drug application and that establishments mixing the drug into feeds are not subject to biannual FDA inspections to determine compliance with Current Good Manufacturing Practices.

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[1] 21 U.S.C. 360 (n).

Authorized sulfa combination drugs may be manufactured upon approval of FDA. Two pharmaceutical companies hold FDA approval to produce the swine combination drug containing chlortetracycline, penicillin and sulfamethazine: these are American Cyanamid and Rachelle Laboratories. One company, Diamond Shamrock, holds FDA approval for manufacture of the same combination substituting sulfathiazole. The final approved swine feed combination is tylosin and sulfamethazine. Tylosin is classified as a new drug, not an exempt certifiable antibiotic. Therefore, producers and users of Tylan-Sulfa must submit new animal drug applications for approval. Many companies hold FDA approval for this combination.

2.2.1.4 Tolerance Levels and Withdrawal Times

The Food and Drug Administration issued a tolerance level for sulfamethazine and sulfathiazole in swine tissues (kidney, liver and muscle) of .1 ppm.[1] This is a negligible tolerance level which was set at the level of sensitivity of the approved assay method[2] back in 1962.

Originally, a seven day withdrawal period for sulfamethazine and sulfathiazole in combination with tetracycline and penicillin was established; the withdrawal period for the sulfamethazine-tylosin

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[1] 21 Code of Federal Regulations 566.670 and 566.690.

[2] This negligible tolerance level was based on residue depletion studies using what is called the Bratton-Marshall colorimetric residue method, the sensitivity of which was considered .1 ppm.

combination drug was five days. When sulfamethazine residue problems gained increased notice, the FDA increased the sulfamethazine withdrawal time to 15 days, reflecting the supposition at the time that a majority of violations stemmed from swine producers failing to allow sufficient withdrawal time before slaughter. Separate regulations establish withdrawal times for other sulfonamides at 10 days.[1]

2.2.1.5 FDA Organization of Responsibilities and Major Policy Issues Related to Animal Drugs

Within the Food and Drug Administration, the Bureau of Foods and the Bureau of Veterinary Medicine are most intimately involved in determination of food safety policy relating to animal drugs. An animal drug must be evaluated to be both safe and effective, entailing two independent sets of regulatory decisions. Safety determinations emanate from the Bureau of Foods while the Bureau of Veterinary Medicine judges animal drug efficacy. Failure on either account can result in rejection of a petition for animal drug approval.

Tolerance determination, then, is chiefly the province of the Bureau of Foods. While a food additive proving carcinogenic must be banned under terms of the Delaney Amendment, a carcinogenic animal drug may be permitted so long as no residue remains. The Bureau of Foods, therefore, has responsibility for designating which methods (along with their associated level of sensitivity) should be utilized

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[1]Office of Technology Assessment, Drugs in Livestock Feed, p. 21.

to establish a determination of residues. An FDA proposal stipulating criteria and procedures for evaluating assays for carcinogenic residues was published as a proposal in March, 1979.[1] This policy is referred to as the "Sensitivity of Method" (SOM) policy. Although still at the proposal stage, SOM is currently being applied to new drug applications.

The method by which the agency will seek to apply the same conservative standards to old drugs (such as sulfamethazine) is through a program of "Cyclic Review," wherein old drugs will be scrutinized by the FDA, with sponsoring companies asked to support new research conforming to today's rigorous standards. The policies are feared by many to mandate excessively costly "defensive research" which would take resources away from new product development. Statements by the Director of the Food and Drug Administration's Bureau of Veterinary Medicine to the effect that "the majority of currently approved food animal drugs and feed additives are not profitable enough to support such research" indicate the opinions of key policy spokesmen for the Bureau of Veterinary Medicine even though he termed the dual efforts of SOM and Cyclic Review "laudable undertakings," "eminently desirable in the ideal world."[2]

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[1] On Tuesday, March 20, 1979 the FDA published in Part III of the Federal Register "Chemical Compounds in Food-Producing Animals (Criteria and Procedures for Evaluating Assays for Carcinogenic Residues)."

[2] Dr. Lester M. Crawford, (then) Director of FDA's Bureau of Veterinary Medicine, reprinted in Food Chemical News, July 28, 1980.

The Bureau of Veterinary Medicine of the Food and Drug Administration has been aware of the unwieldy nature of existing law in the area of medicated feeds including inconsistencies of the sort mentioned above which permit sulfamethazine use without any permits. In 1981 a comprehensive set of new regulations has been published in the Federal Register as a final proposal.[1] Referred to as the "Second Generation of Medicated Feeds Policy," the policy attempts to formulate a systematic approach to allocating regulatory priorities to those drugs and feed articles believed to present the greatest human health risk. The proposed regulations alter current procedures and requirements pertaining to medicated feed applications for new animal drugs and establish Good Manufacturing Practice (GMP) regulations for firms producing medicated feeds that do not require an approved medicated feed application.

If implemented, the program promises major changes in medicated feeds policy, in general, and particularly in policies regulating use of sulfamethazine in swine and cattle feed. An analysis of the potential economic and residue impacts of this proposed policy in relation to the sulfa case is presented in Chapter V.

2.2.2 The Wholesome Meat Act and the United States Department of Agriculture

USDA legislative authority related to food safety stems from a series of legislation including the Federal Meat Inspection Act, the

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[1] Federal Register, January 9, 1981.

Poultry Products Inspection Act and the Egg Products Inspection Act. Most relevant to the sulfa case is the Wholesome Meat Act (signed into law December 15, 1967) which states that residues in excess of tolerances caused by agricultural or industrial chemicals, growth stimulants, feed additives, therapeutic agents and other toxic chemicals constitute adulterants under the law. Adulterated meat cannot legally be sold in interstate commerce.

The USDA Meat Inspection Program (as well as its other inspection programs) enforces chemical residue standards established by the Food and Drug Administration or the Environmental Protection Agency (EPA) along with USDA standards regarding wholesomeness, general sanitation, proper packaging and labeling.[1] In general, USDA jurisdiction over meat products begins at the point livestock reaches the slaughterhouse and extends through further processing.[2]

USDA began monitoring the nation's meat supply for sulfamethazine and other sulfonamides in the early 1970s. Originally residue monitoring was carried out by the Animal and Plant Health Inspection Service (APHIS); in March of 1977 the National Residue Monitoring Program and

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[1] As we have seen, FDA operates under legal jurisdiction provided by the Federal Food, Drug and Cosmetic Act; EPA authority is specified in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

[2] USDA currently has the authority to quarantine live animals on farms for reasons of infectious disease; it does not have equivalent authority in cases of suspected chemical contamination, although a bill was initiated by Rep. Tom Foley at the administration's request in the 1980 legislative session, with no action.

associated activities were transferred to the newly formed Food Safety and Quality Service (FSQS). In 1981 a new USDA reorganization consolidates all inspection and grading activities in a single service while removing them from the jurisdiction of the Assistant Secretary of Agriculture for Nutrition and Consumer Services.[1]

Currently USDA operates four meat inspection programs for chemical contaminants in meats: 1) the National Residue Monitoring Program monitors both Federally and State inspected slaughterhouses on a random basis (taking account of number of animals of each species killed, location, sex of animals and other factors in order to provide the capacity of detecting with 95% confidence any monitored chemical contaminating at least 1% of the general population of animals sampled;[2] 2) the Surveillance Program is a non-random inspection program designed to ensure that meat animals suspected of chemical contamination are cleared by testing prior to moving into the food supply;[3] 3) the Import Program monitors international ports of entry to establish compliance of incoming meat products to U.S. standards; 4) the Contamination Response Program is the newest chemical residue program established by FSQS and is designed to enable timely agency response to any chemical contamination emergency.

The sulfa case illustrates the operation and inspection of three of the chemical residue programs. The National Residue Monitoring

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[1]Position formerly held by Carol Tucker Foreman.

[2]Currently approximately 40-50 compounds are routinely monitored.

[3]One function of the Surveillance Program is to follow up on violations identified under the Monitoring Program.

Program (NRMP) collected data indicating that violative sulfonamide residues were occurring in a high percentage of animals sampled. Standard sampling rates entail approximately 300 analytical samples for each chemical compound being monitored in the suspect population per year.[1] When it became evident that sulfa violation rates were ranging between 7 and 15 percent, FSQS increased monitoring rates to determine whether sample violation rates would change; they did not.[2]

Concern over the rate of sulfa violations keyed Surveillance Program response. Because surveillance programs are designed for special purposes such as attempting to assess the geographical incidence of a particular contaminant; responding to previous violations; or analysis of a sample initiated by inspector request, the results of residue surveillance activities are intentionally biased by nature and not indicative of the general population. Surveillance activities in the sulfa case were related to increasing producer compliance. If a violative producer could be identified, he was then required to demonstrate that five animals from a subsequent market lot were free of contamination before he was permitted to resume marketing. Clearing the animals requires laboratory certification, sometimes at the producer's expense.

Throughout the sulfa case, surveillance activities involved more intensive sampling from plants or geographical regions suspected as

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[1] Interview with Dr. Harold Trabosh, FSQS, USDA, March 2, 1981.

[2] Interview with Trabosh, FSQS.

contaminated. In 1981, for example, certain areas of the Southeast--principally parts of Georgia and Florida--produced violation rates atypically high in relation to national averages. Surveillance activities of plants in this area led regulators to the conclusion that hogs marketed direct to the packer demonstrate a violation rate significantly lower than those marketed through auctions. At the same time, producers marketing direct can be traced whereas producers marketing through auctions are less accessible.[1]

The Imported Products Residue Program is the third FSQS residue program which has been involved in the sulfa case. Federal meat and poultry legislation requires products imported into the U.S. to be inspected by a system qualitatively equivalent to the U.S. meat inspection program. Hence, the inspection system of any country exporting pork to the U.S. must legally be certified by the USDA. Whereas in theory, the U.S. does not itself test incoming meat, in practice incoming meat <u>is</u> sampled both on a random monitoring and a select surveillance basis. Some regulators state that developments in the inspection program for imports have improved performance to the point at which imports are monitored more efficiently than domestic meats.[2]

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[1] Interview with Trabosh, FSQS. Animal identification systems would aid in closing this marketing loophole. This policy option is analyzed in Chapter V.

[2] Interviews with FSQS personnel in charge of the import residue program. Ports are monitored on a random basis taking account of species, poundage, sex, suspect compound and other factors. The import program in contrast to the domestic program now utilizes a system of mini-computers permitting instantaneous response to monitoring reports of violations. If monitoring results indicate cause for concern, sampling rates can be quickly increased. Interview with Bill Brimberry, FSQS, USDA, February 26, 1981.

The U.S. imports pork from Canada and Northern Europe. Canadian pork is primarily in the form of frozen boxed meat; pork from Poland and Scandinavia enters most frequently in the form of processed canned hams. Sulfamethazine residues in pork have been the sulfonamide of primary concern and Canada is the only significant exporting country of concern. In response to U.S. concern over sulfa residues, Agriculture Canada and the Canadian Department of Health and Welfare initiated a series of policy actions in order to protect their pork export markets. An analysis of measures undertaken by Canada is included in Chapter V.

2.2.3 Summary

The preceding sections discuss the Food, Drug and Cosmetic Act and the Wholesome Meat Act along with some highlights of administrative agency structure of FDA and USDA applicable to animal drugs, food additives, the establishment of tolerances and other aspects of food safety policy. The specific status of sulfamethazine and sulfathiazole was then reviewed.

In summary, the law requires that all substances falling within the broad classification of food additives (and not subject to exemption) be proven safe, or disallowed if carcinogenic. It also requires that all so-called "new" animal drugs be proven safe and effective for intended use. If non-carcinogenic, drug residues remaining in foods must be below established tolerances while carcinogenic drugs are disallowed unless no residue can be detected in the carcass as determined by FDA stipulated method.

In effect, sulfamethazine (and sulfathiazole) falls between the slats of these policies. An old drug, "sulfamethazine" has been widely available in straight form from feed supply stores in recent years, even though it is technically illegal to feed sulfa drugs except in prescribed combinations. In addition, the combination drugs ASP-250 and CSP-250 (sulfathiazole) can be purchased without a medicated feed application (FD-1800) over the counter.

Regulatory jurisdiction under the laws cited above falls to the Food and Drug Administration and the United States Department of Agriculture. FDA determines safety and efficacy of animal drugs submitted for approval and establishes tolerance levels and withdrawal times if warranted. USDA under the Wholesome Meat Act inspects meat for chemical contaminants. USDA operates a National Residue Monitoring Program based on random samples and a Surveillance Program designed to follow up concerns raised by the Monitoring Program. Imported meat is also monitored under a third USDA program. These three USDA efforts raised the initial cry and alarm in the sulfa case.

CHAPTER III

FOOD SAFETY AND FOOD SAFETY POLICY ANALYSIS: ASSESSING REGULATORY IMPACTS UPON FIRM DECISION-MAKING AND SUBSECTOR PERFORMANCE

Chapter III develops a conceptual framework for analysis of the impacts of food safety regulation on firm decision-making and subsector performance. Section One begins by considering food safety and its characteristics as a "good." Whether provided by the market or the public sector, uncertainty exerts a critical impact upon conditions of demand and supply. Section Two then reviews dominant economic literature concerning public program and public policy analysis including benefit-cost analysis, risk-assessment, and cost-effectiveness analysis. Deficiencies inherent in these methods for purposes of public food safety policy analysis are revealed by consideration of the problematic nature of estimating risk from public exposure to chemical residues and the nature and magnitude of benefits from public food safety programs.

Rather than attempting to reduce divergent interests in the sulfa case and in food safety regulation to a single and fundamentally misleading measure (such as a benefit-cost ratio or a cost-effectiveness rating), the purpose of the conceptual model developed in Section Three is to provide a diagnostic tool capable of relating food safety regulations to impacts upon firms and firm decisions which subsequently produce industry and systemic impacts upon a number of important performance

variables. Development of such a model assists in predicting the types of impacts different policy formulations are likely to have.

In order to evaluate regulatory impacts in the manner described, it is necessary to model firm decision-making. The decision-making model of Section Four, in contrast to standard competitive models, incorporates uncertainty, transactions costs and other features critical to understanding firm decision-making in the sulfa and similar cases. Food safety problems also constitute decision problems for policy makers (discussed in Section Five). In formulating food safety policy, decision-makers pursue their own goals within an environment influenced by a number of diverse interests, including the economic interests of firms affected by food safety regulation. Understanding the decision-making problems and processes of policy makers, particularly bureaucrats in agencies charged with food safety responsibilities, contributes to an understanding of the interactions between food safety regulation, firm decisions and ultimate performance of the food system.

Section Six relates firm decisions within industries to important performance variables representing aspects of food system performance important to participants. This part of the model completes the linkage of institutional, decision-making and performance variables.

3.1 Characteristics of Food Safety as a Good

Characteristics of the "good" food safety impinge upon conditions of its demand and supply in the market and by the public sector. Food safety can be conceptualized in terms of a continuum of risk involved

in the purchase and consumption of food items. A variety of factors contributes to societal judgments regarding acceptability of risk levels at any given time, including the state of knowledge. In general, the fundamental rationale behind public food safety regulation is the belief that socially desirable levels of safety in foods are not adequately ensured by ordinary functioning of the market. The economic theory of public goods provides some insights into the nature of "food safety," and the problematic nature of articulation of preferences for particular levels of food safety through the market and through the political process.

3.1.1 The Role of Uncertainty and Costly Information

A logical point for beginning a discussion of food safety and public policies to improve food safety is with the matter of uncertainty and information costs. The theme of uncertainty colors any discussion of food safety or any determination of food safety policy. Uncertainty and high information costs in the market provide a major rationale for public food safety regulation. Yet shifting the burden of decision to the public sector in no way eliminates uncertainty; it merely redefines and redistributes it.

Regarding evaluation of the safety of a given food item, not only is it prohibitively expensive and practically impossible for consumers to analyze food items before purchase for the presence of contaminants, but, additionally, the knowledge required to interpret toxicological ramifications of the presence of contaminants to a given human far

surpasses the capacities of most experts. High information costs for consumers, then, provide a major rationale for government regulation or provision of food safety services, given the ethical precept that it is unacceptable to subject unknowing consumers to significant risks of food borne disease or death.

The information problem is not confined to the final consumer in the market but affects producers as well. Draftors of federal food safety legislation, in addition to specifically citing the social unacceptability of a market place doctrine of caveat emptor, also mention the detrimental effects which imperfect knowledge and high consumer information costs have upon the scrupulous, vis a vis the unscrupulous producer in the market place when the latter enjoys a competitive advantage in the provision of contaminated ware.[1] Analysis of potential impacts of the asymmetrical possession of information by parties to an exchange, when coupled with the rational self-interest of participants, suggests that in the absence of opposing regulatory incentives an economic actor may find it rational to subsidize preferred information or withhold damaging information in order to sell a product.[2] Hence, the market alone can offer perverse incentives in regard to satisfaction of consumer preferences for food safety.

In the case of many contaminants which enter the food chain at an input supply stage, all successive exchanges bear imprints of information

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[1] United States Code Annotated, Title 21, Chapter 12, Section 602.

[2] Randall Bartlett, Economic Foundations of Political Power (New York: The Free Press, a division of Macmillan Publishing Co., Inc., 1973), pp. 27-37.

costs so high that buyers and sellers find it impossible to evaluate the purity or safety of that which is being sold. In the sulfa case, the hog producer who purchases manufactured feed experiences information problems similar to the consumer in attempting to assess whether the feed is contaminated. The difference, however, is that the consumer eats the product while the producer is primarily concerned with sale. Unless the producer faces incentives discouraging sale of contaminated products, high information costs encourage the rational producer to ignore contamination problems.[1]

Because food safety information is a concern, political preferences have resulted in the government taking responsibility in this area. Government officials, however, must also deal with uncertainty associated with determining and measuring different aspects of food safety.[2]

3.1.2 Additional Transactions Costs Associated with Food Safety

In addition to information costs, other types of transactions costs can be identified in conjunction with demand and supply of the "good" food safety. While information deficiencies pose a problem for consumers in and of themselves, they do not necessarily supply a sufficient grounds for government provision of particular levels of "food safety" or food safety information. Exacerbating the problem

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[1] Other factors may mitigate this outcome, of course, including producer altruism.

[2] See Eileen O. van Ravenswaay and Beth A. Hull, Department of Agricultural Economics, Michigan State University, "Regulatory Decision-making on Toxic Substances in Food," paper presented at the Public Choice Society Meetings, March 1981.

of arranging alternative institutional forms of voluntary collective supply, however, are the organizational costs of decision-making in large groups. In cases where benefits are widely distributed and slight, the presence of transactions costs operates to discourage large groups from articulating their preferences. A third type of transactions costs, once again related to information uncertainty, is the cost of policing a stipulated quality level.

Provision of certain food safety services may be feasible through market mechanisms, but requirements for policing of quality must be considered, due to consumer information problems associated with detection of contaminants. The success of "organically grown" produce in certain markets attests to the presence of consumer demand for certain pesticide-free products. Demand may similarly exist for "organically" grown meat devoid of drug residues. (A somewhat similar phenomenon is a cited growing consumer demand for livestock raised under conditions approved by animal rights groups.) While revelation of demand in these cases can be encouraged through producer segregation of markets by mechanisms of certification of products, again it should be stressed that consumer policing costs potentially exceed benefits unless exchanges can be based on trust and some measure of loyalty between buyer and seller.

3.1.3 Food Safety Characteristics: High Exclusion Costs, Joint Supply

In the literature of public goods, two characteristics, high exclusion costs and joint supply, are particularly important. In the "pure"

case, the presence of these two characteristics necessitates public provision of the "public good." Even when such goods are desired by a majority of citizens, they will not be supplied through market mechanisms. The characteristic of joint supply (or "joint impact," or "the marginal cost of another user equals zero") means that once the mechanism of a good's supply is in place, it is no more costly to make the good available to additional consumers than to restrict it. (This characteristic is further discussed below.) The exclusion principle suggests that it is possible to exclude from consumption of a good those not paying for the good. Non-exclusion, conversely, refers to the inability or the high cost of discrimination between one who pays and the free-rider. The quality of non-exclusion relates to the lack of an institutional mechanism effective in forcing consumers to reveal their preferences for a good or service. An implication of non-exclusion or high exclusion costs is that a good which many desire and are willing to pay for will not be provided because of this lack of a mechanism stimulating revelation of all bids. Hence, for the individual consumer, rationality implies suppressing a bid in the expectation of riding free. High exclusion costs complicate the determination of consumer demand for various activities associated with food safety provision such as information, research (areas such as drug toxicology, assay methodology, et cetera), information dissemination, food inspection. In respect to each of these activities, a substantial body of consumer preference may coexist with the belief that others will pay. Given this belief, the rational consumer fails to reveal his bid. In the case of food safety services such as research, information and education, high exclusion cost properties

exhibit many similarities to a good such as public television programming for in each of these cases, the consumer may use the good provided yet never contribute toward its expense.

The characteristic of joint supply is frequently described by the statement that the marginal cost of an additional user is zero. Samuelson describes this quality: "Each individual's consumption of such a good leads to no subtraction from any other individual's consumption of that good,"[1] Musgrave terms them goods which "must be consumed in equal amounts by all."[2] The existence of this characteristic implies that once the investment for provision of a good or service is in place, economic efficiency is ill-served by restricting access to the good or service, even if it were possible. The reason cited is that total social welfare is enhanced by permitting the marginal consumption when the economic cost of doing so is negligible. Choice of a pricing rule or financing terms under conditions of decreasing cost, however, carries with it important distributional consequences.

Many services associated with provision of food safety as a good exhibit the properties of joint supply (or joint impact). Many food safety investments (toxicological research is a revealing example[3]) require substantial fixed investments in terms of laboratory costs, highly trained scientists, et cetera. Once these investments are sunk

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[1]Paul Samuelson, cited in Jesse Burkhead and Jerry Miner, Public Expenditure (Chicago: Aldine Publishing Co., 1971) p. 26.

[2]Richard A. Musgrave, cited in Burkhead and Miner, Public Expenditure, p. 26.

[3]Inspection and monitoring activities, use of labs, publication and broadcast of educational materials represent similar phenomena.

and an outflow of research information begins, economic theory deems it economically inefficient in a social welfare sense to restrict access to this information by the marginal consumer even if that consumer's valuation of the good is near zero. Total welfare is enhanced at a cost close to zero if this information is made available to the marginal consumer.

Supply incentives, under marginal cost pricing rules in such cases of large fixed investment and declining marginal costs, are inadequate to spur private provision of the goods when total revenues do not cover costs. Hence, the argument is often promoted that the government should step in to guarantee provision of the good in a quantity related to the amount of consumer surplus generated by expanding production to the point where price equals marginal cost.

The incidence of the costs of government provision depends upon government revenue schemes utilized to finance them, however, and raises equity propositions of the "unwilling rider" who pays taxes funneled into these projects.

3.1.4 Summary of the Public Goods Characteristics Associated with Food Safety

Here it may be useful to summarize the preceding discussion of food safety and associated services prior to a fuller discussion of the supply and demand of "food safety" goods and services.

First, "food safety" refers to socially determined levels of risk judged acceptable in food products. The determination, articulation and provision of these levels of risk is achieved through a complex of

food safety activities and services. These can be categorized in terms of information, research, education, and inspection activities.

In each category of food safety service qualities of high information costs, high exclusion costs, jointness in supply (or impact), high consumer costs of organization and policing combine in varying proportions to create problems in articulation and satisfaction of consumer preferences through the market. Legislative and administrative channels in many cases are judged by the political process to be more appropriate for provision of food safety services, but reliance on these must be recognized to replace problems of market provision with those of public provision, including the problem of unwilling riders.

3.1.5 Conceptualizing Consumer Demand for Food Safety

Economic theory of the public sector which is based on methodological individualism begins with the cornerstone of the individual consumer's demand for a good; in evaluating the performance of the public sector, then, the criterion of maximization of aggregate consumer welfare is used. Measures of welfare are based on effective demand. Traditionally the consumer is viewed as attempting to maximize utility subject to an income constraint. Economic utility flows from the consumption of various goods and services. Three alternative conceptualizations of consumer demand for food safety include the notion that food safety is a continuous variable in a consumer's utility function in its own right, that food safety is a product characteristic in a Lancasterian[1] sense

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[1]K. Lancaster, Consumer Demand: A New Approach (New York: Columbia University Press, 1971), Chs. 1-4.

which is traded off by the consumer against other product characteristics and product price in determination of total consumer demand for the product and thirdly, that food safety is an environmental good in a non-separable utility function which is linked to consumption of a private good, say pork. Consumption of the public good food safety in pork affords no utility when consumption of the private good pork is zero. Variations of these three basic approaches exist. Food safety certification may be conceived as a constraint. Such a construct explicitly recognizes the information problems of the consumer in monitoring food for safety and in exercising judgment as to which levels of risk qualify as safe. The consumer in this formulation does not desire to make the marginal trade-offs between level of risk and price or other product characteristics. Instead, recognizing finite analytical capacities, the citizen acts through the electoral process to have a public collectivity certify food and make the implicit trade-offs.

3.1.6 A Taxonomy of Food Safety Regulation

In order to discuss public supply of food safety services and food safety regulation, a taxonomy is useful. In this instance food safety regulation and services--including performance and process standards, the provision of information and pecuniary impacts--are viewed from the perspective of the firm. Such an approach permits examination of means by which food safety regulation of various formulations figure in firm decision-making.

3.1.6.1 Performance Standards

Many food safety regulations take the form of product performance standards (they regulate the attributes of the final output of a process). Product quality standards may be instituted separately from or in conjunction with process standards (which regulate how the final output is produced). With some notable exceptions, pork producers are generally not regulated with respect to the management techniques they use in producing their product.[1] However, pork marketed in interstate commerce for human consumption must meat quality standards mandated under the Wholesome Meat Act. As such, it must be evaluated by the meat inspection service to be free of disease and acceptably free of chemical contaminants.

Commercial feed firms, on the other hand, are regulated chiefly according to process standards even though product quality standards are on the books and feed products may be occasionally sampled. The differing legislative mandates, regulatory philosophies and inspection budgets of USDA and FDA, help to explain the variable reliance placed upon process and product standards in these cases.

3.1.6.2 Process Standards

A second category of food safety regulations directly affects the firm's autonomy of action (in either production, manufacturing or marketing arenas) by placing constraints on the legally permissible processes which may be employed. Regulations of this broad type will be

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[1]Exceptions include restrictions on drugs which may be legally used in livestock production.

termed process standards; the firm may be required to demonstrate its compliance or ability to comply with specified manufacturing practices, or laboratory practices. Animal health firms, for example, must demonstrate compliance of their laboratories with Food and Drug Administration Current Good Laboratory Practices, commercial feed firms must comply with Current Good Manufacturing Practices (also FDA regulations) and meat packers must be certified with the Packers and Stockyards Administration as well as meeting certain process standards of the USDA, Food Safety and Quality Service (FSQS).

3.1.6.3 Public Provision of Information (and other Goods)

The third type of food safety policy approach considered here from the perspective of the firm is one in which a public body provides a good such as information. Information, by our meaning, covers a fairly broad spectrum of possible services ranging from support of research (basic or applied), or extension services, to preparation of public interest messages for radio or television spots to training sessions. Each of these information goods and services has the effect of lowering transactions costs for the firm.

3.1.6.4 Pecuniary Standards

Food safety regulations are termed pecuniary if they enter the firm's decision calculus in the form of higher (or lower) costs which must be paid in input markets or in the alternative form of lower (or

higher) product prices receivable in the market. Food safety policies of this type include any measures which raise (or lower) the cost structure of input suppliers to the extent that such costs are reflected in the market place for these inputs. The key concept is that pecuniary impacts work through the market. An example of such a food safety policy is the imposition of quality control standards on the drug industry which raises the price of animal health products. From the standpoint of commercial feed firms and hog producers, such a regulatory policy may be termed pecuniary in effect. Alternatively, a regulatory policy is pecuniary if it results in lower (or higher) product price levels for the producer. A food safety policy of this type could be exemplified by a per unit tax on product sold (imagine, for instance, a per unit charge on swine feed) or by a regulatory program or action which shifts the quantity or composition of demand for the product. (In 1967, FDA spokesmen precipitated what is known as the Great Cranberry Scare by announcing a few weeks before Thanksgiving that a significant proportion of that year's cranberry crop was contaminated with a known carcinogen. Cranberry sales plummeted; more recently a great deal of publicity has surrounded the scientific and public controversy over the risk inherent in nitrite-cured pork, especially bacon. To the extent this policy has resulted in an alteration in the price level of bacon and other pork products, it has had a pecuniary effect on pork producers and processors).

To summarize, food safety regulatory policies work in a pecuniary manner if they register their effects in either the market price of inputs or product. At an extreme, a pecuniary regulation may have the

effect of eliminating the market for an input or product if costs are affected too severely.

3.2 Overview of Benefit-Cost Analysis

When government expenditures are used to provide the public with a "good" such as food safety, frequently decision-makers desire a means of analyzing and evaluating public programs either on an ex ante basis or after the fact to see how well the program met its objectives. A number of techniques have been developed to this purpose. In this section benefit-cost analysis is discussed; subsequently, alternatives are highlighted.

The application of economic theory over the years to public program analysis has resulted in the development of formal techniques of benefit-cost analysis. Ideally, the benefits of a public program are evaluated by economists through assessment of what consumers are willing to pay for the program. Costs of the program represent all resources devoted to the program evaluated at their opportunity costs.

In the words of a standard text, economic benefit-cost analysis is a technique for estimating the "total return or productivity or profitability to the whole society or economy of all the resources committed to the project regardless of who in the society contributes them and regardless of who in the society receives the benefits."[1]

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[1] J. Price Gittinger, Economic Analysis of Agricultural Projects, published for the Economic Development Institute, International Bank for Reconstruction and Development (Baltimore: the Johns Hopkins University Press, 1972).

Formal benefit-cost analysis is most frequently utilized in application to public investment projects and differs most significantly from private investment analysis with respect to unit of measure and the application of opportunity cost principles to valuation of resources. Whereas the investment analysis conducted for a single firm emphasizes cost and rate of return to the firm, benefit-cost analysis of public investment projects commonly takes as its standard unit of measurement net changes in national income indicative of something frequently referred to in the literature as social welfare.

In actual practice, the definition of benefits and costs is a largely normative endeavor, and this research reflects the belief that attempting to net together assessments of cost and benefit, even if it were possible, provides a misleading and dangerously simplistic measure for citizens and for decision-makers. Here it is considered preferable to attempt to identify impacts upon different participant groups and display these without an additional level of aggregation.

Haveman and Wiesbrod[1] point out that benefits can only be identified and evaluated with reference to an objective function; the goals of a program serve as the necessary starting point for conceptualization of benefits. Haveman goes on to suggest that project goals generally fall within two broad categories: improvement of allocative efficiency (seeking an increase in the net value of output through a redistribution

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[1]Robert H. Haveman and Burton A. Wiesbrod, "Defining Benefits of Public Programs: Some Guidance for Policy Analysts," in Public Expenditure and Policy Analysis, 2nd Edition, (Chicago: Rand McNally College Publishing Company, 1977), pp. 135-160.

of resources); and improvement of equity (redistributing existing resources in order to increase the welfare of particular groups). Schmid[1] cautions, however, that while social benefit-cost analysis attempts to draw this key distinction between net additions to national income and programs which redistribute existing income, care should be exercised to reveal the normative nature of both objectives. Going an additional step, analysis of most public programs reveals that program objectives and the weighting of program objectives varies among decision-makers (and other food system participants) thus making it imperative for analysts to specify all critical objectives, participant interests and performance impacts in order to assess program performance.

3.2.1 Theoretical Underpinning of Benefit-Cost Analysis

The economic genealogy of benefit-cost analysis traces well back into micro-economic, welfare and public economic theories. Theoretical underpinnings from these theories set the stage for an examination of the applicability (and lack of applicability) of benefit-cost analysis to public food safety program analysis, particularly in the sulfa case.

It is useful to consider the assumptions which are employed in attempting to aggregate individual impacts into societal ones and the practical limitations of translating demand for a good such as food safety into usable empirical measures. These difficulties unfortunately confine the use of consumer surplus constructs to largely heuristic

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[1]A. Allan Schmid, Political Economy of Public Investment, (East Lansing, MI: Michigan State University, 1980).

importance. (Reviewing the voluminous literature concerning the strengths and weaknesses of welfare theory and benefit-cost analysis constitutes an occupation in itself. For some introductory references, see bibliography.)

3.2.1.1 Consumer Surplus

Classical and neoclassical utility theory growing out of the works of Marshall, Hicks and others furnishes the conceptual basis for measuring an individual consumer's demand for a product. The theory develops concepts of consumer surplus (and the approximate parallel, producer's surplus) as the difference between a prevailing uniform market price for a good or service and that which the consumer would be willing to pay to purchase consecutive units of the good in the absence of a uniform price.

So long as the analysis of utility and demand remains confined to the individual, under ceteris paribus conditions, particularly when the good or service in question is one free of characteristics associated with public goods, the concept of surplus is relatively straightforward and the net benefits of a project which either alters an existing product's price or provides a new product can be defined in terms of the net change in the area beneath a demand curve and above the market price line. Samuelson states, "At the level of the individual consumer, cost-benefit welfare analysis can be performed rigorously and unapologetically by means of consumer's surplus."[1]

Certain theoretical complexities arise with reference to the appropriate demand curve to be utilized in the measure: theorists attempt

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[1]Paul A. Samuelson, Foundations of Economic Analysis (Cambridge: Harvard University Press, 1947).

to isolate income and substitution effects of a change in prices, and the Hicksian compensated demand curve (theoretically compensating the consumer for any alterations in income status associated with a change in the price of a good), along with alternative measures of compensating and equivalent variation, employ different reference points with respect to the appropriate measure of change in individual welfare.

3.2.1.2 Aggregation of Consumers into a Society

At this point, the entire business of welfare analysis suffers a quantum leap in complexity--not to mention controversy--when policy makers request the aggregation of individuals into a society in order to say something systematic about the net economic impacts of investment projects. A further and particularly intractable problem of demand conceptualization and empirical estimation arises at both individual and aggregate levels for a broad class of goods not effectively supplied in a market, that is, goods possessing one of a variety of attributes bearing the epithet "public goods characteristics" (discussed above). The upshot of all this is that the composite theory of aggregate demand for public goods becomes a very tentatively balanced high rise house of cards. As if all this were not enough, authors such as Lipsey and Lancaster[1] buffet the theory about some more when they raise bothersome questions regarding the appropriateness of applying policy prescriptions designed for a

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[1] R. G. Lipsey and Kelvin Lancaster, "The General Theory of the Second Best," Review of Economic Studies 63 (1956-57): 11-32.

perfectly competitive situation (that is, a first-best world) to one which must frequently be regarded as third or fourth best.

The theoretical and empirical problems tied up in benefit-cost methodology (as well as the underlying theory of social welfare) imply that while elements of the theory of demand for goods such as food safety provide constructs of heuristic value, their applied value in attempting to estimate benefits of public food safety programs fall far short of theoretical promise.

3.2.1.3 Criteria for Evaluating Improvements in Social Welfare

The relationship between individual and social welfare has understandably presented one of the most troublesome thorns in the side of economic theory over the years. A recognition of the inadequacies of concepts of cardinal utility of Marshall in favor of the weaker but more elegant ordinal rankings of Hicks carried with it the analytical inconvenience that utilities cannot be meaningfully summed across individuals or compared between individuals. Moving into demand-space, how does one consumer's surplus compare with that of another?

Welfare economists struggling with these questions over the years and attempting to establish criteria which would permit evaluation of policy measures in terms of their impact on social welfare divide into a number of camps. The most conservative, represented by Pareto provides the principle that no policy measure should be designated as representing an improvement in social welfare unless at least one person's economic status is improved with none's being worsened. ("This

criterion deliberately rules out any attempts to add up or otherwise make commensurable the welfare measures of different individuals."[1]) Hicks and Kaldor each amended the Paretian criterion to allow the principle of potential compensation to determine acceptability on welfare grounds. In essence, this principle suggests the acceptance of policies resulting in positive net summations of individual welfare changes. Whether the compensation should actually be paid and in what manner further divides economists: if yes, then the state functions to satisfy the original Pareto Criterion which requires that none be made worse off; if not, then society is content in knowing the resources for compensation exist whether or not they are paid. This latter, of course, forms the efficiency criterion of the new welfare economics. This criterion does not account for differences in the marginal utilities of welfare changes.[2]

In addition and contrast to the Paretian and efficiency criteria are criteria more fully and explicitly capturing equity effects. Little[3] proposes an equity criterion (in addition to efficiency) as represented

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[1]A. Myrick Freeman, The Benefits of Environmental Improvement, Pub. for Resources for the Future (Baltimore: The Johns Hopkins University Press, 1979), p. 55.

[2]Economists have opted out of the commensurability debate, for the most part, in all probability due to vexatious explicit value judgments required. This frequently results, of course, in the implicit judgment to equate individuals' welfare, a decision as value-laden. One further manifestation of the normative nature of economic policy analysis is the utilization of price and other market data dependent for its generation upon the underlying income distribution.

[3]Ian M. D. Little and James A. Mirrlees, Social Cost Benefit Analysis, Vol. II of Manual of Industrial Project Analysis in Developing Countries, Development Centre Studies (Paris: Development Centre of the Organisation for Economic Co-operation and Development, 1969).

by a policy effecting improvement in the income distribution. Samuelson and others posit various constructs of a social welfare function comprised of numerous arguments, each weighted in some manner. Social recognition of individual deservingness implies that higher weights are applied to the provision of goods or services to this set of individuals.

Freeman offers the observation:

> . . .unless policy makers are willing to adopt some convention for making welfare changes of individuals commensurate so that an aggregate welfare change can be defined, they must reject the policy change which imposes welfare loss on any individual--no matter how small the loss nor how large the gain to others. The rule for aggregation can specify equal weights for all individuals (the Hicks-Kaldor compensation criterion) or assign different weights on some ethical basis.[1]

In contrast to explicit definition of criteria for making the welfare of different participants commensurate, most policies implicitly trade off the interests of some participants for those of others.

3.2.1.3.1 Empirical Aggregation Problems

Micro economic theory of utility proceeds from the construct of an individual's utility function populated with a number of arguments representing goods and services, to a series of individual demand equations representing effective demand (that is, demand constrained by income availability) for the items in the utility function.

Theoretically, aggregation of individual demand functions for a commodity when summed in conformance to a series of seriously restrictive

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[1] Freeman, The Benefits of Environmental Improvement, p. 60.

assumptions, yields a market demand function for the commodity in question. Concurrently, the summation yields a construct representing aggregate consumer surplus. This aggregate measure is defined as the difference between the maximum amount a member of society is willing to pay for the next unit and the prevailing market price.

Some of the difficulties involved in aggregation and measurement of individual demand curves to attempt to obtain a unique and consistent market demand relation include the restrictions that there be no alterations in societal income distribution associated with the data employed to estimate the aggregate demand curve as well as no policy induced changes in the distribution of income. Alternatively, the income elasticity of demand for the good must be identical for all individuals.[1] Under the best of conditions, the analyst is left with the necessity of rejecting the theory outright or accepting the premise that income elasticities do not vary significantly between individuals or that significant policy induced changes in the income distribution have not occurred. If one has market data, which can be accepted as an indication of aggregate demand for the good in question and, if one can then identify effects of a public investment upon the price or availability of that good, welfare analysis may permit some limited statements to be made regarding net policy impacts on social welfare as narrowly defined by various aggregate components of welfare: consumer and producer surplus.

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[1]See Freeman, The Benefits of Environmental Improvement; Schmid, The Political Economy of Public Investment.

3.2.1.3.2 Summary of Practical Problems Related to Determination of Willingness-to-Pay for Food Safety

As indicated, information problems--inherent uncertainty and high information costs--seriously limit the utility of standard willingness-to-pay conceptual measures of consumer surplus and therefore benefits from food safety programs or projects. Information problems can be summarized for the individual consumer in a couple of questions: What is the personal risk from consuming varying levels of a contaminant during normal eating patterns in the near and longer terms? What should be paid for a reduction in the mean or the variance of this risk over a specified time period?

Consumer willingness-to-pay for a given reduction in risk can be seen to depend upon individual patterns of risk-aversity as well as the price of risk reduction and the entire complex of alternative utility-producing goods and services, including alternative measures to reduce risk (or increase health).

Empirical problems in obtaining estimates of willingness-to-pay are summarized by Freeman and Schmid,[1] along with possible uses of market data. One approach, based on the assumption of weak complementarity between an environmental good Q and a private good X_i in the consumer's underlying utility function, may offer the possibility of attributing changes in demand for X_i--when at least two distinct levels of Q have been available--to varying levels of Q. A critical requirement here,

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[1] Ibid.

however, is consumer consciousness of the potential effects of varying levels of the environmental quality variable, a requirement not met in the sulfa and many similar cases.

3.2.2 Alternative Approaches to Conceptualization of Food Safety Benefits

While conventional economic theory bases demand conceptualization upon individual consumer preferences as revealed in a measure of willingness to pay for a good or service, as stated, in practice the determination of such consumer demand for food safety/public health services frequently cannot be accomplished--in part due to high consumer information costs and other public goods characteristics of food safety.

A variety of rather ingenious attempts to circumvent these difficulties and enable the analyst to say something about the benefits of a public health program has entered the literature. The attempts employ two basic propositions: first, an ability-to-pay criterion is often substituted for the elusive measure of willingness-to-pay; second, the notion of cost-savings or averted public health expenditures is utilized as an additional measure of public health program benefits.

3.2.2.1 Ability-to-Pay

When effective demand for a public health program cannot be determined, analysts frequently substitute calculations of changes in streams of income earnings attributable to a program for measures of consumer surplus. Positive changes in income streams are netted against program costs to yield a measure of the net benefits of a program.

This technique represents the use of an "ability-to-pay" criterion and it is important to understand, as Freeman indicates, that measures of willingness and ability to pay are not equivalent, conceptually or empirically and that reliance upon income savings carries with it the problematic implicit value judgment that an individual's worth is equivalent to his income stream over time.[1] Reliance on income savings in public health program analysis as a measure of program benefits carries with it the risk of biasing results toward those programs which save the lives or reduce the diseases of those earning higher incomes in the marketplace. Hence, many authors point out, such a measure is likely to favor selection of a public health program aimed at protecting the affluent rather than the poor or those who do not produce for the marketplace. (Accordingly, the "congressional diseases," cancer and heart disease, might be favored over tuberculosis control, or programs to benefit unwed minority mothers.)

Additionally, ability to pay criteria make assumptions regarding consumer spending preferences which may be unwarranted. Schmid points out that the difference between willingness and ability to pay hinges substantially on the impact of uncertainty and information costs. When consumers are unaware of risks correspondent with various diseases, they make decisions which differ from those rational under more perfect information. They may be unwilling to pay in cases of uncertainty despite

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[1]Willingness to pay, on the other hand, incorporates the normative premise that benefit conceptualization should be based upon effective demand which casts lustre upon a particular income distribution.

ability. Additional considerations involve individual differences in risk aversion. The ability to pay for a program does not reveal willingness which might or might not exist under various conditions of information and risk preferences.[1]

3.2.2.2 Cost or Resource Savings

Another category of benefits which can sometimes be identified consists of medical costs formerly expended but averted because of a public health program. Reparative expenditures for disease treatment are included here. Mishan, for example, provides one possible taxonomy of medical costs (for goods and services) and its use in calculating the resource savings of a syphilis program.[2]

The accuracy of both cost savings and ability to pay calculations depends upon a knowledge of the dose-response curve operative in the population. Therefore, these techniques do not provide useful alternatives to willingness-to-pay constructs in the current research into benefits and costs of sulfa regulatory programs.

3.2.2.3 Surveys and Non-market Alternatives to Willingness-to-pay

In the absence of market data, non-market methods of estimating willingness to pay may be attempted. Many of these alternatives have

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[1]Schmid, The Political Economy of Public Investment, pp. 121-122.

[2]E. J. Mishan, Cost-Benefit Analysis, new and expanded edition (New York: Praeger Publishing, 1976), pp. 6-8.

limitations of their own. Surveys and voting schemes, for example, each contain problems relating to possible strategic behavior on the part of respondents, biases and the lack of incentives to accurately answer survey questions.

For the policy maker considering the case of sulfa drug use in livestock production, effective use of such methods at present seems unlikely. It must once again be emphasized that the dose-response curve between sulfa exposure in pork and human health effects is currently not well established, particularly in the area of carcinogenicity.

3.2.3 Economic Costs in Benefit Cost Analysis

The preceding sections discussed the theory of demand and benefit determination along with the potential for application to public food safety programs. Benefits were found to be of two major conceptual types: 1) an increase in public health, ideally (but not practically) evaluated according to consumer willingness to pay; 2) a resource savings stemming from averted costs of morbidity or mortality (conceptually problematic but in some cases empirically more manageable).

Turning to the flip side of the ledger to an examination of the economic costs associated with a public health or food safety regulatory program reveals that costs may be categorized in a number of ways. Most simply, the costs of a program consist of those resources invested in the program valued at their opportunity costs.

If the world is divided simply into consumers and producers, then each of these groups can experience benefits and costs from a project.

As discussed above, benefits and costs to consumers are evaluated in benefit-cost analysis according to changes in consumer surplus. Benefits or costs to producers (an increase or decline in factor prices or opportunities) are measured by alterations in economic rent. Mishan notes that, in practice, an asymmetrical treatment of impacts is involved in the usual practice of accepting factor prices as given. He states:

> This asymmetrical treatment is not wholly unwarranted in an economy where factor groupings are few, but where product groupings are many. A project that increases the output of a product or service may result in large changes in its price without appreciable effects on the relevant factor prices.[1]

In situations which do not warrant an assumption of unchanged factor prices, techniques of shadow pricing to approximate true factor opportunity costs can be used.[2]

In a formal benefit-cost analysis, opportunity costs of the project are entered into the economic accounting format through inclusion of a discount rate. Haveman and Weisbrod state:

> Note that in a fully employed economy, the primary benefits also are achieved at the cost of displacing some other project and its benefits. Such 'opportunity costs' must indeed be considered by the cost-benefit analyst. They enter in through the inclusion of an interest rate (cost of capital) and through the estimated cost of purchasing the resources required for the project--resources that must be bid away from competing uses. . . . If all other

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[1] E. J. Mishan, Economics for Social Decisions: Elements of Cost-Benefit Analysis (New York: Praeger Pub., 1973), p. 18.

[2] In calculating net benefits, any difference between the real social cost of resources used and their market cost may be added to project benefits or subtracted from project costs.

> things are held constant, a project which employs idle resources will yield greater net benefits than one which requires that resources be directed from some alternative activity.[1]

3.2.4 Alternative Analytical Frameworks for Program Analysis

Before presenting the specific framework to be used in this research, two alternatives to (or modifications of) formal benefit-cost analysis which offer some advantages in application to public food safety programs are discussed. They include: risk assessment and cost-effectiveness analysis.

3.2.4.1 Risk Assessment

Risk assessment or benefit-risk analysis is in some respects a variant of benefit-cost analysis. However, the technique stops short of attempting to assign economic values to various measures of risk or risk avoidance. Rather, the analysis results in a schedule coupling, say, monetary costs and a measure of human disease incidence or avoidance.

Both demand and supply of risk assessment techniques (and analysis) have escalated in recent years presumably reflecting a heightened recognition of the necessity of accepting some risk in return for a variety of economic benefits and a reluctance to place explicit monetary values on human life and well-being.

In a widely read summary of important elements of risk analysis, Lowrance defines a set of terms: efficacy, risk, benefits, costs and

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[1] Haveman and Weisbrod, "Defining Benefits of Public Programs: Some Guidance for Policy Analysts," p. 147.

safety.[1] The first two, efficacy and risk, are identified as physically measurable or probabilistically inferrable quantities. The efficacy of a product or process refers to its technical efficiency in terms of input-output relationships. Risk pertains to the probability of certain causal relationships occurring between exposure to a source of hazard and potentially adverse effects of that exposure.[2] In both regards our techniques of measuring efficacy and risk are imperfect; however, they can be expressed as physical relationships in probabilistic terms.

Benefits or costs, however, enter the realm of economics by attempting to impute economic values to various levels of efficacy or risk. The previous section reviews economic conceptions of benefits and costs in some detail. One important distinction between risk and benefits and costs is that between positive and normative measures.[3]

Going beyond the "scientific" determination of a product's efficacy or risk and the economist's estimation of associated benefits and costs, one enters the realm of social judgment regarding safety. "Safety" can be defined as socially acceptable levels of risk. As such, a determination of safety involves implicit or explicit balancing of a variety of factors, some physical, some economic and others associated with societal conceptions of what levels and types of risk constitute reasonable risks.

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[1]William W. Lowrance, Of Acceptable Risk: Science and the Determination of Safety (Los Altos, California: William Kaufmann, Inc., 1976).

[2]Four categories of essential questions contribute to an assessment of risk: 1) define the conditions of exposure (who is exposed?, to what levels?); 2) identify adverse effects; 3) relate the exposure with effects; 4) estimate overall risk.

[3]All measures are normative at a fundamental level. Input-output formulations depend upon a normative definition of product and waste; risk measures similarly depend upon estimations of undesirable hazard.

Criteria of "reasonableness" emerge over time and relate intimately to social values regarding what is fair. Various dimensions of reasonableness of risk include: whether risk is assumed voluntarily (and with accurate knowledge of effects) or borne involuntarily; whether effects are serious or slight, borne by many or few, appear immediately or are delayed far into the future, whether exposure is essential or a luxury, whether alternatives to the exposure are available or not.[1]

To summarize these brief comments regarding risk-benefit assessments and the analysis of safety: risk analysis provides a valuable tool for identification of the foundation stones upon which economic and societal evaluations of trade-offs between a product's risk and efficacy must necessarily be made.[2] With respect to the sulfa case, however, present knowledge of potential adverse effects from exposure to sulfa residues is considered insufficient by the FDA to adequately evaluate risk at this time.

3.2.4.2 Cost-Effectiveness Analysis

Cost-effectiveness analysis begins with a policy prescription and asks: What is the least-cost means of achieving the prescribed end? An example is establishing a goal of eliminating some or all sulfa residues

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[1] Lowrance, Of Acceptable Risk: Science and the Determination of Safety.

[2] For an informative discussion of the information requirements of an ideal risk-benefit analysis, see van Ravenswaay and Hull, "Regulatory Decisionmaking on Toxic Substances in Food,"

in swine and then evaluating alternative methods of achieving the reduction.

Cost-effectiveness analysis, in effect, ignores the question of benefits, either absolute or relative. Again, using the sulfa example, cost-effectiveness analysis does not attempt to estimate the value of achieving complete or partial reduction of sulfa residues in terms of public health or the relative contribution to public health of a sulfa program vis a vis a tuberculosis program or an alcoholism program of equivalent cost.

Benefit-cost analysis, then, represents a preferred analytical technique for informing broad choices between alternative policy programs. It is more complex to conduct than cost-effectiveness analysis, however, requiring information regarding benefits. In the measurement of public health impacts from food safety regulatory programs, many gaps exist in our understanding of the risk associated with exposure to chemical residues in foods across the population and over time.

3.2.4.3 Impact Analysis

Impact analysis approaches the task of public program analysis from a slightly different perspective and employs a different framework than the methods outlined above.

Rather than attempting to net social costs or risk against benefits in order to determine changes in social welfare, impact analysis seeks to establish causal links between a program's use of inputs, performance of activities, production of outputs, and ultimately, the measurable

effects of these outputs in terms of performance indicators (see Figure 3.1).[1]

Definition of program goals and objectives plays a critical role in the subsequent design of all aspects of the program information structure. Objectives may be broadly or narrowly conceived. However, emphasis is generally placed less upon the identification of program impacts upon global measures of welfare than on program effects upon specific program objectives. The approach is particularly useful when employed to systematically account for various distributional impacts of concern to decision-makers. It is also an expandable concept which can be modified to permit identification of participant interests and formulation of performance variables corresponding to these interests.

3.2.5 A Conceptual Framework for Regulatory Program Analysis

For purposes of economic analysis of alternative regulatory procedures to control sulfa residues this research, in essence, combines elements of cost-effectiveness and impact analysis, outlined above, with an empirical examination of firm decision-making. It seeks to identify economic costs and benefits to various participant groups associated with a range of policies as well as to construct a ranking on the basis of selected costs and benefits. This research identifies behavioral incentives incorporated in various program designs in order to understand probable impacts upon firm decision-making, likely ramifications for the

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[1] For a complete discussion, see Schmid, Political Economy of Public Investment, pp. 18-61.

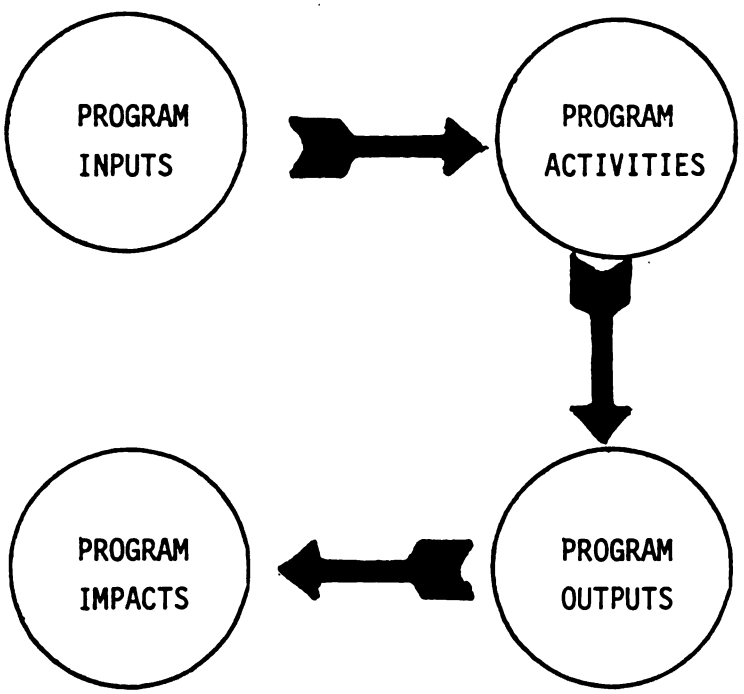


FIGURE 3.1. PROGRAM IMPACT ANALYSIS

effectiveness (and workability) of programs, and ultimate impacts on performance.

A few words spent laying a common semantic groundwork appears a prudent investment at this juncture. In this spirit, the following two comments are made:

1) Ex Ante vs. Ex Post Analysis. Policy analysis is of two major types. Ex ante asks basically "What if?" while ex post wonders "What did occur?" Esthetically speaking, it might be preferable to avoid the mixed suits of combining ex ante and ex post analysis. However, reality intervened in the sulfa case in the form of one of a selection of policy options actually being implemented during the course of the current research. Accordingly, the desirability of attempting to deal analytically with the set of policy measures actually implemented to reduce sulfa contamination became apparent, the more so because the measures accompanied a significant decline in sulfa violation rates and might therefore (depending upon costs) represent an effective means with which to address similar future drug or chemical residue problems. Secondly, an ex ante analysis of alternative policy programs offers the opportunity to provide policy makers some notions regarding how these alternative measures compare with the measure actually implemented in terms of distributive impacts and program cost-effectiveness.

2) Status Quo. The specification of the status quo is important in policy analysis and in this study refers to the period from the outset in 1973 of the initial monitoring of sulfa residues in hog carcasses (by USDA) until the formation of an interagency-interindustry sulfa task force in 1978. While this was not a period of complete uniformity in

policies related to sulfa, still relative constancy prevailed and the violation rates for sulfa residues in hogs varied most frequently around 10 percent of sampled hogs. It is important to realize that the analysis does not begin from a situation in which sulfa use in hog production was unregulated. Rather, Food and Drug Administration determined tolerance levels for sulfa drugs were in effect, and the USDA was monitoring residues under its meat inspection program. The analysis which follows, then, develops an information structure capable of integrating the series of relationships shown in Figure 3.2. As can be seen, this expanded version of Figure 3.1 differs in that it explicitly considers problem situation, program objectives, and firm decision-making. Firm decisions determine the success or failure of regulatory policies, suggesting that an understanding of the factors influencing firm decisions will facilitate estimation of program impacts.

3.4 Decision-making Related to Animal Drugs and Food Safety Regulations

The procedures of impact analysis employed in this research emphasize the importance of understanding firm decision-making in order to assess the influence of different types of food safety regulation on firm decisions and ultimately, selected performance variables. Decision-making procedures at the micro level of the firm and within the regulatory agency provide the focus of this section. Theory and empirical evidence in the sulfa case suggest four principal classes of decisions for consideration:

1) the production and sale of animal drugs for profit;

2) the purchase and use of animal drugs as inputs into a production process;

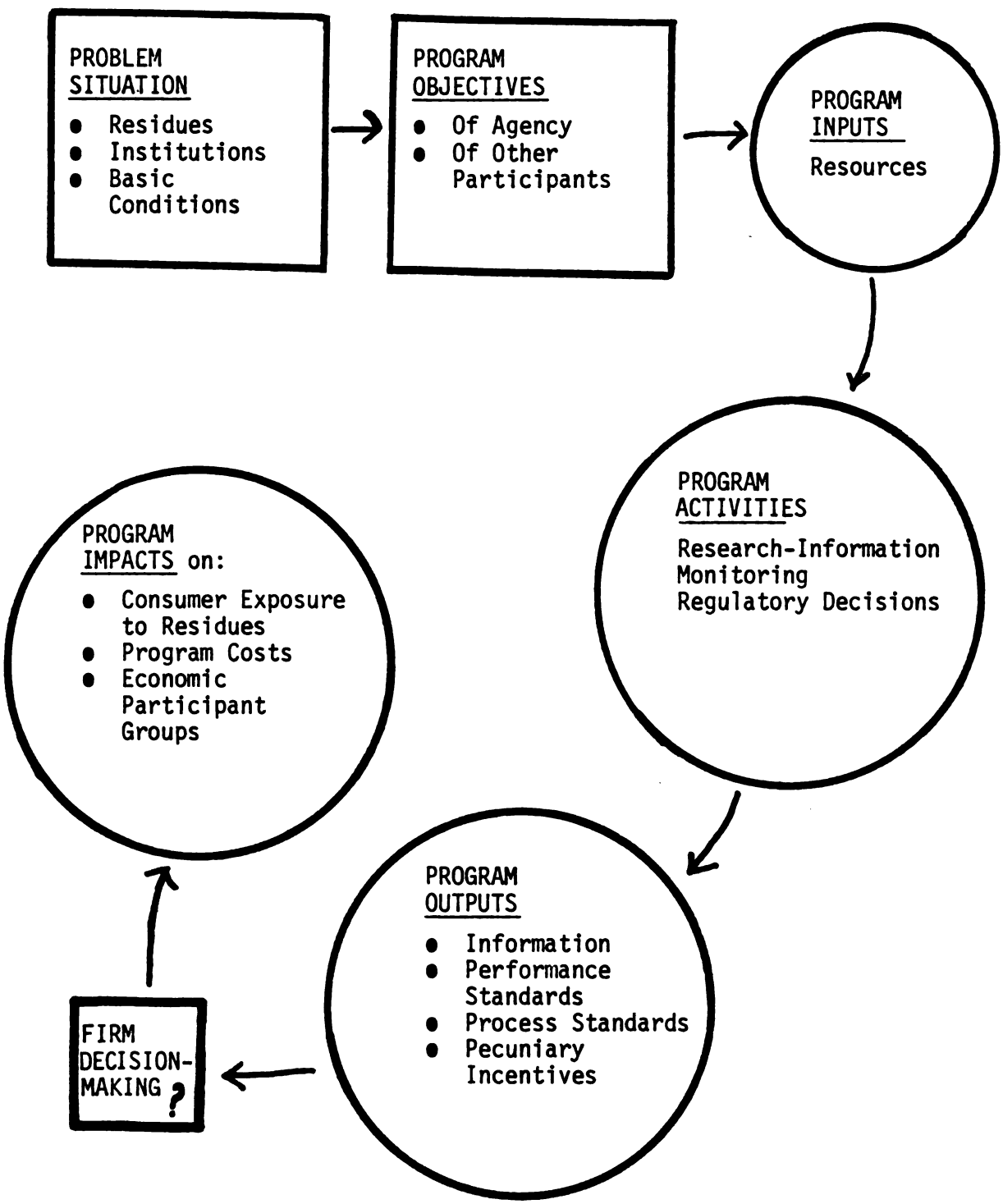


FIGURE 3.2. EXPANDED VERSION: FOOD SAFETY PROGRAM IMPACT ANALYSIS

3) avoidance or toleration of drug residues as contaminants;

4) the design of food safety/animal drug policy in which the multiple roles of animal drugs in the capacity of product, input and contaminant are balanced, generally by regulators and public officials, in the principal interests of third parties.

Although the decision cases are listed singly, the sulfa case reveals that industry participants frequently face a mixture of decision problems. Chapter IV demonstrates that the animal health industry is most concerned with sulfa as a product; the feed industry combines concerns regarding animal drugs as products, as inputs and as contaminants. Hog producers use sulfa and other drugs as inputs into the hog production process and experience penalties, or the risk of penalties, because of drug residues classified as contaminants. Meatpackers, others in the marketing chain and final consumers view sulfa most visibly as contaminants although they share concerns regarding the price and quality of pork products. Mixed decision cases, then, are of obvious importance not only to firms but to regulators who must design incentives which increase the firm's propensity to comply with regulation.

3.4.1 Decision-making in the Competitive Model

Much of economic theory and the policy prescriptions eventually growing out of economic analysis is premised on the competitive model. Regulation in this model to a large extent attempts to replicate the outcomes of a competitive market or correct for so-called "market failure." In order to discuss the applicability and inapplicability

of this theory to problems of articulation of preferences for product purity and to problems of supply of desirable levels of food safety, this section briefly considers assumptions upon which conventional neoclassical competitive theory is based and consequences for the four decision cases listed above. It will be seen that some critical deficiencies of the theory include the neglect of information problems, transactions costs, and spillover effects which result in imperfect firm compliance with food safety regulation and other unintended policy consequences. The design of effective regulations requires an understanding of the contingencies of reinforcement operative in firm decision-making in an uncertain environment, and also an appreciation of the incentive structure impinging on the actions of public policy-makers.

Conventional microeconomic theory of the firm derives its insights by positing a rather simple organizational entity acting in self-interest, this usually assumed to involve profit maximization. By assumption, the firm possesses perfect knowledge costlessly, perfect rationality (similarly priced) and at the same time enjoys a situation devoid of problems of management, quality control or vertical coordination.

The firm in the strict competitive model regards sulfa or other animal drugs either as product or as input. If conditions of truly perfect and universally available information obtain, however, much of the food safety problem and concern with contaminants evaporates. This is because if it were possible for all economic actors to detect the presence of contaminants and understand the effects of exposure, then (in the absence of transactions costs) preferences for product purity could be fully articulated in the market. Similarly, the public

policy problem of balancing the roles of animal drugs as product, input and contaminant takes on a straightforward character in the competitive model very unlike the policy problem explored later with the introduction of an expanded model.

The prototypical profit-maximizing firm produces a single, or multiple products in unique or numerous plants. In nearly all competitive cases, the firm, dedicated to profit maximization, follows an equimarginal principle of quantity adjustment so that revenues and costs of the last unit produced are equated at the margin. The firm has no meaningful decision related to the market except one of input or product quantity adjustment. It has no control over aggregate supply, demand, or product price; similarly, if it purchases inputs in a competitive market, it enjoys no control over input prices. Focusing upon internal functioning of the firm, the assumptions of competitive theory present, in essence, a black box. Assumptions of homogeneous product eliminate problems of quality or the costs of quality assurance either in input purchasing or in manufacturing or other materials handling processes internal to the firm. The firm is assumed to employ optimal technology. Problems of organizational structure, multiple objectives of firm participants, discretionary effort of managers or employees and related problems of organization slack do not arise. Cases of contamination enter economic literature most frequently in the guise of pareto-relevant externalities attributable in some important respects to a market's failure to appropriately price these substances. By this reasoning, externalities such as contaminants represent cases wherein

social valuation diverges for some reason from private economic valuation.[1] When, in the competitive model and given the state of the art, a production process yields a product containing contaminants, the potential buyer of such a product offers his bid in full knowledge of the product's characteristics, both desirable and undesirable, as well as the impact of these qualities on his own production process (if the good is an input) or consumption enjoyment (if the commodity is a consumption good). The buyer's bid summarizes his balancing of all features.

If and when innovation results in the development of production processes yielding a superior quality product at the former price, those firms continuing to utilize inferior technology are penalized in either the price attainable or the quantity that can be sold in the short run. In the longer term, firms producing inferior products are driven from the market unless suitable price discounts for inferior quality obtain.

The policy problem confronted by public decision-makers in the competitive case is one of balancing the interests of consumers and producers. In cases where the market fails to accurately value contaminants, the government's role in cases of contamination externality has conventionally been regarded by economists as one of bringing social and private valuations into accord. Classic remedies for stimulating socially desirable levels of contamination include optimal taxation of the

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[1] Externalities are classified in a variety of ways. One well-known work, Francis M. Bator's "The Anatomy of Market Failure," Quarterly Journal of Economics 72 (1958): pp. 351-79, presents a classic explanation of market failure.

producer of a contaminant, optimal subsidization of the inadvertent consumer or efforts to bring about internalization through organizational mergers or integration. The intent of each of these policy measures is to satisfy the series of marginal conditions denoting a situation of general equilibrium and optimal social welfare.[1]

Problems of uncertainty erode the utility of these policy prescriptions. In the presence of uncertainty, policy makers are uncertain of consumer valuations of health and security, they are uncertain therefore of the optimal tax, the optimal subsidy or other neo-classical measures which might be devised. Explicit consideration of important factors which shape decision-making and performance in the real world is necessary in order to construct reasonable policy alternatives.

3.4.2 Elements of an Expanded Decision Model: Uncertainty, Imperfect Markets, Transactions Costs

Expanding the conventional model of the firm to include uncertainty, imperfect markets and a variety of important transactions costs permits consideration of salient environmental and structural factors influencing decision-making in the sulfa and similar cases and influencing the firm's compliance with food safety regulation.

3.4.2.1 Uncertainty

Bartlett, Williamson, Cyert and March and others examine problems of uncertainty facing the firm.[2] Defined broadly, "uncertainty" refers

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[1]Ibid.

[2]Bartlett, Economic Foundations of Political Power; Oliver E. Williamson, Markets and Hierarchies: Analysis and Antitrust Implications

to a condition of imperfect knowledge regarding some important aspect of the state of the world. Uncertainty may refer to events or conditions of the past, the present, or the future. Uncertainty can be summarized as to source: the market, the institutional structure and, indeed, the firm's own internal performance. The market produces pecuniary uncertainty in the short run. Additionally, market behavior of other firms over time, along with modifications in the character of demand for the firm's products, combine to ensure a dynamic and uncertain market arena for firm decision-making. Institutional uncertainty, including regulatory uncertainty, stems from the changing complex of rules circumscribing property rights of the firm in relation to the market.

The general nature of the regulatory problem can be stated in two parts. First, the firm is uncertain about the current and future letter of the law of food safety regulations as they apply to the firm. Second, the firm is uncertain regarding the likelihood and expense of regulatory sanctions befalling the firm should it act in a particular manner. A third source of firm uncertainty is its own performance including production quantity and quality. Both yield and quality of product can be influenced to a pronounced degree by climatological and other factors exogenous to the firm; they are also significantly related to management and labor performance within the firm.

(New York: The Free Press, 1975); R. M. Cyert and J. G. March, A Behavioral Theory of the Firm (Englewood Cliffs, NJ: Prentice-Hall, 1963). For a recent review of some of the economic literature which approaches uncertainty from a statistical decision theory approach, see J. Hirschleifer and J. G. Riley, "The Analytics of Uncertainty and Information--An Expository Survey," Journal of Economic Literature XVII, No. 4 (December, 1979): 1375.

To summarize: the firm confronts 1) uncertain market conditions including prices and costs and the changing nature of market supply and demand over time; 2) uncertain institutional conditions including the changing character and impacts of regulation on the market and on processes internal to the firm; and 3) uncertain performance of the firm with respect to production quantity and quality.

3.4.2.2 The Information Problem

When an economic actor confronts a situation of costly and imperfect information, the choice of an informational strategy is an economic problem. An economic actor assesses something of the hazard inherent in his current state of uncertainty and weighs this against the costs of seeking, acquiring and utilizing information. (One alternative is to seek insurance; it is evident, however, that the decision to insure also involves an information problem.)

Bartlett[1] develops a model of uncertainty, information, and influence which is useful in understanding the nature of the information problem faced by economic and political actors in positions of uncertainty. His actors attempt to strike a balance between total costs of information (the sum of costs of being uninformed and those of acquiring information) and the benefits of obtaining information. For a rational actor, search is positively associated with magnitude of risk and negatively with the magnitude of cost. The interesting aspect of Bartlett's

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[1]Bartlett, Economic Foundations of Political Power.

treatment centers around his observation that one person's information demand frequently provides another's opportunity, particularly when the outcome is of interest to the information provider, and one choice is preferred. As a rational actor he has an incentive to subsidize information which might encourage, and withhold information that might impede the desirable choice.

A final element Bartlett introduces is the possibility of learning. Subsidized information is more likely to remain within certain bounds of reliability if repeat transactions occur and if the seeker is able to validate the information.

Bartlett applies his model to transactions between producers, consumers, bureaucrats, and elective politicians. His analysis provides useful insights into how different firms acquire and supply goods and services to their customers and negotiate the exchange of goods and services with the public sector.

3.4.2.3 Imperfect Markets

Information costs and economic power result in imperfectly competitive markets which influence firm decision-making and market performance. Economic theory provides a number of models of imperfectly competitive markets, including oligopoly, monopoly and imperfect competition. Despite the fact that outcomes of these models are indeterminate in many cases, impacts of imperfect market organization are usually summarized to include: non-optimal output reflecting the fact that imperfectly competitive firms have no incentive to produce an

output corresponding to minimum long-run average cost; prices higher than in a competitive setting; "excessive" expenditures on advertising or promotion and superfluous or cosmetic product differentiation.

Ferguson comments on oligopoly: "Since the market is divided between the two (or few), most courses of action by one rival will have its counterpart in a maneuver by the other. Thus, many different courses of action may result. The rivals may spend their lives trying to 'second guess' each other; they may tacitly agree to compete by advertising but not by price changes; or, recognizing their monopoly potential, they may form a coalition and cooperate rather than compete. In fact, there are just about as many different results as there are oligopolies."[1]

3.4.2.4 Transactions Costs: Problems of Decision-making, Coordination and Control

In addition to information costs, transactions costs include decision-making costs, problems of ensuring satisfactory coordination within and outside the firm, and problems of control in the face of uncertainty.

Until relatively recently, economists have largely ignored matters of organizational structure and the processes and economics of internal decision-making of the firm. Implicit in conventional competitive theory is the prototypical entrepeneur-owned firm in which managerial and owner objectives coincide. However, features of many modern manufacturing and agricultural firms increasingly diverge from the simple firm

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[1] C. E. Ferguson and J. P. Gould, Microeconomic Theory, 4th Ed. (Homewood, Illinois: Richard D. Irwin, Inc., 1975), p. 330.

conceptualized by classical theory.[1] Leading manufacturing firms tend to be large in sales, amount of labor and capital employed; they tend to be multi-product, multi-plant companies operating in large market areas. Ownership and management forms vary. Many firms are integrated in various ways, forward into further processing and marketing or backward into input production. Many large firms operate in imperfectly competitive markets and enjoy pricing or alternative forms of discretion not available in perfectly competitive markets. The organizational structure of firms in imperfectly competitive markets contributes to firm strategic decisions. Caves defines organizational structure as that "internal allocation of tasks, decision rules, and procedures for appraisal and reward, selected for the best pursuit of strategy" chosen to achieve desirable firm performance.[2] Analysis of firm structure suggests possibilities of intra-firm specialization in the functions of product quality control, risk management, and regulatory affairs. In tasks such as these, organizational adaptation, often in the form

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[1]Organizational features of the large corporation offer broad diversity to the analyst. Some firms are characterized by functional divisions, by multiple product or geographical divisions and still others combine functional and multidivisional attributes in a matrix format. See: O. E. Williamson, Markets and Hierarchies: Analysis and Antitrust Implications; for a comprehensive review of some of the contributions of chiefly non-economist organization theorists and business historians, see Richard E. Caves, "Industrial Organization, Corporate Strategy and Structure," Journal of Economic Literature XVIII (March, 1980) 64-92; Joan Woodward, Industrial Organization: Theory and Practice (London: Oxford University Press, 1970); and Stanley M. Davis and Paul R. Lawrence, Matrix (Reading, Massachusetts: Addison-Wesley, 1977).

[2]Caves, "Industrial Organization, Corporate Strategy and Structure," p. 64.

of functional specialization, can facilitate achievement of economies for the firm. Alternative organizational patterns also carry with them associated costs of coordination, management and consensus-building.

Separation of ownership and management authority is another factor raising questions regarding whose objectives are sought by the firm.[1] Many authors have recognized that the establishment of organizational consensus is a problem compounded by uncertainty and transactions costs.

Analysts such as Cyert and March theorize that an organization at various times pursues seemingly competitive goals, that it frequently attempts to achieve suboptimal targets, and that in the interests of reducing uncertainty to tolerable levels, it adopts sequential problem-solving search techniques, frequently operating on the basis of short run feedback rather than consistency with a long-run plan.[2]

Finally, Galbraith develops the notion that technocracies exist within large corporations and operate under an imperative of growth similar to any public bureaucracy; technocracies exercise power through the control of resources of specialized knowledge.[3]

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[1]Pickering distinguishes between managerial and behavioral theories of the firm: the former posit optimization of managerial utility functions comprised of pecuniary and non-pecuniary arguments; the latter view firm behavior as satisficing and resulting from bargaining between individuals. J. F. Pickering, Industrial Structure and Market Conduct (London: Martin Robertson and Co., 1974).

[2]Cyert and March, A Behavioral Theory of the Firm, p. 8.

[3]John Kenneth Galbraith, The New Industrial State (Boston: Houghton Mifflin Co., 1967), pp. 1-430.

Impacts of organizational structure and standard operating procedures of the firm are important as they affect the manner in which regulatory policies are perceived by the firm and broken down within the firm as decision problems. If food safety regulation is the exclusive responsibility of regulatory affairs staffs and legal experts within the firm, then bureaucratic incentives, satisficing behavior, and functional specialization may portend different results than if management were directly confronted by a regulatory policy.[1]

The second category of transactions costs which influences firm behavior is manifested in the problem of vertical coordination as it relates to product quality. Vertical coordination is frequently defined as a process including "all the ways of harmonizing the successive vertical steps, or stages, of production and marketing. Vertical coordination may be accomplished through the market price system, vertical integration, contracting, cooperation, or any other means, separately or in combination. There is always some kind of vertical coordination if any production takes place."[2]

The firm experiencing problems with the quality or purity of purchased inputs may choose from a variety of potential coordinating

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[1]A recent article develops this theme: Robert B. Reich, "Regulation by Confrontation or Negotiation?" Harvard Business Review (May-June, 1981):82-93.

[2]U.S. Department of Agriculture, Vertical Coordination in Agriculture, by R. L. Mighell and L. A. Jones, ERS-19 (Washington, DC: Government Printing Office, February, 1963).

mechanisms to solve the problem;[1] the exercise of voice,[2] the use of contracting, the use of quality control procedures for purchased inputs; attempts to modify the institutional structure, vertical integration, use of courts.[3]

The third type of transactions costs influencing firm behavior can be summarized as costs of control. Control refers to the firm's ability or power to achieve objectives instrumental to firm goals. Perfect control is not synonymous with perfect information, although over some range control appears to be directly related to knowledge of available options and their consequences. Similarly, perfect control is not synonymous with perfect subsector coordination. Subsector coordination is a systems concept; control, on the other hand, pertains to the performance of the firm in relation to the industry and the subsector. Maximization of control by the firm can lead to suboptimal system coordination.

Previously mentioned were information strategies employed by the firm to improve control over market uncertainties. Other market oriented strategies include innovation, price competition, non-price competition (product differentiation, advertising, provision of services), entry into various types of coordinating arrangements mentioned above.

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[1]Oliver E. Williamson, "The Vertical Integration of Production and Market Failure Considerations," American Economic Review 61 (May 1971): 112-123,

[2]Albert O. Hirschman, Exit, Voice and Loyalty: Responses to Decline in Firms, Organizations and States (Cambridge, Mass.: Harvard University Press, 1970), pp. 1-162.

[3]The PBB contamination case in Michigan has resulted in product liability claims totaling in the millions of dollars. See Edwin Chen, PBB: An American Tragedy (Englewood Cliffs, NJ: Prentice-Hall, Inc., 1979), pp. 1-329.

Quality control problems within the firm form a subset of broader organizational control problems. Control can be explained in terms of the notion that a firm in the real world does not operate upon its production possibility frontier in the normal course of events. Instead it operates somewhere in the interior of this frontier due to x-inefficiency, or slack.[1] X-inefficiency and organizational slack are related concepts referring to the frequent situation in which firm resources are not allocated to achieve maximum acceptable production. (A corollary is that excessive payment to factors occurs.) In relation to quality of product, the existence of slack can result in non-optimal or unsatisfactory formulation of product.

Liebenstein develops a theory of discretionary effort in the employment relation to explain x-inefficiency.[2] In this theory, employees maintain significant discretion regarding the degree of effort expended in the performance of employment tasks. Perfect managerial control is costly; imperfect control is accepted by most firms. In some cases, given human behavior, the technical difficulty of achieving suitable levels of quality exceeds realistic expectations of firm performance. When managerial objectives conflict, then organizational processes for resolution of differences influence the ultimate quality level the organization sustains.

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[1] Hirschman, Exit, Voice, and Loyalty; Harvey Liebenstein, General X-Efficiency Theory and Economic Development (New York: Oxford University Press, 1978), pp. 1-189.

[2] Ibid.

Regulatory control problems comprise the final set of transactions costs encountered by the firm operating in an uncertain world of imperfectly competitive markets.

In order to exert control over the uncertainty stemming from the institutional environment, the firm makes three interrelated sets of decisions:

1) choice of an information strategy;

2) choice of a strategy designed to influence the letter or the enforcement of laws and regulations;

3) choice of a compliance strategy for those regulations considered desirable, inevitable, or unavoidable.

Information and influence strategies were discussed above. Compliance strategies vary in scope, substance and cost. At the same time, firm resources and organizational capacity vary. Often considerable discretion is permitted the firm in complying with regulation and in exercising this discretion economies may be achieved. As in the decision to seek regulatory information, the rational economic actor in choosing a compliance strategy weighs the costs of potential actions against the expected pay-offs. One determinant of the benefit of compliance with food safety regulation is regulatory policy regarding the enforcement of food safety rules. Firms observe that a variety of rules governing a broad expanse of activities exist on the books; not all are enforced with equal zeal. Firms also appreciate, despite occasional statements to the contrary, that regulators do not possess unlimited resources to devote to the pursuit of perfect compliance. Additionally,

the cost of various penalties varies broadly from mere inconvenience to prosecution, including fines, potential suspension from the market, or the loss of image associated with unfavorable publicity attributable to food safety violations.

The firm, therefore, develops a means of evaluating both the likelihood of apprehension by regulators and others should firm actions not meet the letter of the law and the potential cost of any sanctions imposed as a result.

In the functions of both information acquisition and subsidization, economies of size permit large, complex firms to exploit a broad range of control techniques which are not equally available to the small firm. The firm's organizational adaptation to regulatory demands over time itself represents an important control strategy for economically reducing regulatory uncertainty.

3.5 Regulatory Decision-making in the Food Safety Process

Decision-making among policy makers influences the formulation of regulation and its ultimate workability. The final group of participants, for simplicity labeled bureaucrats, views sulfamethazine as a regulatory problem. At the outset it is important to specify the meaning of a "regulatory problem" from the perspective of a decision-maker within a regulatory agency. Webster defines regulation as "an authoritative rule dealing with details of procedure, a role or order having the force of law issued by an executive authority of a government."[1]

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[1] Webster's Seventh New Collegiate Dictionary (Springfield, Mass.: G. and C. Merriam Co., 1967), p. 722.

Such regulations frequently establish rules for parties external to the agency.

The manner in which an individual decision-maker views a regulatory problem depends upon a variety of factors including the legislative mandate and general operating procedures of the agency as well as individual job and task descriptions within the agency.

Bureaucrats participate through agencies in an ongoing food safety policy process yielding a variety of outcomes. Outcome possibilities include rules which expedite or prohibit, grants, taxes, provision of services, preservation of the status quo. Outcomes include both intended and unintended impacts upon the property rights of individuals throughout the food system. Outcomes of the bureaucratic process establish precedents for future action. In a dynamic, learning system, bureaucratic decisions in one context often circumscribe possibilities for future system performance.

In order to model the food safety regulatory process relevant to the sulfa case, it is necessary to describe: 1) bureaucrats, 2) the agency, 3) the broader policy system, and 4) the food safety decision-making process.

3.5.1 The Bureaucrat

The food safety bureaucracy, by assumption, is composed of individuals motivated primarily by self-interest. The approach is one of methodological individualism. Utility functions include economic and non-economic arguments and vary across individuals. Individuals are influenced by a variety of factors including, among other things,

personality, ideology, disciplinary training, job experience, et cetera. As the relationship between individual behavior and these sorts of factors is complicated and beyond the field of economic expertise, a convention of sorts is adopted; it is reasoned that instrumental to a bureaucrat achieving most major goals reflected in his utility function is his continued employment. As a proxy, therefore, security may be used as the primary goal of the bureaucrat. It is a goal toward which he satisfices rather than maximizes.

As expected, the bureaucrat functions in a job-setting circumscribed by rules and regulatory procedures. He performs designated tasks. Specification of the details of each task varies, in part reflecting rank and degree of responsibility.

The bureaucratic challenge is to resolve problems in a satisfactory manner in order to maintain security. Problem solving efforts are evaluated by superiors on the basis of both official and unofficial criteria. Official criteria include established agency work measures; unofficial criteria include conformance to informal measures established by superiors in order to promote their purposes.

3.5.2 The Agency

The bureaucrat functions within an administrative agency. An organization comprised of individuals, formal institutions and informal operating procedures, the agency is generally established to implement policy or perform tasks mandated by Congress. Formal agency institutions include rulemaking procedures, budgetary procedures, personnel

procedures, and regulations--as a special case, formal methods of establishing agency priorities may be specified. Less formal operating procedures include standard methods of short cutting or further specifying formal procedures, including informal methods of establishing agency priorities. Informal operating procedures represent means by which agency management and personnel routinize problem-solving and other operations in order to conserve resources. For all practical purposes, the legal mandate for potential agency activities is infinite whereas the agency's operating budget is not. Allocation of the budget, then, requires formal or informal establishment of agency priorities. The agency agenda refers to this list of priorities.

As a whole, the agency benefits from the selection of an agenda which evokes a satisfactory support level. Budget support flows from Congress. Congressional budget and legislative support is motivated by belief that the agency is performing in a manner acceptable to influential constituency groups. Congressional perceptions in this matter reflect the intensity and the magnitude of "public" opinion pressure exerted by constituency groups.

The agency as a hierarchical organization possesses a group of politically appointed top managers. While managers bring to their jobs unique combinations of the same behavioral and social attributes as other bureaucrats, the political nature of appointment and a position at the top of the decision-making hierarchy creates a distinctive combination of political pressures, a relatively short planning horizon and some managerial discretion. As a result, agency

managers frequently exercise considerable broad influence over the composition of the agency agenda.

However, top managers experience greater difficulty in being well informed of the details of any particular problem or agency position. Accordingly, details of implementation are delegated in agency procedures to individuals further entrenched in the agency organization and responding to those incentives important to them.

3.5.3 The Broader Policy System

The bureaucrat and his agency comprise one major participatory entity in the broader food safety policy system. Other agencies are active at federal and state levels. (Chapter II describes legislative mandates and roles of the Food and Drug Administration and the United States Department of Agriculture.) Each agency possesses a distinctive legislative mandate, procedural rules, a unique body of administrative case law and clientele groups which have developed over the years. These factors contribute to different philosophies and processes of problem definition and resolution, particularly in cases where jurisdictional boundaries overlap. Any resultant conflict then requires a process of resolution.

In addition to the personnel of administrative regulatory agencies, a variety of other participant groups and institutional entities participates in the food safety decision-making process:

1) Congressional bodies including general legislative bodies and important committees (for example, appropriations committees) and

important individuals (for example, senators holding hearings on particular issues);

2) the judiciary, including administrative law judges and other relevant courts;

3) organized interest groups comprising Congressional lobbying bodies (trade organizations, consumer groups, single issue groups, etc.);

4) the press;

5) academic and professional groups.

While not exhaustive by any means, this list of participants suggests something of the diversity of potential interests and perspectives which might be stimulated to focus upon any given food safety issue. It also points at the complexity of identifying a policy capable of integrating or reconciling almost certain disparities in objectives.

3.5.4 A Sketch of the Food Safety Decision-making Process

In very general terms, the individual bureaucrat, the agency and other important participants in the broader food safety policy system were identified. It was suggested that the individual bureaucrat performs tasks mandated by the agency, tasks permitting varying degrees of discretionary behavior.

The agency was described as an organization established to formulate and implement policy originally mandated by Congress but also an organization constrained to be sensitive to the exigencies of an ill-defined, ongoing political consensus. In this situation, members of agencies are frequently beset by competitive requirements: to execute

appropriate activities to satisfy oversight and appropriations committees that the agency is adequately fulfilling its legislative mandate, and at the same time to handle politically sensitive problems so as to maintain Congressional support by not raising the ire of politically influential interest groups.

An agency therefore requires a plan for establishing and executing a routine agency agenda in conformance with mandate and a means of dealing with problems which grow politically sensitive. Even more desirable is a method of anticipating and, if possible, preventing acute political problems. The processes by which an agency solves routine and political problems frequently differ, therefore, along with the personnel who become involved in resolving such problems.

In general, routine problems are resolved at lower levels and according to standard procedures while political problems require resolution at more elevated levels and using more ad hoc procedures. At an extreme, resolution requires going outside the agency.

In recent years, the food safety policy arena has grown increasingly politically volatile. One consequence of this phenomenon has been the highlighted frequency with which food safety decision-making authority has been removed from an agency having legal jurisdiction. This is manifested whenever Congress passes legislation or otherwise functions to negate agency positions[1]; it also occurs when the courts reverse agency

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[1] In Michigan, the state legislature passed a law establishing lower tolerance levels for residues of the chemical fire retardant PBB in edible livestock tissues and in milk than those levels established by the FDA. The legislature took this action in the face of extraordinary political controversy regarding the physical dangers of exposure to

actions.[1] A different though related response to political problems is the use of strategic action by one agency in order to influence the actions or enlist the support of another.[2]

Two food safety problem-solving paradigms can be observed--routine and political. A problem-solving paradigm refers to the model by which a food safety policy problem is perceived, defined, disaggregated, delegated to individuals, resolved, and the components again aggregated into a policy response.

It is important to remember that individuals whose decisions do have a bearing on something which could be legitimately though abstractly labeled "the food safety policy process" mat not, and probably do not, perceive food safety policymaking as a primary responsibility. It is more probable that an individual would be most concerned with dispensation of a

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minute levels of PBB and various degrees of economic disaster facing livestock and milk producers and other economic interests in the food chain. (See Edwin Chen, PBB: An American Tragedy.)

[1]An interesting and complicated case has been that of the synthetic growth stimulant, DES, commonly used in cattle. After years of FDA attempts to withdraw the substance from the market and industry attempts to retain it, FDA finally banned DES from the market Nov. 1, 1979. Subsequent to that time, numerous instances of cattlemen continuing use of DES in violation of the law were discovered. In Kansas, 170,000 pounds of beef, considered violative, were impounded by the FDA and held off the market. In a recent decision, U.S. District Court Judge Patrick Kelly has ruled that the agency erroneously determined the violative residues posed any danger to humans. The case is expected to be appealed (Manhattan Mercury, May 7, 1981, p. 1).

[2]This phenomenon includes formal and informal agreements between agencies. For example, a number of administrative agencies participate in the recently established National Toxicology Program; one of the policy issues under consideration is establishment of uniform guidelines relating to determination of carcinogenicity.

workload of fairly routine tasks having only a partial cognizance of its probable relationship to eventual resolution of food safety issues.

It is assumed here that the manner in which a routine problem is handled by an agency is reflected and affected by the agency organization chart. Agency organization is generally formulated to facilitate accomplishment of those tasks perceived to be mandated and of highest priority. Funding levels and, therefore, material and human resources reflect both agency and legislative priorities.

Political problems, almost by definition, demand extraordinary organizational response. Political problems may be of two major types: internal political problems arise when individuals performing specific tasks within an agency either cannot agree upon results or cannot concur on the importance of particular results; external political problems result when an agency decision carries with it unpopular impacts upon the property rights of large or vocal or influential groups.

Empirical evidence suggests the hypothesis that organizational response may be of two major types, in part corresponding to the short and longer term.

In the short term, an external political problem--if it has escalated beyond the point where controversy can be dissipated by agency statements or denials--is apt to stimulate agency formation of some sort of ad hoc organizational entity (such as the Sulfa Task Force), an entity superimposed upon existing agency structure. Such a move has at least four distinct advantages; it satisfies the perceived requirement for expedient action; it can be highlighted as an evidence of agency concern;

it provides a procedure permitting the integrated effort of individuals who might otherwise be difficult for formal procedural reasons to bring together; an ad hoc organizational entity may be readily dissolved if it is concluded the problem was unique or expanded and institutionalized if the problem was evaluated as precedent-setting.

In the long term, then, agency response to an external (or internal) political problem is likely to include a reformulation of agency rules and/or an agency reorganization to reflect the belief that the political problem may be typical of a class of problems liable to arise in the future and which management wishes to short-circuit before these also gain political volatility.

3.6 Linkages of Firm Objectives, Decisions and Policy Performance Variables

The preceding section outlined a variety of factors influencing the decision-making of individuals, firms, policymakers and agencies. Uncertainty, organizational complexity and imperfect competition each color the economic decision context of diverse subsector participants to varying degrees. Due to uncertainty and limitations in resources, satisficing behavior is the norm at each decision level.

Analysis of the impacts of food safety policies upon the interests of the several subsector participants depends upon a specification of those interests. The following range of participant interests were identified: interests in sulfa as product, as input, as contaminant and as policy problem. Possibilities of mixed interests were considered, especially for firms within the feed and swine industries.

Participant interests in animal drug/food safety policies, then, largely flow from these economic interests in the regulated substance. Producers of sulfa products can be expected to rationally evaluate food safety/drug policies on the basis of anticipated policy impacts on firm profitability; participants using sulfa as production inputs, on the basis of recurring impacts on production costs or product prices (as well as impacts on firm operating autonomy); consumers and other purchasers of products containing sulfa contaminants, on the basis of safety and cost; policy makers on the basis of cost-effectiveness and political acceptability. Firms constituting mixed decision cases balance these various concerns according to the perceived benefits and costs to unique individual circumstances.

CHAPTER IV

DECISION-MAKING IN THE SULFA CASE: PRESENTATION AND ANALYSIS OF CASE EVIDENCE

Chapter IV presents and analyzes case evidence of firm and regulatory decision-making in the sulfa case based on an extensive series of interviews with members of industry, government and universities as well as secondary sources regarding relevant industries. A thorough examination of this important case with its series of events, decisions and outcomes suggests conclusions regarding potential food safety regulatory impacts in similar cases. While any specific case contains unique elements, many of the economic and agency participant groups, motivations (both economic and political), aspects of chemical technology, and conceptual and measurement issues of risk, benefit and cost associated with sulfa food safety problems and regulation clearly pertain in numerous food safety cases.

The case evidence and analysis presented here concern the four major industries involved in the sulfa case, proceeding sequentially from the animal health industry through feed manufacturing and hog production to the meat-packing industry. The two major administrative agencies involved in food safety regulation, FDA and USDA, are also considered. Figure 4.1 depicts the general organizational approach of the chapter. For the four major industries in the value-added process beginning with sulfa drugs and resulting in pork, major decision strategies directed toward the market, the policy arena and

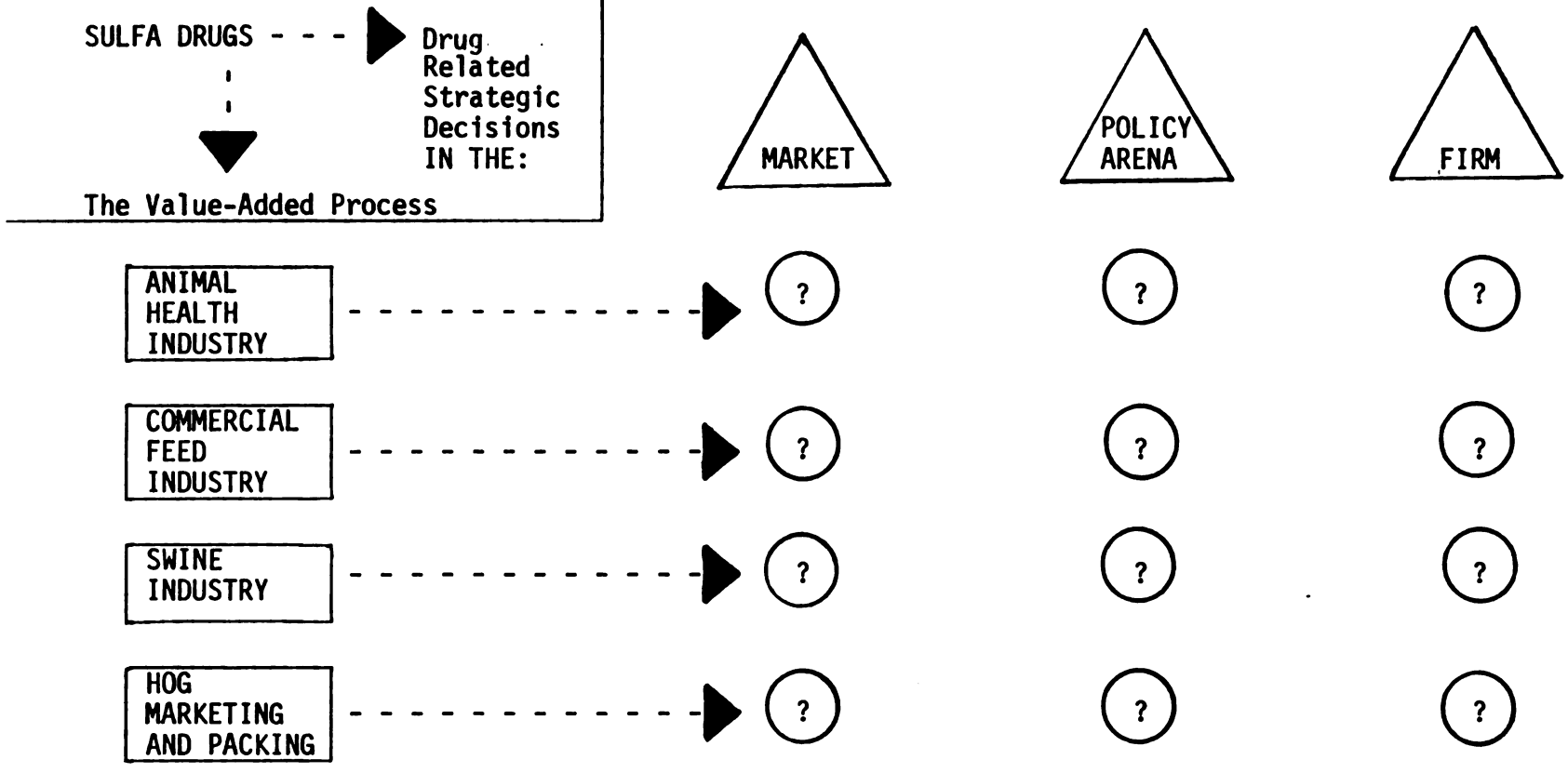


FIGURE 4.1. CONCEPTUAL APPROACH TO DATA COLLECTION AND ANALYSIS, CHAPTER IV

internal matters of organizational (and quality) control are identified from case evidence and analyzed for economic and policy impacts in the sulfa case. Arguments in support of the conceptual framework for policy analysis (presented in Chapter III) which underlies this research center on the premise that comprehension of the broad impacts of a given regulation must be based upon an understanding of the manner in which the regulation affects decision-making at the firm level.[1] Firm management, in pursuit of its objectives, confronts uncertainty and attempts to exert control in the market, the regulatory arena and within its own organization. Regulatory concerns provide one important area of concern to the firm, but this concern, properly understood, must be viewed as interdependent with market and organizational decision problems. As previously suggested, the firm may work through the market to attempt to alter the regulatory environment; or it may do the reverse. In general, an intendedly rational and self-interested firm attempts to expend resources in that area with the highest pay-off toward accomplishment of firm objectives.

In order to demonstrate the types of market, institutional or organizational strategies and strategic trade-offs operative in the sulfa case, the research procedure initially called for identification of each firm's major interests in sulfa (as a product, an input, a contaminant, or some combination) and subsequent identification of the manner in which the firm handles sulfa (and other animal drugs) and related food safety regulation.

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[1] If the incremental nature of policy incentives at the micro level is not adequately understood, then firm compliance may erroneously be pegged at an unrealistic rate by policymakers and hence mismatched with the desired level of residue control. Failure to achieve adequate residue control may then result in undesirable public health impacts.

Accordingly, Section 1 examines strategic decisions of specific corporations within the swine feed additive market of the animal health industry. Here, large pharmaceutical corporations pursue market and regulatory strategies related to various sulfa products and competitive animal drugs.

Section 2 examines aspects of commercial feed industry structure and case evidence from a variety of firms demonstrating how individual firms cope with marketing, regulatory and quality control problems related to sulfa drugs in their multiple roles as products, inputs and contaminants.

Section 3 examines the swine industry, presenting case evidence of hog producers' problems and decisions related to sulfa and regulation. For hog producers, sulfa drugs represent important inputs but also potential contaminants.

Section 4 provides perspective on the meat-packing industry including its interests in, and probable reactions to, regulatory policies designed to resolve food safety problems associated with chemical residues.

Because the influence of regulatory measures upon various industry participants is of major concern, evidence of regulatory decisions and effects flows throughout Chapter IV. Section 5, however, explicitly considers decision-making of policy makers in the sulfa case so they perceived and responded to problems and new facts which came progressively to light.

The final section of Chapter IV (Section 6) summarizes major decision-making features of the sulfa case and provides major analytical conclusions of the chapter regarding the nature of interactions between industry participants, regulators, the market and regulation

in the sulfa case. The diagnostic model developed and validated to this point then sets the stage for subsequent analysis of several distinct regulatory scenarios proposed in the sulfa case and appearing in Chapter V.

4.1 The Animal Health Industry and the Sulfa Case

This section on the animal health industry is organized to explore: the economic importance of the sulfa products involved in the sulfa case to their manufacturers and purchasers; characteristic strategies employed by these manufacturers in the market and the regulatory arena in relation to sulfa and other animal drugs; and finally, the series of events which occurred in the sulfa case involving interactions between corporate and regulatory decision-making.[1] An understanding of the contribution of sulfa products to the economic position of the corporation and the manner in which animal drug products are routinely handled, provides a context in which incremental impacts of various food safety regulations on industry strategic decisions related to drug products can be assessed.

The firm operating in imperfect markets under uncertainty attempts to establish control in the market place, the institutional arena and within the organization. One important set of decisions involves acquisition and utilization of information (including information subsidization); another set of decisions involves optimal organizational response to problems stemming from the environment. A third set of

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[1] In order to establish an historical sense of events in the sulfa case, chronological presentation is followed whenever possible. In some cases marketing and regulatory strategies are rather artificially separated for analytical purposes even though highly interdependent.

decisions relates to choice of appropriate strategies of regulatory compliance. Specific strategies which the economically powerful firm might employ can be summarized to include:

1) strategies directed toward uncertain market conditions, including information strategies, measures of price and non-price competition and additional measures to enhance the structure of demand and supply over the longer term from the firm's perspective,

2) strategies directed toward uncertain institutional conditions, including measures to mitigate regulatory impacts upon the market or affecting processes internal to the firm considered disadvantageous to the firm and/or aggressive strategies to influence regulation and other aspects of the institutional structure for the firm's distributional gain;

3) strategies directed toward the firm's own corporate performance, including measures to improve communication, quality control, and overall management.

4.1.1 The Economic Importance of Sulfa Drugs to the Animal Health Industry

The initial spotlight of this particular drama of sulfa drugs falls upon a small but select group of large corporations supplying the major share of the market for swine feed additives. The cast includes American Cyanamid (of "Formica" brand fame), a highly diversified firm manufacturing and selling agricultural and specialty chemicals and medical and consumer products in the United States and approximately 150 other countries; Diamond Shamrock, operating in principal business segments of exploration, production and marketing of oil and gas, coal,

industrial chemicals, plastics, specialty and agricultural chemicals and health products; Eli Lilly and Company's agricultural products subsidiary, Elanco Products Corporation, with agricultural sales in 1981 of approximately $800 million and impressive parent company interest in markets for human pharmaceuticals, medical instruments (for example, cardiac pacemakers) and the cosmetics industry (Eli Lilly owns the Elizabeth Arden organization); and finally, Rachelle Laboratories of Long Beach, California, with major interests in human antibiotics markets and a subsidiary of International Rectifier Corporation. The firms vary in many respects: asset size, product line, marketing strategies and other characteristics; each of the companies, however, is similarly distinguished by its production of either a sulfamethazine or a sulfathiazole combination feed additive for swine.

How economically important are the sulfa products to these corporations participating in the animal health industry market segment consisting of swine feed additives? The question is an important one because it carries with it ramifications regarding the degree of corporate commitment an intendedly rational firm might devote to promote or defend an "embattled" product. As with many other questions, however, a simplistic answer can be misleading. Examination of various dimensions of economic importance in the context of a complex firm operating in imperfectly competitive and uncertain markets enhances understanding of firm behavior in this and similar cases.[1]

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[1] Initial intuition in a case in which an "embattled" product appears to represent only a small percentage of total corporate sales or profit perhaps suggests that the rational corporation might adopt a passive stance in regard to its product, merely electing to allow events to run their course. Actions in the sulfa case contradict this intuition.

4.1.1.1 Sulfa Production Statistics

Sulfamethazine, sulfathiazole and other sulfonamides are initially produced in the form of bulk medicinal grade chemicals before subsequent formulation into finished pharmaceutical preparations. The United States International Trade Commission (USITC) compiles data on annual production and sales of bulk form medicinal chemicals excluding finished pharmaceutical preparations (see Table 4.1).[1] As indicated, three corporations including American Cyanamid, Rachelle Laboratories and Salsbury Laboratories reported combined production of bulk sulfamethazine of 1.3 million pounds in 1979; dollar sales were not disclosed. No domestic production or sales were reported for sulfathiazole alone. Sources within USDA indicate that Diamond Shamrock Corporation is the sole domestic importer of sulfathiazole, obtained in Poland.[2]

The USITC figures contain significant limitations due to the necessity of protecting confidentiality of information. As indicated in Table 4.1, total sulfonamide production in 1979 was 5.9 million pounds; of that sulfamethazine comprised 1.3 million pounds or 22 percent. Reported sales quantities of total sulfonamides were substantially lower

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[1]Data are given for individual chemicals only when there are three or more producers, no one or two of predominance, in order to protect confidentiality of market information. Data are only reported by producers of medicinal chemicals where volume of production or sales or value of sales exceeds 1000 pounds or $1,000. Statistics are reported in terms of undiluted materials. Differences between quantities produced and sold are attributable to changes in inventory, losses in processing or intra-company transfers or transfers to wholly owned subsidiaries (these are not reported).

[2]United States, International Trade Commission, Synthetic Organic Chemicals: United States Production and Sales, 1979, USITC Publication 1099 (Washington, D.C.: U.S. Government Printing Office, 1980) pp. 117, 124; interview with Howard Teague, Science and Education Administration, United States Department of Agriculture, Washington, D.C., September 26, 1979.

TABLE 4.1. BULK MEDICINAL CHEMICALS INCLUDING SULFONAMIDES: U.S. PRODUCTION AND SALES, 1979

MEDICINAL CHEMICALS	PRODUCTION 1,000 pound	SALES QUANTITY 1,000 pound	SALES VALUE 1,000 dollars	SALES UNIT VALUE per pound
Grand Total Medicinal Chemicals*	313,040	225,655	1,043,145	$ 4.62
Anti-infective agents (except antibiotics), total	35,338	10,478	58,026	5.54
Sulfonamides, total	5,951	721	8,179	11.34
Sulfamethazine**	1,358	---	---	---
All Other	4,593	721	8,179	11.34

*The difference between production and sales reflects inventory changes, processing losses and captive consumption of medicinal chemicals processed into ethical and proprietary pharmaceutical products by the primary manufacturer.

**Manufacturers of sulfamethazine reported were American Cyanamid Company, Rachelle Laboratories and Salsbury Laboratories.

Source: Compiled from U.S. International Trade Commission, Synthetic Organic Chemicals: U.S. Production and Sales, 1979.

than production quantity: 721,000 pounds of sulfonamides were reported sold in bulk form in 1979 out of total production of 5.9 million pounds; this amounts to 12 percent. Much of the difference probably stems from captive consumption of medicinal chemicals which were subsequently upgraded through formulation into proprietary pharmaceutical products. As shown by Table 4.1, no sales figures are reported for either sulfamethazine or sulfathiazole due to the limited number of producers and market confidentiality requirements. In order to arrive at a suggestive figure, however, if sulfamethazine's share of sales is approximately equal to its percentage of production and priced at the average unit price for all sulfonamides ($11.34 per pound), then bulk medicinal sales of sulfamethazine resulted in approximately $1.8 million sales in 1979.

The primary value of sulfamethazine products to producing companies is realized after further processing.[1] The 1979 value of sulfa swine feed additives to the four companies examined here is estimated at approximately $50 million.[2] During the value-added process, sulfa drugs undergo considerable changes in price. Production, sales and ultimately use data at subsequent levels of the value-added process provide insights into the economics of this agri-business marketing system.

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[1]"Different pricing rules apply to different types of products. Undifferentiated, commodity-type chemicals move at 'competitive market prices leaving little room for discretionary price action. Unique, specialty-type chemicals permit a range' of price action depending on the price and availability of substitutes that can serve the same function." W. F. Christopher, Hooker Chemical, quoted in Jules Backman, The Economics of the Chemical Industry (Washington, DC: Manufacturing Chemists Association, 1970) p. 144.

[2]Data supplied to author by IMS America, Ltd. Note that the $50 million figure represents sulfa combination drugs containing either penicillin and chlortetracycline or tylosin in addition to sulfa.

4.1.1.2 Purchases in the Swine Feed Additive Market

Focusing upon the swine feed additive market provides additional information regarding the economic value of sulfa products to producing firms. It also permits a clarified view of some features of market structure of the animal health industry. As a note, the meaning and extent of market concentration in the animal health industry depends critically upon definition of market. Whereas some analysts have constructed impressive arguments in the past regarding the rigorously competitive nature of the overall chemical industry[1], the picture in specific market segments appears markedly different.

Market information is provided by three major organizations which collect data on various market segments of interest to the animal health industry.[2] Data base, purpose and clientele group of these market research organizations differ significantly. The Animal Health Institute, a professional trade organization, collects market data primarily for use on Capitol Hill in promoting the industry. The data are fairly aggregative and designed to illustrate industry economic power and enhance industry political clout. For purposes of product sales analysis, firms in the industry turn to two primary sources: Doanes

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[1]For example: "The chemical industry is intensely competitive and that competition has many dimensions. . .among chemical products. . . competition with products of other industries, competition in research, competition from new competitors with a base in other industries or by extension of product lines by chemical companies and non-price competition." Backman, Chemical Industry, p. 9.

[2]Representatives of the three organizations interviewed were: Dr. Jerry Brunton, Director of Scientific Activities, Animal Health Institute, Washington, D.C., February 19, 1980; Bob Holmes, Product Group Manager, Marketing Sales/Production, Doanes Agricultural Services, Market Research, St. Louis, April 15, 1981; Stephen B. Schectman, Vice President, IMS America, Ltd., Washington, D.C., February 23, 1981.

Agricultural Services, Market Research; and IMS America Ltd. Doanes collects quarterly data on use of medicinal and non-medicinal feed additives by livestock producers on farms; the IMS data base indicates purchases of feed additive products by the feed industry, veterinarians, buying cooperatives, the integrated poultry industry, drug stores and feedlots. Doanes market statistics are of interest, then, to those interested in trends of medicated product use at the farm level while IMS statistics emphasize product sales at the wholesale level.[1] In the course of this research, interviews with representatives of the three market research organizations yielded the picture of the market for swine and other livestock feed additives presented in Table 4.2 and below.[2]

Purchases of sulfamethazine and sulfathiazole feed additive products by feed mills and manufacturers, feed stores, hay and grain stores, veterinarians, buying cooperatives, drug stores and feedlots, are estimated by IMS on a national basis for the years 1973 to 1980. Prices paid by these purchasers include a combination of manufacturer, wholesale, or dealer prices, depending on the source of purchase. Hence, dollar volume at the manufacturer's level is overstated to the extent figures include wholesalers' or dealers' margins.

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[1]Regulatory agencies also avail themselves of these (expensive) sources of market information: USDA possesses a set of Doanes market statistics while FDA has purchased IMS market information.

[2]Special assistance was received from IMS America, Ltd. which retrieved from its files computerized product information for various animal health feed additive products for the years 1973 through 1980. These data provide the basis of information displayed in Table 4.2.

TABLE 4.2 NATIONAL PURCHASES OF SELECTED LIVESTOCK FEED ADDITIVES CONTAINING SULFAMETHAZINE AND SULFATHIAZOLE BY THE COMMERCIAL FEED INDUSTRY, VETERINARIANS, FEEDLOTS AND DRUG STORES, 1973-1980 (PURCHASES IN THOUSANDS $)

Product Class	1973		1974		1975		1976		1977		1978		1979		1980	
	$	%	$	%	$	%	$	%	$	%	$	%	$	%	$	%
Totals, Antibiotic and Antibacterial Combinations (excluding vitamin combinations)	29,212	100%	36,599	100%	36,845	100%	44,657	100%	52,754	100%	48,858	100%	70,736	100%	62,425	100%
Sulfamethazine																
American Cyanamid																
ASP-250	15,150	52	19,890	54	21,808	59	27,403	61	34,819	66	32,396	66	35,394	50	26,796	43
AS-700	3,333	11	3,448	9	2,375	6	4,038	9	7,108	14	9,289	19	19,721	28	9,236	15
AS-500	156	1	319	1	2,576	7	2,783	6	192	-						
Aureomix									966	2	693	1	2,066	3	2,231	4
Elanco (Eli Lilly)																
Tylan Sulfa	975	3	2,885	8	2,967	8	3,725	8	3,876	7	1,814	4	3,769	5	4,588	7
Rachelle Labs																
Chlorachel-250	3,936	14	2,227	6	2,085	6	3,557	8	4,929	9	3,332	7	5,960	8	9,223	15
Super Chlorachel-250	7	-	59	-	661	2	1,095	3	-	-	-	-	298	-	507	1
Sulfathiazole																
Diamond Shamrock																
CSP-250	1,423	5	447	1	354	1	1,327	3	823	2	1,287	3	3,499	5	9,810	16
Subtotal of Sulfamethazine and Sulfathiazole Products Listed*		86		79		89		98		100		100		99		81

*Non-sulfa products comprise remaining percent of combination class.
Source: Information supplied by IMS America Ltd.

Antibacterial and antibiotic products are broken by IMS into three subgroups: plain antibiotics, antibacterials (arsenicals, nitrofurans, other) and combinations ("with vitamins" and "other combinations"). The sulfa products with which this research is concerned fall into the "other combination" category, denoting antibiotic or antibacterial combination drugs without vitamins. Although the statistics are not specifically differentiated with respect to livestock class, in most cases, products are livestock class specific. American Cyanamid's ASP-250 and Rachelle Laboratories' virtually identical Chlorachel-250 are used exclusively as swine feed additives; the same is true for the Diamond Shamrock sulfathiazole product CSP-250 and the Elanco sulfamethazine-tylosin combination drug Tylan-Sulfa. The only other major feed additive containing sulfamethazine is the American Cyanamid product AS-700, used exclusively as a cattle feed additive.

As indicated by annual dollar purchase figures, American Cyanamid's ASP-250 is by far the most prominent product of any of the feed additives in the category of antibiotic and antibacterial combination feed additives. Purchases rose each year in dollar volume after 1973 until 1977; since that time purchase figures have fallen two years out of three, dropping $8.6 million in one year (from 1979 to 1980) from $35.3 million to $26.7 million. Corresponding figures on the percent of the antibiotic-antibacterial combination feed additive market attributable to Cyanamid's ASP-250 show an increase from 52 percent to 66 percent of the market between the years 1973 to 1977, then a decrease to 43 percent between 1978 and 1980.

Figures for other products, particularly for the three years 1978-1980, demonstrate a 433 percent increase in market share for Diamond Shamrock's sulfathiazole combination product CSP-250 from three percent to 16 percent of the market in 1980 and a 114 percent increase for Rachelle Laboratories' sulfamethazine product Chlorachel-250 to 15 percent of the market in 1979.[1]

The cattle feed additive AS-700 attained a sales peak in 1979 at projected national purchases of $19.7 million and a market share of 28 percent. This fell off to $9.2 million in 1980, representing a market share of 15 percent.

A variety of factors potentially contributing to the figures and trends noted here includes: pricing of individual products; company marketing strategies; aggregate changes in derived demand for feed additives due to livestock cycles; changes in the composition of derived demand for swine feed additives due to heightened concern over drug residues and associated regulatory sanctions.

4.1.1.3 Features of the Markets for Sulfonamides and Sulfa Feed Additives: Summary

Facts presented thus far regarding the economic importance of sulfa drugs, particularly sulfamethazine and sulfathiazole combination[2] swine feed additives reveal the following points which pertain to subsequent discussion:

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[1]Market share is measured by percent of total national purchases in the IMS class of feed additives.

[2]Combinations, to reiterate, refer to FDA approved combination drugs containing penicillin and chlortetracycline or, alternatively, tylosin.

1) The market for sulfamethazine and sulfathiazole bulk medicinals is oligopolistic, characterized by few sellers: three domestic corporations produce sulfamethazine in the U.S., and one domestic corporation imports sulfathiazole in bulk medicinal form.

2) A substantial majority of sulfonamides produced by the manufacturers of bulk medicinals are not sold in this form, but further processed. For all sulfonamides, approximately 12 percent are sold in bulk medicinal form. For sulfamethazine, which constitutes 22 percent of total sulfonamide production, sales figures are not available.

3) The market for sulfa combination swine feed additives is also oligopolistic with four firms (American Cyanamid, Rachelle, Diamond Shamrock and Elanco) supplying virtually 100 percent of the market in terms of purchases by the feed and veterinary industries. In the market for antibacterial combination additives, the same four firms supply between 79 and 100 percent of the market in terms of purchases, depending on the year (figures from 1973 to 1980).

4) The economic value of sulfa combination feed additives for swine and cattle is approximately $50 million as reflected by purchases of the feed industry, the veterinary profession, and large poultry integrators. (The figure overstates the revenue received by pharmaceutical producers slightly, to the extent dealer and wholesaler margins are included; it also reflects the value of penicillin, chlortetracycline and tylosin in sulfa combination drugs.)

In addition to the criteria of the contribution of the product to market share, total sales or, less determinable, profit, the following features of the industry also bear upon corporate assessments of the economic importance of particular products: the contribution of a

particular product or product component to the company's market position in various market segments (because the product contributes to a company's capacity to supply a complete line of products, or to building brand recognition, etc.); the product's value in permitting the company to utilize by-products and joint-products or otherwise exploit economies of scale and recuperate high capital and research and development costs.

4.1.1.4 Economic Features of the Industry Impinging on Industry Assessments of the Importance of Sulfa

The preceding section presented information and analysis regarding the economic importance of sulfa drugs, both as bulk medicinals and after formulation into swine feed additives. Oligopolistic characteristics of the markets for bulk medicinals and for swine and other livestock antibacterial feed additives were also noted. Here, additional structural features of the chemical and pharmaceutical industries impinging on operating procedure as well as evaluation of the importance of specific sulfa products are examined more fully.

Understanding the economics and standard operating procedures of the animal health industry requires an appreciation of distinctive attributes of the industry with respect to product development and industry structure. The animal health industry label applies to a composite of diverse companies, most of them multiple product companies, many of them large and operating in a number of related and unrelated markets. Backman's description of the parent chemical industry applies equally well to the animal health industry:

> The chemical industry broadly defined embraces a complex of subindustries. The borders of the industry and its subindustries generally are indistinct. Large expenditures for research and development create new products and new technological processes which continually alter the product

> mix of the industry and create opportunities for companies already in the industry as well as for those in other industries.[1]

The industry is distinguished by high capital costs, high research and development expenditures, changing products and processes which represent a payoff of high research expenditures and, in general, the incentive to exploit marketing and other strategies to recuperate and gain a return on the high sunk costs of product research and development. Research and development and market identification activities are important strategies associated with the industry's attempts to develop and protect markets for its products.

4.1.1.4.1 Research and Development

Prior to a pharmaceutical company entering the market for animal drugs, a product is required. Basic research plays a fundamental role in overall market-directed strategies of the animal health industry. Research represents a substantial resource commitment, one that has risen continually over the past 25 years. The Animal Health Institute placed expenditures of its corporate members at over $97 million in 1979; this sum represented an expenditure of 13 cents for every dollar of net domestic product sales.[2]

In addition to general factors of inflation, regulatory requirements for substantiation of product safety and efficacy have increased sharply and contribute both to raising barriers to market entry and to the substantial degree of uncertainty surrounding the research and

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[1] Backman, The Chemical Industry, p. 1.

[2] Fred Holt, "The Animal Health Industry," Feedstuffs, October 29, 1979.

development process for any new product. According to recent estimates, research requirements incorporating regulatory demands now result in a necessary planning horizon for a single new drug of from 10-20 years and between $15-20 million.[1] In addition to these requirements is the persistent risk that sunk resources could at any moment be rendered virtually useless by an adverse toxicological discovery.

In the face of resource demands of this magnitude and substantial associated risk of product failure and adverse regulatory developments, firms in the animal health industry adopt a number of strategies including attempts to exploit economies of size and scale in research and development. Basic research of a company such as Eli Lilly or American Cyanamid, for example, attempts to identify a new antibiotic or chemotherapeutic agent showing potential promise for a number of markets. The preferred market for such a substance is the human pharmaceutical market due to its greater size. In the words of one market research expert, "The human health industry is ten times the size of the animal health industry and there are very few cross-over drugs. In many ways, the Animal Health Products Division is a second class citizen when it comes to research and development."[2]

Only a small percentage of chemical substances or antibiotics identified ever reach the product development stage. In addition,

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[1] Interview with Brunton, Animal Health Institute. Parallel developments in the pesticide industry are remarked in United States Department of Agriculture, The Farm Pesticide Industry, Agricultural Economics Report No. 461, USDA Economics, Statistics, Cooperatives Service, 1981.

[2] Interview with Harry Jamison, Director of Market Research, Merck, Sharp and Dohme Research Labs, Princeton, New Jersey, April 14, 1981. Worked in same capacity for American Cyanamid during the period of the sulfa case.

some substances showing obvious medicinal promise are not compatible with human health treatments: some drugs broadly used in livestock production, for example, have disagreeable side effects for humans. When the human health market is judged unavailable for some reason, then attention turns to animal health markets, either domestic or, increasingly, international.

4.1.1.4.2 Product Development and Market Identification

Once the fixed costs of basic research have been sustained, the pharmaceutical company benefits from exploitation of as many potential market outlets and product applications as possible in order to recover such costs. In general, a firm benefits when it can gain approval for a drug's application: in many forms, in multiple species, and in combination with other drugs (again, for multiple species). Additionally, the company can extend sales if it wins access to international markets. Finally, the firm spreads costs when it markets by-products, joint products or products utilizing similar processes.

The seeds of the sulfa case were planted over thirty years ago when early research work at American Cyanamid into the characteristics of the sulfonamides led to the discovery that sulfamethazine appeared particularly advantageous for many therapeutic purposes due to its effectiveness in attaining high blood level concentrations. Cyanamid also developed its Aureomycin(R) brand of chlortetracycline (used in ASP-250) in approximately the same time period, the late forties and early fifties.

Cyanamid currently manufactures sulfamethazine and other sulfonamides and a number of tetracyclines as bulk medicinals, plus a variety of sulfamethazine products including powders, water medications and boluses for cattle, a sulfamethazine-chlortetracycline feed additive (AS-700) for cattle, ASP-250 for swine, and a chlortetracycline bisulfate-sulfamethazine bisulfate water medicant approved for swine. In summary, Cyanamid produces a large variety of products related in their use of tetracyclines and sulfonamides which permits the company to appeal to different tastes and preferences within the feed additive and livestock pharmaceutical market and thus expand total sales.

The importance of this fact that a company may produce a number of products utilizing a particular chemical compound or drug should not be discounted from the perspective of influencing a firm's regulatory strategies. A company like American Cyanamid with an investment in over a dozen products incorporating sulfa drugs is likely to view regulatory scrutiny of just one of its products with seemingly disproportionate concern until consideration is given to the extent of the company's economic interest. Should all sulfa drugs or all sulfamethazine products be implicated as carcinogens, for example, the company's potential loss would be far greater than the loss of ASP-250 alone.

4.1.1.5 Economic Importance of Sulfas: Summary and Conclusions

The preceding section presented information and analysis regarding the economic importance of sulfa drugs, both as bulk medicinals and after formulation into swine feed additives. Market information on purchase of sulfa feed additives by the commercial feed industry,

veterinarians and others who subsequently sell them in some form to hog producers indicates that after a period of generally strong growth through the mid-seventies, purchases have fluctuated and in some cases slowed in the past two years. Some individual products, such as American Cyanamid's market leader ASP-250, have lost ground while others have gained, specifically Rachelle's virtually identical product Chlorachel-250 and Diamond Shamrock's sulfathiazole competitor CSP-250.

Regarding structural features of the industry, oligopolistic characteristics of the markets for bulk medicinals and for swine antibacterial feed additives were noted, as well as economic structural features of the chemical and pharmaceutical industries impinging upon determination of the importance of specific sulfa products. Distinctive features of these industries include: high research and development costs, high capital costs, and consequent attempts to expand sales and recuperate costs through the exploitation of by-products, joint products and the identification of market segments for sale of multiple products in multiple forms.

Because of difficulties in assigning fixed capital and sunk research costs to particular products, the profitability of particular products is frequently difficult to determine although sales figures can be used to provide one useful yardstick of importance. Frequently, however, a company's willingness to defend or promote an embattled product goes beyond the point ostensibly warranted from mere examination of sales. Explanations for a company investing in elaborate regulatory maneuvers, lawsuits, advertising and promotional campaigns and extensive strategizing for a product of limited importance in relation to total corporate sales include the motivations

that: it is considered important to maintain the image of a product which appears under a company brand to protect the integrity of the brand; it is considered important to protect market access for a particular drug or chemical which appears in a host of products as the loss of the drug in one application may imply future loss of market access for related products. And finally, in a complex organization the issue of multiple objectives and bureaucratic incentives arises. Whether or not sulfa feed additives contribute critically to total company sales or profitability, the products are important to particular managers and regulatory affairs personnel. As indicated, within the animal feed additive market segment, sulfa drugs are very important; management responsible for these products, therefore, takes the regulatory status of the products seriously. Similarly, regulatory affairs personnel gain importance within the company according to their "victories" in achieving regulatory settlements in the company's interest. The loss of an "embattled" product reflects unfavorably upon the performance of persons responsible for regulatory affairs.[1] Implications of organizational complexity, particularly functionally specialized regulatory affairs staffs, are examined below.

4.1.2 Information and Marketing Strategies

Characteristic strategies utilized by pharmaceutical firms attempting to market animal drugs include the acquisition and subsidization of information and competitive strategies involving price

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[1]For an interesting discussion of this point, see Robert B. Reich, "Regulation by Confrontation or Negotiation," Harvard Business Review 59:3 (May-June 1981), pp. 82-93.

and non-price competition. In this section, case evidence of methods used by animal drug firms involved in the sulfa case in these areas is presented to demonstrate the manner in which the industry manages uncertainty, in some cases successfully exploiting it, and the impact that food safety regulation has upon decision-making.

4.1.2.1 Uncertainty and Information Strategies of the Animal Health Industry

In an uncertain environment, all aspects of a firm's operations bear the imprint of uncertainty. The preceding section indicated purchases of sulfa swine feed additives in the neighborhood of $50 million by the feed and veterinary industries. It was argued that this figure substantially underestimates the economic importance of sulfa products to the four animal health firms involved if inter-dependencies between sulfa swine feed additives and other products are considered. Along with this rough and minimal measure of risk (in the dollar amount of expected loss which the handful of firms in the market segment might absorb should sulfa products be withdrawn from the market), recent changes in the market shares of American Cyanamid, Diamond Shamrock, Rachelle and Elanco were noted,[1] the most dramatic of which revealed American Cyanamid's market share decreasing while Diamond Shamrock's and Rachelle's increased.

Structural features of the pharmaceutical (and chemical) industry including competitive pressures and high capital and research and development costs provide incentives for firms in the industry to

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[1]Market share refers to antibacterial combination feed additives, as defined by IMS.

exploit marketing and regulatory strategies promoting and expanding markets for products in order to manage risk inherent in the industry's operation. Central to all other strategies is the firm's use of information. This section explores issues creating market and regulatory uncertainty influencing the actions of major firms in the animal health industry and emanating from the market and regulatory arena, major sources of information utilized by these firms in their attempts to reduce uncertainty, organizational adaptation of the firms to cope with information problems and customary procedures utilized by "information specialists" in relation to the regulatory/institutional structure. The section concludes with comments on the impact of information handling strategies for the design and implementation of effective regulatory measures.

Factors creating market uncertainty in the animal health industry include price levels and variability for products and inputs, changes in demand and the structure of demand (derived demand) and alterations in the structure and quantity of supply. Food safety regulation can create impacts in each of these determinants of the firm's profit position. Specific issues emanating from the regulatory arena which contribute substantially to the level of uncertainty in the animal health industry include:

1) "Cyclic Review," an FDA policy which would systematically subject old drugs to current scrutiny. Not only would this policy impose increased costs of defensive research upon firms producing the product, but it would also increase risk to the firm that adverse experimental findings might force withdrawal of the product from the market;

2) "Sensitivity of Method," a proposed policy for establishing experimental procedures to be utilized in assessment of carcinogenicity in animal drugs and the determination of levels at which "no residues" are judged present, in conformance with the Delaney Amendment. Industry contends that this policy would raise costs of product research and development and create problems with the disposal of radioactive toxic waste from experimental procedures (the proposal is discussed in Section 3 of this chapter);

3) "Second Generation of Medicated Feeds," currently a proposal for comprehensive re-organization of the regulations pertaining to animal drugs and the feeds in which they are used (the impacts of this proposal on the sulfa problem are examined in Chapter V);

4) proposed antibiotic policies which would ban or curtail the use of tetracyclines and penicillin in livestock production, thus substantially eliminating the market for feed additives containing these drugs;

5) Good Laboratory Practice (GLP) regulations setting standards for experimental procedures of drug sponsors;

6) individual issues and cases such as the case of DES or the sulfas. These cases are carefully scrutinized by market participants for potential ramifications involving their own market opportunities.

Each of these policies or regulatory actions, if implemented, promises substantial costs to the animal health industry in terms of increased costs of research ("defensive research," in the words of the industry), or distributional costs to firms losing market access

for products.[1] It is in the interest of firms in the industry, therefore, to develop and maintain information gathering mechanisms to remain abreast of regulatory developments in order to reduce and control regulatory uncertainty.

Major sources of information can be summarized to include market information sources and regulatory sources. Functionally specialized market research staffs within large animal drug corporations conduct research utilizing a variety of sources. Purchase information for members of the feed industry, the veterinary profession, large integrators and others is available for various segments of the animal health industry: IMS America, Ltd. was mentioned previously. Doanes Market Research provides comparable statistics regarding usage patterns for feed additives at the farm level. Distributors provide information on prices of competitors which is carefully scrutinized. The company's own sales history provides a valuable source of market information. The United States Department of Agriculture and large agri-business consulting firms such as Chase Econometrix provide output from simulation models of various agricultural sectors which indicates performance of livestock sectors influencing the derived demand for animal drugs and feed additives. This list of information sources is not meant to be comprehensive, merely illustrative of the point that an array of information resources exists for this group of large firms and represents a response to demand by the industry in order to reduce market risk.

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[1]Distributional costs to some firms also imply distributional gains to others.

Similarly, a menu of sources providing information upon regulation and trends in regulation affecting the firm is commonly utilized by large pharmaceutical firms. According to one regulatory affairs specialist, the first order of activity on any new day is reviewing developments documented in the Federal Register.[1] Other publications valuable to regulatory affairs specialists include Food Chemical News, the Food, Drug and Cosmetic Law Reporter, trade publications such as Feedstuffs and many others. Membership in trade organizations is a strategy employed by all major firms in the sulfa case; all are members of the Animal Health Institute which provides a variety of services to members including regulatory information, interpretation of pending policy measures, and analysis and lobbying for industry interests. The trade association frequently hosts prominent agency officials at industry meetings to discuss issues of concern to the industry. Additionally, company lobbyists provide first hand information derived from contact with regulators, legislators and other public officials. Finally, the revolving door provides a popular method of utilizing expertise gained in regulatory decision-making for corporate benefit.[2]

The previous summary of information sources regarding regulatory rules, issues and trends, once again, is not exhaustive but indicative of the point that the acquisition, utilization and provision of

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[1] Interview with Sondra Flick, Regulatory Affairs Specialist, Diamond Shamrock Inc., Cleveland, May 26, 1981.

[2] The draftor of American Cyanamid's citizens' petition to the FDA regarding sulfamethazine tolerance level changes is a former employee of FDA; the National Pork Producers Council hired the former head of the Bureau of Veterinary Medicine as its governmental affairs specialist.

information regarding the institutional environment is an economic decision influenced by expected costs, benefits, and available resources of the firm. An important point illustrated by examination of the experience of firms involved in the sulfa case is that these firms possess resources of a magnitude sufficient to permit them the opportunity of exploiting a range of regulatory information sources, resources not equally available to firms with smaller resource endowments.

Organization theorists hypothesize that successful large corporations adapt functionally and organizationally to problems originating from the environment.[1] Uncertainty, specifically regulatory uncertainty, constitutes one class of "problems." Functional specialization in the area of information acquisition and information provision permits the firm to improve control over market and regulatory uncertainty while economies of size contribute to the large, complex firm's ability to exploit a broad range of information media and control options. In a slightly different context, Newman distinguishes between investment in resources of knowledge--a fixed information-gathering cost (for example, a regulatory affairs staff)--and the acquisition of market intelligence which is constantly changing and can be regarded as a variable cost (for example, subscription to a market news letter, or taking a regulator to lunch).[2] Larger firms are better equipped to make an investment in an institutional apparatus providing the firm with both the resources of knowledge regarding the content and future

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[1]Richard E. Caves, "On Corporate Strategy and Structure," Journal of Economic Literature XVIII (March, 1980).

[2]Mark D. Newman, "An Evaluation of the Economic Potential for Coordination of Export Marketing by U.S. Farmer Cooperatives" (Ph.D. Dissertation, Michigan State University, 1980), pp. 122-137.

direction of market performance and food safety regulation and the market and regulatory intelligence that indicates frequently changing developments. Further, the firm may be able to exploit complementarities which exist in the functions of information acquisition and information subsidization. To the extent regulators utilize subsidized information to fill their information needs, and to the extent that powerful firms have an advantage over less powerful firms in providing the information, formulation of regulations may reflect the interests of one economic group at the expense of another.[1]

The examples provided by three large firms involved in the sulfa case demonstrate the degree of functional specialization which evolves in the case of regulatory information acquisition (and subsidization) and benefits associated with this specialization from the standpoint of the firm. The examples also illustrate complementarities in information "products" permitting realization of economies by the firm.

Elanco Products Company of Indianapolis, Indiana maintains a regulatory affairs staff comprised of a director, a number of product managers and assorted subsidiary personnel. Different subject matter specialties within the area of regulatory affairs develop as the need arises. The manager of animal products of this staff reports that he has devoted nearly full time over a period of months to developing and promoting the company's interests with regard to FDA's proposed Sensitivity of Method policy. Commenting on this allocation of his

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[1]This observation is repeated again below in connection with the commercial feed industry and the proposed Second Generation of Medicated Feeds policy.

time, he responded, "We have to take these proposals seriously, because FDA begins implementing them before they are approved."[1]

This man's boss, the Director of International Regulatory Services for Elanco, provided examples of ways in which regulatory information could be acquired by a regulatory affairs staff already in existence to expand markets into international arenas, thus permitting the firm to reduce or spread risk attendant on operation in domestic markets alone. Selected personnel within the regulatory affairs staff have come to specialize in the rules governing market penetration in particular European countries, the U.K. or Japan. Knowledge of these procedures affords a pay-off in other international market areas, specifically some of the less developed countries. "We have discovered that if we can get marketing approval in either the U.S., the U.K., Germany or a couple of other countries, this will generally permit us access to Latin American markets, for example. They generally accept these approvals on trust."[2]

The regulatory affairs staff at Diamond Shamrock includes specific specialists in the regulations and administrative procedures of the FDA which relate to the company's chemical and drug products and the EPA, an agency with different procedures. Staff specialists in regulatory affairs maintain direct access to the company's senior

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[1] Interview with G. Dean Lindsey, Manager, Animal Products, International Regulatory Services, Elanco Products Co., Indianapolis, July 31, 1980.

[2] Interview with Jerry Probst, Director of Regulatory Affairs, International Regulatory Services, Elanco Products Co., Indianapolis, July 31, 1980.

corporate counsel and his staff which coordinate legal aspects of regulatory affairs.[1]

Another example of corporate regulatory affairs specialization and attempts to supply information in order to modify regulations is provided by American Cyanamid (and examined in more detail below). The manager of quality assurance for American Cyanamid has spent a large proportion of his time over a one to two year period developing and submitting a petition designed to provide evidence to FDA which would persuade the agency to modify the established tolerance level for sulfamethazine. Such an action by the agency would be in the direct interest of American Cyanamid. This move is examined below.

Summarizing, functional specialization within large, economically powerful firms represents an organizational adaptation to problems originating from the environment (either market or regulatory) which enables the firm to gain the benefits of specialization stemming from economies of size. Due to factors of economic power, firms are able to support personnel as they become expert in the decision-making procedures of a particular agency or agency branch or agency office, in the intricacies of administrative procedures or a proposed policy. The benefits of organizational specialization in information acquisition translate in large part to benefits involved in information subsidization to policymakers requiring information for their own decisions.

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[1] Interview with Robert Hill, Senior Counsel, Diamond Shamrock, Inc., Cleveland, April 21, 1981.

Additionally, information acquired regarding future developments in the regulatory arena possesses value as it is used for strategic planning of product and market research and development over multi-year periods.

4.1.2.2 Marketing Strategies

Marketing strategies of firms in the chemical and, particularly, the animal health industries are briefly surveyed here for insights provided regarding standard procedures used in relation to animal drugs to control uncertainty and enhance market performance. Economic theory indicates that imperfectly competitive markets are frequently characterized by non-competitive pricing and by measures of non-price competition. These factors are examined in turn.

4.1.2.2.1 Pricing Decisions

The seller in a competitive market has no incentive to cut price since he can sell all he wishes at the market price. (He faces a perfectly elastic market demand.) He is unable to price discriminate due to perfect consumer information--(few consumers would pay more if they could pay less)--and abstraction from marketing problems of place and time. All that remains for the seller is to produce that quantity, given market price, that equates marginal cost and marginal revenue.

In a world of imperfect buyer information, and markets imperfectly competitive in other respects, the seller possesses some power to price discriminate on the basis of variable elasticities of demand. This power is further enhanced if the seller is a multi-product/multi-plant

firm and can cross-subsidize the purchase of one product with the revenue from another. The objectives of such strategies may range between simple market introduction of a new product to underpricing a competitor long enough to drive him from business.

Pricing in the chemical industry and its subindustry, the animal health industry, is an administered activity performed by corporate officials in accordance with formal or informal principles of corporate pricing policy, including pricing goals, responsibilities and standard procedures.[1]

Possible pricing goals include: attaining a satisfactory return on investment, meeting competition, maintaining or expanding market share. Standard operating procedures which develop pertain to standard discounts negotiated or calculated for quantity, geographical, functional, internal transfer, or cash purposes.

A variety of product or market characteristics which influence pricing decisions includes: degree of product standardization, commodity or specialty status, presence of pharmaceutical or other types of substitutes in consumption, existence of by-products, the importance of derived demand, the ease of market entry for competitors, whether the product requires specialized manufacturing equipment, whether costs can be determined, what costs are.

As illustrated above by the relative costs of sulfa in bulk medicinal and feed additive form, specialty items such as finished pharmaceuticals command a higher price than bulk medicinals which are

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[1]This section derives in large part from Backman, The Chemical Industry, pp. 141-156.

nearer commodity status. In this regard, a spokesman for W. R. Grace commented: "Specialized items developed to meet particular market requirements are more frequently characterized by long-term customer relationships and price stability than non-specialized products."[1]

4.1.2.2.2 Non-price Competition

Non-price competition plays an important role in imperfectly competitive markets. Two major forms of non-price competition involve the use of patents and various mechanisms of product differentiation.

Patent laws were established to encourage innovation. Corporations use them to enable recovery of research and development costs and, more generally, the benefits of market power and a degree of monopoly discretion. In the case of combination animal drugs, FDA regulations and patent laws combine to enhance competitive power of some members of the animal drug industry.

Product differentiation may be accomplished in a number of ways: 1) by actual or cosmetic alteration of the physical product; 2) by provision of services offered in conjunction with the product; 3) by advertising and promotion (which may complement #1 and #2). Possibilities for non-price competition stem in part from imperfect markets permitting the exercise of market power and partially from a relaxation of the standard neoclassical assumption of homogeneous products. Once heterogeneity is permitted, firms may alter the physical appearance, quality or other characteristics of a product to expand demand for the product by appealing to different preferences and exploiting different price and income elasticities of demand. Opportunities for product

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[1]Cited in Backman, p. 143.

differentiation frequently correspond with the presence of transactions costs which contribute to problems of vertical coordination (and enliven the study of marketing). Possibilities for combining product characteristics with marketing or other services afford firms an important means of product differentiation. In this regard, the role of regulation bears mention. Regulation and requirements of regulatory compliance provide another important opportunity for provision of corporate services to customers and thus assist in differentiating a product or a line of products.

The final form of non-price competition discussed includes the advertising and promotion of products. When a product is undifferentiated, firms may participate in generic advertising and promotion in a concerted attempt to shift overall demand for the product (a phenomenon evidenced recently by pork producers attempting to influence consumer demand for pork products in a period of large pork supplies). However, when sellers discover they can differentiate individual products on some basis, they frequently engage in advertising or promotional activities to expand sales of distinct brands. They engage in puffery or point out the undesirable characteristics of competitors' products, both strategies corresponding with the theory of information subsidization.[1] Finally, sellers devise promotional schemes of various types to influence both demand and supply sides of the market: to expand sales by emphasizing the differentiating qualities of their products and by providing motivating incentives for salesmen. In an imperfectly competitive world, incentives in

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[1]See Bartlett, Economic Foundations of Political Power.

marketing and distribution systems contribute importantly to a firm's competitiveness in the market place.

Drugs or drug manufacturing processes or drug applications may be protected by patent for a period of 17 years. (Renewals are not permitted.) A patent can prevent competitors from manufacturing an identical drug or from making identical label claims for a product. Hence, economically a patent affords innovative companies a chance to recover costs sunk in research and development. With patent protection, and without pressure from close substitute products, a firm faces no compulsion for prices to be "competitive." Various strategies exist for competitors to circumvent patents, however, meaning that patent protection does not provide an iron-clad barrier to market entry. One practice is that of creating a minor modification in an existing product, but one sufficient to circumvent the patent.[1] A second is the strategy of manufacturing a drug, regardless of patent, and gambling. In effect, then,a satisfactory agreement can be achieved with the patent holder, frequently including payment of the royalties.[2]

In the sulfa case, Food and Drug Administration regulations were published in the Federal Register of July 6, 1963 permitting the use of a new combination drug (ASP-250) combining 100 grams of chlortetracycline, 100 grams of sulfamethazine and 50 grams of penicillin per

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[1] In 1962 Senator Estes Kefauver held extensive hearings on the pharmaceutical industry. One practice that emerged which he strongly criticized was an allegedly excessive proportion of research expenditures devoted to "me too" research, designed to discover means of circumventing patents.

[2] Interview, Sondra Flick, Diamond Shamrock Co.

ton of feed. American Cyanamid was the sole initial sponsor of the product which it formulated using two of its own patented drugs, Aureomycin(R) chlortetracycline and Sulmet(R) sulfamethazine. ASP-250 was patented in 1965 with the patent period running through 1982.

An interesting feature of U.S. animal drug regulatory policy has been Food and Drug Administration policy approving a number of fixed-combination drugs. (These are drugs comprised of established proportions of individual drugs.) FDA regulatory stances are viewed by many as favoring fixed-combination over single drugs in contrast to European countries where regulators have generally taken the position that combination drugs are undesirable, inefficient and result in over-medication.[1] A policy favoring combination drugs benefits animal health firms when combinations imply that three drugs are used in place of one and when patenting of a combination and its associated claim permits a company to exercise some monopolistic pricing perogatives.

American Cyanamid literature states that the combination of penicillin (a narrow spectrum antibiotic effective against gram negative bacteria) with sulfamethazine (active against both gram positive and negative bacteria) and the wide spectrum antibiotic chlortetracycline gives growth and disease control beyond that obtainable from any existing feed additive.[2] In addition, the three drugs in generic form are "old" drugs which can be manufactured by any company. The FDA policy approving only the sulfa combination

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[1] Interview with Harry Jamison, Merck and Co. (formerly of American Cyanamid).

[2] American Cyanamid, Aureo S.P. 250: Technical Bulletin, 2nd ed., (Princeton, New Jersey, 1963).

drugs, coupled with patent protection, has contributed to American Cyanamid's spectacular success in the swine feed additive market.

Three competitors of American Cyanamid attempted to appropriate some of the swine feed additive market for themselves by introducing substitute products including Rachelle Laboratories, Diamond Shamrock, and Elanco.

Diamond Shamrock's CSP-250 is identical to ASP-250, except for the substitution of sulfathiazole for sulfamethazine in its formulation. (Again, Diamond Shamrock is reputed to be the only U.S. importer or producer of sulfathiazole.) CSP-250 was approved by the FDA, patented and first marketed in the early 1970s.

Rachelle's product, Chlorachel 250, is identical in composition to Cyanamid's ASP-250 and was initially marketed in the latter 1960s, raising the question of marketing tactics used by Rachelle in order to bypass Cyanamid's patent protection on ASP-250. Spokesmen for Rachelle were either unfamiliar with the patent arrangements for Chlorachel 250 or reluctant to divulge information of this nature. An interview with Jack Snow, Vice President for Quality Assurance and Regulatory Affairs, Rachelle Laboratories, resulted only in the comment that patent arrangements were extremely sensitive and that he could not comment.[1]

A final word is relevant here regarding the legal and economic impacts of patents. In cases where patents have expired on a drug, there may not exist sufficient economic incentives for private corporations to invest in further research. Hence, in regulatory cases when

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[1] Interview with Jack Snow, Vice President for Quality Assurance and Regulatory Affairs, Rachelle Laboratories, Long Beach, California, May 28, 1981.

questions are raised about an old drug such as sulfamethazine, some industry spokesmen argue that expiration of patents implies no company in the private sector will undertake research designed to vindicate the drug. However, the fact that sulfamethazine is permitted in only two combinations for use in swine, one of which is approved for manufacture by only two companies, mitigates this argument somewhat. One example of continuing industry interest in sulfa drugs is provided by manufacturers' investments in product modifications.

4.1.2.2.3 Modifications in Product Characteristics (Sulfa Case)

Modifications in product characteristics may be cosmetic or real. In the sulfa case, all major producers of sulfamethazine combination feed additives have jumped on the product modification band wagon in an attempt to produce a product without the objectionable tendency to hang up in feed equipment. The nearly simultaneous timing of the respective announcements of processing breakthroughs by the three major corporations producing sulfamethazine feed additives raises interesting questions regarding information flows between market participants.[1]

In general, a genuine quality improvement can give a firm a jump on the market if it can be achieved. In oligopolistic markets where firms closely scrutinize the actions of rivals, however, an incident such as the one which occurred in the sulfa case is not surprising. In such cases, timely innovation may represent a requirement for survival.

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[1]This incident is discussed in more detail below.

4.1.2.2.4 Differentiation Through Services (Sulfa Case)

As stated previously, the imperfectly competitive firm frequently benefits from differentiating its product. One effective tactic is that of providing services in conjunction with the product, either marketing services, diagnostic services (showing why the animal health product is valuable) or, sometimes, regulatory services. "Free" regulatory services are provided to buyers coupled with product sales or in order to generate good will.

Animal drug regulations in general, and the sulfa case specifically, have presented animal drug companies with the opportunity (some say the necessity) of providing a variety of services to their customers. In economic terms, pharmaceutical companies have felt themselves economically capable of bearing regulatory transactions costs originally imposed upon others.

An example is provided by Elanco. Elanco's sulfamethazine combination drug Tylan-Sulfa is classified as a new animal drug unlike the ("not-new") sulfa combination drugs of its competitors. This classification means that purchasers and users of Tylan-Sulfa must conform to FDA requirements concerning new animal drugs by completing and filing each year either a new animal drug application (NADA), also called an FD-1800, or a drug establishment registration form (an FD 356). Elanco considers this regulation both inequitable and a marketing obstacle.[1] To overcome producer reluctance to handle the product, Elanco provides the service of completing FD-1800 paperwork for

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[1] Interview with Probst, Elanco.

consumers, thus saving them the time and effort involved. The purpose of the FD-1800 has been for the FDA to guarantee that users of medicated feed articles meet regulatory requirements. In reality, the process of filing NADAs at the producer end and reviewing them at the FDA have become, in the words of the Special Assistant to the Director of the Bureau of Veterinary Medicine, "one big rubber stamp operation."[1]

Another service provided by drug manufacturers is that of conducting drug assays on commercially manufactured feeds for customers. FDA Current Good Manufacturing Practices (CGMPs) stipulate minimum requirements for the number of feed drug assays which must be performed per time period to determine drug content and quality of mix. Most animal health product manufacturers perform these assays for customers free of charge. (During the sulfa controversy, however, American Cyanamid stopped offering this service due to volume of requests.[2])

Rachelle Laboratories has taken a slightly different tack; throughout the sulfa residue controversy, the company has aggressively challenged the assay methodology employed by the government[3], claiming it to be inaccurate for the purposes of low-level screening to which it has been applied. Specifically, the company believes the test produces false positives because of its non-specificity for

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[1] Interview with William Bixler, Bureau of Veterinary Medicine, FDA, Washington, D.C., February 15, 1979.

[2] Interview with Jerry DeSwaan, Director of Quality Control, Hamilton Farm Bureau Coop., Hamilton, Michigan, August 10, 1980.

[3] The American Association of Operating Chemists (AAOC) has approved the Bratton-Marshall assay and this is used by FDA and USDA in modified form.

sulfamethazine.[1] In 1980, Rachelle initiated a program encouraging feed manufacturers to draw duplicate samples of any feed sampled by FDA and to send these to Rachelle Laboratories in Long Beach, CA in order to cross-check the results utilizing high-pressure liquid chromatographic (HPLC) techniques. A spokesman for Rachelle indicated the program "has gotten good response," is still ongoing, and that results differ significantly from those obtained by FDA.[2] In addition to providing customer services, this program appears to exert some pressure on FDA to lighten up on feed mill enforcement by discrediting the agency's laboratory results. The Rachelle spokesman did not expect a change in official FDA assay methodology at any near date, describing the agency as "extremely slow to move on any changes."

This section has discussed provision of services to purchasers of animal health products, both feed manufacturers and hog producers, as a competitive strategy which does not involve price cuts. Examples of corporate services aimed at providing assistance to hog producers and feed manufacturers to comply with animal drug regulations were presented.[3] Hence, ironically, many large pharmaceutical companies

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[1]Rachelle distributed a fact sheet on sulfamethazine efficacy and government test methodology to members of the feed industry urging support of American Cyanamid's citizen's petition (see below).

[2]Interview with Snow, Rachelle. The procedure is more expensive than the Bratton-Marshall to run but the Rachelle spokesman had "no idea how much it costs--because we do it free."

[3]The principle of tying service provision to product marketing as a marketing strategy extends beyond regulatory compliance services to a host of other possibilities although regulatory compliance was stressed here.

have been able to turn to marketing advantage regulations which on first appearance would appear to throw up obstacles to their efforts. By assuming transactions costs associated with feed safety regulations which were originally imposed upon market participants in other industries, the animal health industry has exploited its greater market power to advantage. The effect on compliance with food safety regulation must be seriously questioned, however (along with the design of the regulations), as the intent of the regulations is subverted by the actions of large drug firms.

4.1.2.2.5 Advertising and Promotion

Advertising and promotional activities represent important market strategies of non-price competition in the animal health industry as elsewhere. In an imperfectly competitive industry with administered pricing, in addition to providing product information to consumers, the intention of advertising is to differentiate animal drug products, thereby creating preferences and demand for the firm's brand products. If brand preferences can be instilled in consumer utility functions, the firm may benefit from attaining a partial monopoly position and some degree of control over prices.

Cohen and Cyert raise the dilemma confronted by welfare economists in attempting to determine the social welfare impacts of advertising. When advertising results in new patterns of tastes and preferences:

> In trying to compare two successive states of the economy, i.e., two different patterns of resource allocation, it is not clear whether the before-tastes or after-tastes should be used as standards when these are different. . . . The criterion of consumer well-being, which is the heart

> of modern welfare economics, does not indicate who the economic arbitrator should be in the circumstance. . . . Economic activity which affects consumer tastes cannot be evaluated on the basis of these changing tastes.[1]

In the animal health industry, animal drug regulation--particularly government publicity about, and enforcement of sanctions relating to sulfamethazine residues in swine--has created both problems and opportunities for major firms advertising in the swine feed additive market.

American Cyanamid and Rachelle responded to the regulation and the residue situation by undertaking defensive advertising to protect their previous market shares. American Cyanamid stresses in its copy, "There's no substitute for ASP-250" and Rachelle emphasizes the importance of sulfamethazine attaining high blood levels.

For Diamond Shamrock, the situation has presented both problems and opportunities. The bad news for Diamond Shamrock was the fact that very little press or other media coverage distinguished between sulfamethazine and sulfathiazole, thus unfairly implicating CSP-250 as a cause of residues frequently described merely as "sulfa" residues.[2] On the other hand, the good news in the situation concerned the same fact, that sulfathiazole was responsible for less than one percent of sulfa violations reported in swine. Diamond Shamrock has stressed the safety of its product to distributors and hog producers.

The product's success has been modest in relation to American Cyanamid's ASP-250, but in the last two years a combination of events

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[1] Kolman J. Cohen and Richard M. Cyert, Theory of the Firm (Englewood Cliffs, New Jersey: Prentice Hall, Inc., 1975) p. 503-4.

[2] Interviews with Hill, and Flick, Diamond Shamrock.

appears to have increased the CSP-250 market share in the antibiotic combination market. A major factor contributing to the increase seems to be concern, principally among members of the feed industry, that continued use of sulfamethazine might result in product liability problems, either with customers or regulators. (This will be discussed more fully below.) Because the great majority of animal health products are distributed to hog producers by the commercial feed industry, decisions at this level as to which products to mix, sell and promote carry with them major implications for ultimate sales.

For producers of substitute growth promotants with no required withdrawal periods, the residue controversy has afforded a heyday, permitting these companies to accentuate features of convenience, no problems with residues and no economic losses from either waiting out withdrawals or tangling with regulators.

Advertising and promotional efforts of the animal health industry are aimed at a variety of different markets. The majority of animal health products, particularly feed additives, are marketed by the commercial feed industry and the veterinary profession. However, animal health industry firms also target their advertising toward livestock producers as well as feed manufacturers and feed supply stores. Radio advertising, use of trade media, promotional activities at industry days, trade fairs, conventions, television, coupons, and assorted other tricks of the advertising and promotion trade are

extensively used by large pharmaceutical firms to establish preferences for brand name additives whatever the form of purchase (as a premix, concentrate, or in complete feed).

On many occasions the feed industry and animal health firms attempt to benefit by cooperative advertising, sometimes at a price. A district marketing supervisor for SmithKline, a large pharmaceutical firm, for example, was able to strike a bargain with Ralston Purina whereby SmithKline agreed to promote a line of Purina's products with the understanding that SmithKline would become the sole supplier of pharmaceuticals for the product line[1], thus easing out the other major supplier. ("I explained to them that we didn't have any incentive to advertise for another company's benefit.")

The most recent development in the sulfa case has set off a flurry of advertising which appears to be directed at feed manufacturers, for the most part. In April 1981, American Cyanamid, Rachelle Laboratories and Elanco and Company each purchased full or multi-page ads in weekly magazines such as Feedstuffs to proclaim their separate discoveries of new manufacturing processes for their sulfamethazine combination drugs--processes which will reduce the electrostaticity of sulfa and consequent drug hangup in feed equipment.

4.1.3 Regulatory Control Strategies in the Sulfa Case

Prior to the advent of the Sulfa Task Force, violative sulfa residues discovered in slaughtered swine were generally attributed

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[1]Interview Jerry Kennon, Field Marketing Representative, U.S. and Canada Operations, SmithKline Animal Health Products, Manhattan, KS, January 20, 1980.

to the management practices followed by swine producers. Early regulatory responses were aimed at swine producers and included lengthening mandatory pre-slaughter drug withdrawal times. When violation rates remained at levels considered excessive, new approaches were sought.

Research conducted under the aegis of the Sulfa Task Force identified sulfa contamination problems in commercial feeds, a discovery which stimulated an awareness of a potentially more serious contamination problem, involving as it did, multiple stages or levels of the food system.

As concern and awareness of the pervasive nature of the sulfa problem increased, uncertainty began to mount within the animal health industry, and particularly at American Cyanamid and Rachelle Laboratories. Persons within the FDA began to speak of the possibility of a sulfa drug ban. It was known within the industry that FDA had for many years been working on regulatory procedures which would strictly limit or prevent use of selected antibiotics and antibacterials in livestock feed.[1] The regulatory climate of the mid-seventies contained numerous uncertainties from the standpoint of the animal health industry as described above.

4.1.3.1 American Cyanamid's Citizen's Petition

American Cyanamid's initial response to growing publicity and increasing pressure due to sulfa residues was to attempt to achieve

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[1]Precedent for such action exists in Great Britain which restricted feed additive use of several pharmaceuticals in the sixties.

a modification in the rules of the game. Prominent members of the feed manufacturing industry and, to some extent, hog producers, were growing increasingly concerned over FDA scrutiny, either actual or anticipated, of their own operations. Initially, American Cyanamid's sales of ASP-250 remained strong into 1978. As regulatory actions continued, however, particularly FDA investigations of feed mills, feed companies began to alter demand for sulfamethazine products, substituting other products in some cases. American Cyanamid's market share began to slip.

American Cyanamid twice attempted to modify the regulatory rules of the fame by petitioning FDA to increase the permissible tolerance level for sulfa residues in liver from .1 ppm to .3 ppm, on an interim basis. The petition was submitted in the fall of 1979 and subsequently denied in spring of 1980. Current tolerances denote as violative any residues in excess of .1 ppm in muscle, kidney or liver. American Cyanamid argues that the level of .1 ppm is unnecessarily low for a drug which has as long a history of use in both livestock production and human health treatment as sulfamethazine does, and that it incorporates a safety factor far in excess of that necessary or even customary for similar drugs.

The petition document marshals a substantial body of evidence including laboratory studies on various sulfonamides (sulfamethazine and other closely related sulfa compounds), inferential evidence regarding the apparently benign effects of human exposure thus far ("if a drug so widely used over a period of 25 years had any adverse effects on human health, surely these would be noted by now"), and arguments

regarding the farfetched quantities of pork liver or kidney that any given human would need to consume to begin to approach a danger level according to results of animal tests.

As part of its documentation efforts, American Cyanamid hired three top academic human toxicologists to review the data on toxicological characteristics of sulfamethazine. The toxicologists concluded that ingestion of sulfamethazine residue at the modified levels would pose negligible risk to human health.

The first American Cyanamid citizen's petition was submitted September 5, 1979 and denied by FDA six months later on March 5, 1980. The rationale for denial by FDA was that the agency had not been furnished with sufficient evidence to permit it to conclude that raising the tolerance level would not pose unacceptable risk to the public health. Essentially, FDA relied upon a burden of proof argument, placing responsibility at the doorstep of the drug sponsor to substantiate any claims which might call FDA decision-making into question. Specifically the agency felt that a long term toxicity study was necessary.

American Cyanamid was not alone in its efforts to modify tolerance levels. An identical petition was filed by the National Pork Producer's Council (NPPC). In addition, the effort enlisted the support of the commercial feed industry as represented by the American Feed Manufacturers Association (AFMA); the American Farm Bureau Federation;

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[1]Dr. Robert Olson, St. Louis University; Dr. John Ooulb, University of Kansas; Dr. Joseph Bonzelleca, University of Virginia.

the National Farmer's Union; and the National Association of State Departments of Agriculture. These trade groups did not formally sponsor the petition, but did appeal to members for support while promoting the petition in lobbying efforts in Washington.

The respective interests of the commercial feed and the swine industries in supporting an increase in tolerance levels relate to a belief in both industries that the low tolerances were unnecessary from the standpoint of public health and penalized even conscientious feed manufacturing firms and hog producers who became victims, in a sense, of tolerance levels set too low for the state of the sulfa handling art.

Subsequent to FDA's denial of the first American Cyanamid petition, political pressure began to grow in Congress in favor of raising the tolerance level for sulfa residues in swine tissues. Nineteen senators directed a letter to FDA Commissioner Jere Goyan stating:

> Your denial of the citizens' petition to modify the action level of sulfa residues in pork has left unresolved the problems faced by pork producers who are using sulfamethazine according to label directions.[1]

A similar effort in the House enlisted 12 signatures from Representatives urging prompt action in support of increasing the action levels. A spokesman for Cyanamid reported that one congressman actively supporting the petitions was Representative Goodell of the major hog producing state of Iowa.[2]

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[1] Cited in "Pressure Mounts to Raise Sulfa Residue Level," National Hog Farmer, May 15, 1980.

[2] Interview with John Farnham, Manager of Quality Assurance, American Cyanamid, Princeton, NJ, May 26, 1981.

Upon receiving notification of FDA denying its petition in March of 1980, American Cyanamid turned around and resubmitted it, essentially unchanged but with some additional documentation. Apparently Cyanamid felt it had nothing to lose for its efforts, and in the words of the petition's architect, "Frankly, things change. We added some new evidence. We thought they might take a new look at things."[1] Congressional criticism of FDA policy and an admonition of the agency in congressional letters to Commissioner Jere Goyan to do something positive[2] contributed to Cyanamid's optimism.

Throughout the summer of 1980, Cyanamid kept its ear to the Washington grapevine and was not encouraged by the response of FDA to the resubmitted petition. FDA appeared to be delaying its response and, meanwhile, Cyanamid's sales continued to suffer. The company felt, in the words of one individual responsible for market research for Cyanamid, that "It was critical for the company to take some action to regain its credibility with the feed industry."[3] Research on various means of modifying the physical form of the drug in order to reduce problems of electrostaticity began in the summer of 1980.

In January of 1981, despite political pressure, the FDA again rejected the citizens' petition of Cyanamid. In early 1981, Rachelle Corporation presented FDA with a proposal for a granulated form of

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[1] Ibid.

[2] National Hog Farmer, May 15, 1980.

[3] Interview with Jamison, Merck, formerly of American Cyanamid.

sulfamethazine in its Chlorachel 250 product which was designed to reduce the electrostaticity of sulfamethazine and associated drug carryover problems.[1]

American Cyanamid had experimented with alternative methods of formulation; one similar to Rachelle's, in which only the sulfamethazine is granulated, and another approach in which the entire combination drug is granulated. Cyanamid was dissatisfied with the mixing characteristics of the premix when only the sulfa was granulated. However, the combination drug pellet is more expensive to produce.[2]

When Rachelle preempted Cyanamid in asking for FDA approval for its new manufacturing process, American Cyanamid made its decision to go with the more expensive production method. In the words of a long-time Cyanamid employee, "They hustled their butts down there after Rachelle to get their own approval."[3]

As to the competitiveness of the higher cost method of formulation, Cyanamid's director of quality assurance observes, "I imagine we'll eat the cost."[4]

In May, 1981 Elanco Products Company announced that it, too, had obtained FDA approval for its own minigranulated formulation of a sulfa combination drug (Tylan-Sulfa), thus bringing to three out of three the number of major corporations in the market announcing modifications in the physical form of their sulfamethazine combination drugs in a space of just over five months.[5]

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[1] Feedstuffs, March 2, 1981, p. 3.

[2] Interview with Farnham, American Cyanamid.

[3] Interview with Jamison, Merck, formerly of American Cyanamid.

[4] Interview with Farnham, American Cyanamid.

[5] "Minigranular Form of Sulfa Premix Approved for Elanco," Feedstuffs, May 11, 1981.

How much time and effort went into this research and development activity? Firm estimates are currently unavailable. However, the former director of market research at Cyanamid offered an opinion: "It couldn't have been too difficult. They only spent nine months on it."[1]

4.1.3.2 The Burden of Proof: American Cyanamid, FDA, and Sensitivity of Method

The Food and Drug Administration's major sticking point with respect to raising tolerance levels for sulfa residues in swine has related to the question of carcinogenicity. Issues of risk associated with sulfamethazine's potential role as an allergen or as a contributor to an antibacterial-resistant gene pool have not fostered the reservations that potential carcinogenicity has.

FDA concern centers upon experimental evidence in small animal trials that sulfamethazine exposure causes an abnormally high incidence of hyperplasia (enlargement) of the thyroid in some species. The association between this tendency and potential carcinogenicity in humans is uncertain. A second source of suspicion regarding sulfamethazine is the suspected carcinogenic properties of a closely related sulfonamide.[2]

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[1] Interview with Jamison, Merck, formerly of American Cyanamid.

[2] Interview with Steve Montgomery, Toxicologist, Division of Toxicology, Bureau of Foods, FDA, Department of Health and Human Services, March 9, 1981.

FDA, specifically the Bureau of Foods, has taken the position that without additional testing, evidence of safety is insufficient to justify reducing the currently operative 2000-fold safety factor thereby permitting an increase in tolerance levels (see Figure 4.2).[1]

Given the regulatory stance of FDA, American Cyanamid initially found itself under pressure from FDA to conduct a long term toxicity test which would supply results with the requisite degree of certainty desired by FDA to permit alteration of the tolerance level.

American Cyanamid resisted for a number of reasons. Estimates of the cost of a long term toxicity study vary depending upon the protocol followed (including the scale of the experiment). A spokesman for Cyanamid indicated a two-year study such as the FDA desired would run in the neighborhood of $200-400,000.[2] In addition, the company perceived itself bearing a disproportionate share of expenses in undertaking the study, as well as feeling resentment toward FDA for disregarding evidence already generated at Cyanamid's expense.[3] A large quantity of sulfamethazine sold in the U.S. is imported by such companies as Rachelle Laboratories and Elanco, while Cyanamid

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[1] Farnham states that the Bureau of Foods is not safety oriented with respect to conditions of use but instead is bent on showing carcinogenic potential at any dose and administered in any way. He stated some members of the Bureau of Foods carry an anti-business bias. Interview with Farnham, American Cyanamid.

[2] Interview with Farnham, American Cyanamid. (In light of other cost estimates, this appears to be minimal.)

[3] Interview with Johnson, Bureau of Foods, FDA.

General Formula:

$$\frac{\text{(no effect level)}}{\text{(food intake)}} \times \frac{\text{(weight of man)}}{\text{(safety factor)}}$$

= maximum permitted tolerance.

Formula Applied to Sulfa Data:

$$\frac{\text{(7 mg/1 kg)}}{\text{(.5 kg)}} \times \frac{\text{(60 kg)}}{\text{2,000}}$$

= .42 ppm* or mg/kg

where: 7 mg/kg = no effect level in most sensitive species, rats
60 kg = weight of man (132 lb.)
.5 kg = intake of food containing residues per day (1.1 lb/day)
2,000 = safety factor

* the tolerance level for sulfamethazine and sulfathiazole is set at .1 ppm, the prevailing level of assay method sensitivity.

FIGURE 4.2. FORMULA FOR DETERMINATION OF MAXIMUM PERMITTED TOLERANCE OR RESIDUE LEVEL

is the major domestic producer. The company did not choose to bear the costs of generating experimental evidence which would benefit competitors.[1]

The eventual resolution of the toxicity test dilemma illustrates the manner in which regulatory decision-making and political factors coalesce. FDA established a tolerance level at the level of sensitivity of the best existing assay methods in the early 1970s. The tolerance did not change, but assay methods and USDA monitoring rates for sulfamethazine compounds in swine did. The combination of these factors led to increased detection, if not evidence, of violative sulfa residues. A significant share of these residues consisted of low level violations in liver tissues, reflecting the fact that the liver tends to concentrate sulfa.

The FDA did not believe it could credibly raise its tolerance levels in violation of its own guidelines; it required additional evidence. However, refusal by American Cyanamid to supply the desired evidence placed the FDA in a politically untenable position. Pressure from pork producers, feed manufacturers and the animal health industry began to focus on what was perceived to be an unreasonable attitude at FDA considering the lack of any serious evidence implicating sulfamethazine in public health problems. Industry pressure was directed at Congress after the agency proved unresponsive.

Meanwhile, the FDA cast around for solutions to the impasse. Generally, the Food and Drug Administration is not in the business of tying up its own agency resources on the types of toxicity testing it

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[1]Interview with Farnham, American Cyanamid, and Jamison, Merck, formerly of American Cyanamid.

requires from corporations sponsoring drug petitions. Animal drug regulations in general require that such testing be supplied by the private sector.

However, concurrent to the sulfa controversy was another major animal drug issue involving FDA proposals which would establish experimental protocols for determining the carcinogenicity of chemical residues. The cachet summarizing this proposed body of experimental protocols is termed the Sensitivity of Method (SOM) proposal and was published as a proposal in May of 1979. The document drew the instant outrage of the Animal Health Institute when it appeared as a published proposal. The trade association promptly filed a lawsuit claiming the final proposal had been altered in significant respects from previous versions offered for public comment.

In general, industry concerns center upon the costs associated with testing requirements for new drugs and the required method of testing for metabolization of different substances. Regarding the latter, industry claims that the required pharmaco-kinetic methodologies necessitate use of radioactive substances for which no adequate disposal methods or sites currently exist. Testing methodologies in this area increasingly utilize radioactive particles in order to radio-label or stain the parent compound. The process then incorporates a variety of analytical procedures for blood and tissue in order to identify the fate of the parent compound as it breaks down in the body during metabolism. Procedures incorporating radio-labeling surpass the sensitivity of previous techniques which relied

upon colorimetric methods. With radio-labeling, use is made of either liquid or gas chromatography to separate out metabolites as they are identified. The Sensitivity of Method protocol requires the testing of all metabolites if a compound is classified as suspicious. At the outset, the potential number of metabolites of a given compound is frequently unknown with the implication that research planning and budgeting in this area is highly uncertain.

Amidst all of the controversy raging over the dual issues of the Sensitivity of Method proposal and sulfa residue tolerance levels, the FDA saw a chance to kill two birds with one stone. FDA decided to select sulfamethazine as a test case for the Sensitivity of Method proposal and sponsor and fund at least one life-span mouse study[1] and a multigenerational rat study, the latter involving three generations, with the rat embryos being exposed to sulfamethazine en utero. It is furthermore conceivable that life-span studies might be required for the metabolites, but this is unknown at present.

The costs of the sulfa testing program (carried out by the National Center for Toxicology Research) cannot yet be calculated, but records of costs are being kept by FDA. If it follows its own proposals, the FDA will finance experiments involving both the parent drug sulfamethazine and any metabolites identified during test procedures. Testing procedures include the use of both short and long-term studies, in vivo; and some threshold assessment studies performed

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[1]Protocol for the sulfamethazine life span study calls for a total number of mice of 2 x 864 (per sex) = 1,728 mice.

in vitro using screening tests such as the Ames test for mutagenesis. The approximate plan of attack is: 1) initially a short term (90 day) toxicity study is conducted to identify, among other things, relevant dosages for further study;[1] 2) next metabolite studies are dictated by the SOM proposals. These involve the identification of metabolites in the target species (swine in the case of sulfamethazine) and subsequent use of screening tests such as the Ames test mentioned previously. SOM also calls for tests on two species of animals of similar metabolization characteristics to the target species; 3) the final stage of the SOM involves life span studies. In the case of the sulfamethazine testing program, these will cost $4-500,000 to perform. In calculating the costs of the sulfamethazine testing program, it is necessary to account for such fixed-costs services as animal care personnel, data systems evaluation people and others devoting portions of their time to the study.

The move by FDA to conduct SOM studies on sulfamethazine (of all possible drugs) was seen by many as a political decision. One trade association representative in private questioned the propriety of FDA conducting tests on a drug of major benefit to one corporation. "They should let those who expect to profit by it do the tests. Why did they assume American Cyanamid wouldn't conduct them?"

One Cyanamid spokesman believes, "They (FDA) saw sulfa was a hot issue. They saw a chance to get an appropriation for it." A

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[1]The FDA uses the concept of the "maximum tolerated dose" at this stage, defined as the dosage which, when administered over a 90-day period, results in weight loss of ten percent." Interviews with Farnham, American Cyanamid, and Flick, Diamond Shamrock.

toxicologist at the Bureau of Foods states flatly, "FDA caved in to political pressure. Some Congressmen and Senators began pressuring the agency to do the tests itself."

What has FDA accomplished by its agreement to undertake SOM testing of sulfamethazine? A number of things: it has bought itself time--so long as long-term testing is ongoing (and it may be ongoing for at least five more years), the agency postpones the necessity of either raising tolerance levels or banning the drug. It can content itself to co-exist with sulfamethazine residue violation rates in approximately 5 percent of those swine (livers) sampled and by doing so, it essentially eliminates an uncomfortable political situation.

Additionally, the agency was able to obtain an appropriation from Congress on the basis of sulfamethazine[1] in order to further one of its important agenda items, Sensitivity of Method. Another corporate observer of the FDA envisions an even less obvious agenda operating connected with furtherance of the National Toxicology Program. The FDA is one important participant of the National Toxicology Program established by the former Department of Health, Education and Welfare on November 15, 1979 in "a department-wide effort to provide needed information to regulatory and research agencies and to strengthen the government's toxicological data base on chemicals of a public health concern."[2] Counsel for Diamond Shamrock perceives the National Toxicology Program as an effort by some involved "to bring onto

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[1] Interview with Farnham, American Cyanamid.

[2] FDA, U.S. DHEW. Quarterly Report, 1st Quarter, Fiscal year 1979. pp. 37.

themselves the preeminent role of this important area of regulation of carcinogens in the country."[1] Issues of cancer research and the regulation of carcinogens increasingly affect a broad spectrum of American business, government and society.

4.1.4 Decision-making in the Animal Health Industry: Summary and Conclusions

This section presented empirical case evidence and analysis of decision-making of the four major pharmaceutical firms involved in the sulfa case. The firms were found to employ a variety of strategies to develop and promote the sale of animal drug products and, at the same time, to attempt to significantly reduce[2] the expected costs of food safety regulation, exploiting wherever possible positive opportunities stemming from regulation.

In important respects, the case evidence validates the conceptual model developed above of complex, economically powerful firms operating under conditions of uncertainty. The model suggests that the firm confronts uncertainty and risk in the market, the institutional arena and with respect to its own performance. In attempting to control uncertainty, firm management makes economic decisions regarding the acquisition and utilization of information (including its subsidization). Successful oligopolistic firms generally are capable of exploiting a

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[1] Interview with Hill, Diamond Shamrock.

[2] Due to uncertainty, transactions costs and finite resources, the firm satisfies rather than optimizes.

full range of information sources. Frequently these firms adapt organizationally to cope with information requirements, forming specialized market research and governmental affairs staffing units within the organization. One important function of governmental affairs personnel is supplying information in quarters which are perceived advantageous. In the sulfa case, all four animal health industry firms involved invested considerable resources in activities of supplying information to customers and regulators in order to encourage sales and reform the rules of the game to their individual advantages.

Finally, in 1980, the three major producers of sulfamethazine combination feed additives began research upon a technological modification in the production process for sulfamethazine which culminated in early 1981 with the announcement of a granulated form of sulfamethazine. The procedure has been heralded as promising to markedly reduce problems of sulfa cross-contamination in feed mills. Contaminated feeds have been identified as a major contributor to the sulfa residue problem in pork.

Interestingly, the move by animal health firms came about after an approximately seven year history of illegal sulfa residues in swine products, a period in which hundreds of thousands of manhours and millions of dollars were expended by members of the swine industry, the commercial feed industry and within several branches of government in the attempt to find a solution to residue problems.

Evidence in the sulfa case seems to suggest that characteristics of the animal health industry, including substantial economic power

and firms distinguished by their capacity to adapt organizationally in order to control regulatory uncertainty for the benefit of the firm, effectively insulate these firms for a prolonged period and to a substantial degree from the necessity of bearing responsibility for the externalities produced in other industries by their own products.

Regulators, in seeking solutions to the sulfa problem, focused at a rather early date on problems of the electrostaticity of sulfamethazine (and other drugs) as currently produced. However, regulators could not avail themselves of any direct method of either persuasion or coercion toward the producers of sulfamethazine feed additives to modify their production processes, an effort that one executive long with American Cyanamid described as taking relatively few resources.[1] Rather, regulatory efforts were repeatedly countered with moves by the producers of sulfamethazine to either adjust the tolerance level in order to define the problem out of existence or to discredit the government's sulfa assay methodology.

Only after product sales began to suffer as a result of a residue controversy did the pharmaceutical companies undertake research on procedures to granulate the product.

Given the market power and regulatory expertise of the firms in the chemical/pharmaceutical industry, a less adversarial relationship must be fostered in order to encourage some cooperation. Otherwise these firms have the resources, talent and bureaucratic incentives to

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[1]The procedure which was developed should prove applicable in the production of other drugs as well.

tie up nearly any regulatory action for years. Early identification and exploration of potential technological solutions with cooperative development, particularly when a problem pertains to multiple products, might provide a useful alternative to years of adversarial moves and counter moves, exposure of the public to residues categorized as dangerous and illegal and countless problems and costs borne by other economic actors in an extended subsector such as the swine subsector in the sulfa case.

4.2 The Commercial Feed Industry

The commercial feed industry became involved in regulatory aspects of the sulfa case in the late seventies when regulators discovered sulfa contamination in various feed articles which were not intendedly medicated with sulfa, but had become cross-contaminated in the process of manufacture. In a broader sense, the feed industry's involvement with sulfa drugs is of much longer duration. Sulfa drugs possess one of the longest histories in the U.S. in terms of use in livestock feeds, dating back to the early fifties. In the words of several persons interviewed in the process of this research, "Sulfa drugs are in the system." They have been around so long--have been used and misused--that in many respects the drugs have been taken for granted. For many years their potential for contamination was unknown or simply ignored. The purpose of this section is to examine firm decision-making related to animal drugs as product, input and contaminant in the feed industry under conditions of uncertainty and next to identify the interaction

of food safety regulation and these decisions. In conclusion, specific empirical evidence of firm decisions in the sulfa case is presented and analyzed.

4.2.1 Objectives of the Feed Industry and the Economic Importance of Sulfa Drugs

The commercial feed industry produces a variety of products, for several species of livestock, in a multitude of final forms, and supplies a gigantic geographical marketing area. Firms within the formula feed industry are in the nutrition business, attempting to profit by matching an acceptable profile of nutrients for each animal species, sex, age group and location at minimal costs. In this regard, a marriage of convenience has occurred in the last thirty years between the animal health and the commercial feed industries. The commercial feed industry has incorporated the use of sulfa and other animal drugs because it has found this practice to be in its interests.

The demand for feeds is derived from consumer demand for livestock products. Medicated feeds are demanded by livestock producers because animal feeds provide a convenient conduit by which to provide livestock with drugs promoting growth, feed efficiency and preventing disease. The feed industry benefits, therefore, from sulfa and other drugs in the role of product. Specifically, animal drugs afford the feed industry a way to compete through product differentiation and thus expand demand, while generally making it less price elastic. Sulfa and other animal drug products permit the feed manufacturer to differentiate products by: 1) changing product quality (enhancing

the feed conversion, disease control and growth promoting qualities of ordinary feed products); 2) tailoring the feed to specific animal characteristics; 3) providing the livestock producer a service (such as mixing animal drugs into feeds, or providing on-farm consultations regarding herd health and herd performance); 4) permitting advertising and promotion of a differentiated rather than a generic product.

In addition, the inclusion of medications in feed articles permits feed manufacturers to exercise some pricing discretion by varying the margins charged on feed items of various drug concentrations. The impact of feed industry pricing practices for medications is one of cross-subsidization; those livestock producers purchasing high concentration drugs subsidize those producers purchasing lower concentration items. Similarly, those producers purchasing unmedicated feeds pay higher unit costs associated with drug handling and quality control costs attributable to medications but not reflected in price differentials for medications.[1]

As in the case of the animal health industry discussed above, adequate understanding of the operations of the feed industry requires an appreciation of the influence of uncertainty and the role of animal drugs in relation to uncertainty. As indicated elsewhere, in some regards animal drugs assist the industry in reducing uncertainty; in others, animal drugs increase uncertainty. The fact that the commercial feed industry handles the vast majority of animal drugs

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[1]See the case of the Hamilton (Michigan) Farm Bureau cited below. Also, conversations with Robert Schoeff and Robert McElhiney, Department of Grain Science and Industry, Kansas State University, 1980; and Harry Pfost, editor, Feed Manufacturing Technology (Arlington, VA: Feed Production Council, American Feed Manufacturers Association, Inc., 1976).

produced and sold reveals that the industry's expected benefits from animal drugs outweigh expected costs. Regulatory factors can tip the balance, however, as demonstrated below in case evidence in the sulfa case.

4.2.2 Uncertainty and the Role of Animal Drugs

Feed industry diversity and complexity make simplification somewhat risky. However, an understanding of general sources of uncertainty within the industry and the economic role of sulfa drugs in relation to uncertainty provides a basis for identifying the incremental impacts of regulation on firm decision-making within the industry. Regulatory measures can influence the manner in which the feed industry strikes a balance between the expected costs and expected benefits from handling animal drugs.

The conceptual model developed in Chapter III identifies three principal firm economic interests in sulfa drugs: as products, as inputs and as potential contaminants and three principal sources of uncertainty. In its role as an industry product, sulfa in feeds produces benefits for the feed industry as it is used to differentiate products, increase prices, expand demand, and reduce the risk inherent in competitive markets, risk associated with cyclical demand and essentially homogeneous feed products. In the dual role of input and potential contaminant, on the other hand, sulfa drugs entail costs to the industry and increase industry uncertainty due to price and supply uncertainties; product liability and regulatory risks. The

three major sources of uncertainty confronting the firm are the market, the institutional arena and the firm's internal performance.

4.2.2.1 Market Uncertainty

Market uncertainty consists of short term pecuniary uncertainty reflected in input and product prices and longer term questions relating to the structure of demand and supply over time. Short term market uncertainty in the feed industry relates intimately to agricultural fluctuations and to the derived nature of demand for livestock feed products: in 1980, for example, livestock cycles in beef and hog industries were in decline with respect to animal numbers, as producers responded to a period of over-supply and, particularly in the case of swine, disastrously low prices. The impact of livestock cutbacks frequently affects the formula feed industry through sharply curtailed demand for feed products and changes in the composition of demand.

Longer term uncertainty in the feed industry reflects changing trends in the demand for various feed articles brought about in large measure by changes in the cost structure of agriculture in general. The availability of new feed handling products also influences demand. For example, the economics of energy (including high fuel costs) combined with the availability of portable mix-mills favors the economics of on-farm mixing for hog farmers, particularly those producing their own grain. The impact for the feed industry has been a major shift in the composition of demand

away from high tonnage feeds toward more intensive use of concentrates. In the longer run, companies must adapt to such trends as this one toward the use of low inclusion feed articles (the base mix or super concentrate). As a spokesman for Central Soya indicated, "We saw the trends Doanes was picking up and although we resisted turning to premixes, we've had to respond."[1]

The preceding section sketched the nature of both short and longer term market uncertainty faced by the formula feed industry. It also stated that animal drugs in their role as products produce economic benefits for the industry, while entailing economic costs insofar as these inputs must be purchased (frequently from oligopolistic sources) and as they increase the product liability risk borne by the industry through their potential for contamination. This section examines empirical evidence of interrelationships between animal drugs and market uncertainty in the feed industry and standard industry procedures for reducing uncertainty through the handling of animal drugs.

4.2.2.2 Strategies to Control Market Uncertainty Relating to Animal Drugs

Short-term strategies to control market uncertainty facing the formula feed industry in order to increase profits include pricing practices, production decisions and cost and inventory control techniques. In the longer term, firms in the industry must adapt to

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[1] Interview with Chuck Klinger, Director of Regulatory Compliance, Central Soya, Ft. Wayne, August 14, 1980.

structural changes in the agricultural economy as these influence conditions of demand and supply in the commercial feed industry. These factors are intimately related to decisions associated with medicated feeds as products and with animal drugs as inputs.

4.2.2.2.1 Pricing Decisions for Medicated Feeds and Other Industry Products

Strategies to control market uncertainty resulting from demand and supply fluctuations or changes in the regulatory environment include the critical decision of setting prices for a complete line of products, often numbering well over 100.[1] Pricing practices are fairly well standardized in the industry in the sense that manufacturers begin with a base price for bulk form mash, then progressively add mark-ups for different ingredients, forms (crumbles, pellets, cubes), for bagging (the standard bag is the 50 pound paper), for inclusion of medications and for transportation (usually by zone) if the article is shipped.[2] Thus, pricing determinants include ingredients costs, manufacturing costs (determined over time) and mark-ups (also determined over time and by changing conditions).

Beyond these simple principles, those in the feed business are reluctant to talk about pricing practices for a number of reasons.

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[1]FCX, a regional farmers cooperative, for example, recently announced the opening of a new feed mill in Gaston, SC, which will manufacture a complete line of feeds numbering 125 different products. "FCX Opens Full-line Feed Mill," Feedstuffs, June 1, 1981.

[2]This section benefitted from discussions with Dr. Robert Schoeff and Robert McElhiney, Department of Grain Science and Industry, Kansas State University, Spring and Summer, 1980. Each has extensive industry experience: Schoeff worked for Central Soya; McElhiney was production manager for 25 years with Carnation and later for Conagra.

One cited was some feed industry trouble with the Federal Trade Commission (FTC) in the early 1970s over the issue of alleged price decline contracts with members of the dairy and beef industries.[1] Industry experts recall reports that the FTC at that time made life somewhat troublesome and expensive for some of the larger feed companies. Another reason cited is that once manufacturing costs are divulged and if the cost of protein is known, buyers of feed can readily calculate margins on different items.[2]

In examining the pricing of medicated feeds ingredients costs, manufacturing costs and margins are examined in turn. General ingredient cost control techniques include the use of futures markets to hedge ingredient prices, purchasing from subsidiaries or in spot markets to take advantage of favorable prices, weekly use of least cost formulation techniques to accurately incorporate significant changes in relative prices of ingredients and, where scale of operation permits, centralized purchasing to exploit potential economies, for instance price discounts frequently available for quantity purchases.

Playing a central role in the maintenance of control over ingredient costs is the procurement agent. Purchasing assignments vary with the organization of a given company, but in general, incentives are structured through the use of bonuses, other payments,

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[1] Interview with James Ego, Manager, Feed Division, Illinois Farm Bureau Services (Growmark), Bloomington, Illinois, August 15, 1980; and Schoeff, Kansas State University.

[2] Interview with Pfost, editor Feed Manufacturing Technology, June 1980.

or promotion and reputation in such a manner that the less a procurement agent pays for an ingredient the bigger hero he is.[1]

The cost of sulfa drugs to a feed mill varies, depending among other things upon the form in which the sulfa is purchased. If sulfa drugs are purchased in straight form (either sulfamethazine or sulfathiazole) and subsequently mixed by the feed mill or the hog producer into the combination drug containing aureomycin and penicillin (or tylosin) unit costs are less than if a pre-mix is purchased.)Manufacturing costs, however, are higher.) Additionally, the unit cost of large bags is consistently lower than for small bags, yielding potential economies in purchasing.

As inputs, animal drugs contribute to feed industry uncertainty. Animal drug prices vary along with available quantity. As indicated above, market segments for particular types of products are oligopolistic. The feed industry has reacted to the tendency of animal drug inputs to increase uncertainty in a variety of ways.

1) Large companies such as Purina utilize centralized national purchasing for animal drugs and other micro-ingredients.[2] This strategy followed by a company of the stature of Purina enables the buyer to exact more favorable terms than a market exchange in which an oligopolistic buyer sells to a firm with no market power. Ralston-Purina purchases drugs for national distribution out of

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[1] Interview with McEllhiney, Kansas State University.

[2] Interview with Kennon, SmithKline.

corporate offices in St. Louis. While the company buys drugs from a variety of suppliers, frequently the supplier of a particular drug might furnish that drug for a complete line of Purina feed products. Purina, for example, arranged to purchase SmithKline's furox product for inclusion in both Purina's animal health and Chow product lines in return for SmithKline's promotional assistance with these product lines.[1]

2) Large companies have generally established the practice of manufacturing drug pre-mixes in specialized facilities for subsequent distribution to company plants. Ralston-Purina, for example, manufactures sulfa pre-mixes for all of its plants at a Ralston Company, Health Industries, in Bridgeton, Mississippi.[2] Many smaller companies pre-mix micro-ingredients with a diluent in a small mixer in the plant, then apportion the blend into several batches of feed running through normal mixing equipment.

The traditional argument for pre-mixing is one of quality control, based on the reasoning that many large mixers don't do a good job of uniformly distributing 250 mg of drugs throughout a ton batch of feed and economics, based on the costs of duplicating precision equipment involved in pre-mixing in each plant, maintaining new drug inventories and duplicating labor costs involved in pre-mixing. Sharply rising energy costs of all types, however, have forced feed

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[1] Interview with Kennon, SmithKline.

[2] Interview with Jim Wilson, Production Manager, Ralston-Purina Plant, Lansing, Michigan, January 22, 1981.

industry experts to take a sharp look at ways to cut this direct and indirect component of costs. Transportation costs, especially, manifest the increasingly high costs of energy. Both transportation and labor costs contribute to a new assessment of the decision, especially by a multiplant company, of whether and where to pre-mix drugs and other micro-ingredients before inclusion of these items in the normal batch mixing process. Recently, industry experts have advanced the arguments against pre-mixing on quality control[1], as well as economic grounds.

3) A third means by which firms attempt to control the costs of ingredients, including drugs, is through substitutions whenever possible. The formula feed industry embarked on a new era in the late 1950s when techniques of linear programming gained application to problems of least cost feed formulation. The classic application establishes a series of constraints, based upon animal requirements for protein and other nutrients (plus palatability) and calculates the least cost combination of ingredients meeting required standards. Utilization of this technique is widespread, permitting feed manufacturers to substitute many ingredients over a range when relative prices change. Whereas large companies generally maintain programming capacities in-house, smaller firms frequently contract for a variety

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[1]Robert McEllhiney, "Pre-mixing--The Case Against," for publication in Feed Management Magazine, received from author, July 15, 1980.

of services supplied by consulting firms.[1] Drugs are more insulated from opportunities for input substitution than undifferentiated ingredients due to a greater degree of livestock producer brand loyalty. However, substitution does occur for reasons of price between ASP-250 and CSP-250.[2] Many companies specify the sulfa medication in their feed products as SP-250 and substitute between them.[3]

4) Finally, firms attempt to control market uncertainties associated with the purchase of animal drugs by anticipating market supply conditions. One Purina regional purchaser cited an instance a couple of years ago when aureomycin was in short supply. Anticipating this, the regional purchaser requested a four-fold increase from central purchasing in an attempt to ensure adequate supplies in the future through stockpiling.

The four strategies outlined here illustrate means by which feed industry firms attempt to control costs and uncertainty associated with drug ingredients. Ingredient prices play a prominent role in the pricing practices of the feed industry. In 1972, the cost of ingredients represented 66 to 88 percent of the average sales price per ton (F.O.B. plant).[4]

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[1]Dawes Parametrix Formulation Service of Chicago, for example, supplies a large number of firms with formulation advice in the Midwest.

[2]Interview with Michael Barton, hog producer and primary feed manufacturer, Homer, Michigan, August 16, 1980.

[3]Interview with Elmer Heisler, Jr., hog and corn farmer, Albion, Michigan, August 14, 1980.

[4]Cited in Robert W. Schoeff, "The Formula Feed Industry," Feed Manufacturing Technology, p. 15.

The next most important component of cost is manufacturing costs, representing from 5 to 9 percent of the average sales price per ton of feed. Manufacturing cost estimates evolve over time. The feed industry differentiates a number of standard functional requirements (often set up as cost centers) consisting of receiving, processing, mixing, pelleting, packing, warehousing, maintenance, plant foremen. Different products require various combinations of these manufacturing activities. Additionally, different products--including medicated feeds--carry with them different requirements for quality control in terms of record keeping, necessities for proper sequencing, flushing or cleaning of equipment, and general maintenance, all of which reduce labor efficiency if this is measured solely in terms of tonnage per manhour.

Many industry sources believe that cost accounting for different products is frequently weak throughout a large segment of the industry. They believe that the temptation to employ averages, guesstimates or to follow the competition in setting prices on various items, results in cross-subsidization of higher cost products by lower cost items or loss of profits. For example,

> The feed manufacturing industry has, generally, failed to recognize the incremental nature of product costs preferring outdated rules of thumb, executive mandate or 'what the market will allow' to establish costs, hence prices, for products. Computers provide formula costs, package costs are known; but manufacturing costs are either estimated or an average cost is used. Such a system fails to provide management with real costs and can result in disastrous pricing and profit results.

> An improved product costing system is needed for the determination of manufacturing cost differentials by product type (form or unit).[1]

This general statement appears to apply in particular to sulfa medicated products even though increased regulatory surveillance of the feed industry raised the consciousness of feed manufacturers regarding necessities for changes in product handling in the late 1970s.

The third major component of feed product prices is the margin established on the product.

Margins at the feed manufacturing level encompass a variety of factors. They are influenced by the competition (exchange of price lists between large companies frequently proceeds as a "matter of courtesy"); by freight rates (feed companies including transport costs in price frequently cross-subsidize distant customers at the expense of proximate ones in order to compete over a larger market area); by the type of feed (hog feeds with seasonal demand generally contain a higher margin than dairy feeds); and by the company's desire to sell particular types of products.[2]

Regarding this last factor, a major issue confronting the feed industry (particularly in the Midwest) is the proper margin to place on premixes. Some of the old line companies such as Purina or Central Soya prefer to sell complete feeds or concentrate/supplements; their capital investment is in physical plants built for bulk, high tonnage production.

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[1]Robert R. McElhiney, "1980 Feed Manufacturing Technology Short Course: Product Costing," Department of Grain Science and Industry, Kansas State University, Manhattan, KS.

[2]Interview with Schoeff, Kansas State University.

These companies wish to encourage purchase of supplements or concentrates (300-700 pounds per ton of feed) rather than premixes or super base mixes (approximately 50 pounds/ton). Thus, to provide service and to meet demand, companies such as Central Soya have introduced a line of base mixes and drug premix mini-packs. However, to encourage sale of concentrates, they may discriminate on margins.[1]

4.2.2.2.2 Price Data for Hog Feeds and Sulfa Medications

Table 4.3 presents prices of various hog feeds and sulfa-medicated feed articles sold by the Hamilton (Michigan) Farm Bureau Services Cooperative in the week of June 3, 1980. As shown, 16 percent protein sulfamethazine-medicated complete feed is carried as a stock item. This feed is designed for grower hogs between 40 and 125 pounds. The price differential between medicated and unmedicated complete feed is $12 per ton or 60¢ per cwt. The $12 price difference purchases 250 g of ASP-250 consisting of 100 g each of sulfamethazine and chlortetracycline and 50 g of penicillin, as well as a carrier consisting of soybean products.

If a livestock producer purchased ASP-250 in a 50-pound bag, the price per pound was $2.45, a 20¢ per pound savings over purchasing the premix in smaller quantities. For the producer to add 250 g of ASP-250 to a ton of farm-mixed feed, he needed to add five pounds of premix (at $2.45 per pound) which cost him $11.25, a savings of 75¢ per ton of complete feed (excluding labor and transportation), over buying the medicated feed. Had he paid $2.65 per pound of premix, the price of

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[1] Ibid.

TABLE 4.3. PRICES OF ASSORTED HOG FEEDS AND SULFA ADDITIVES

Item	Price/100#	Price/ton
12% Hog (over 125#)	5.40	108.00
14% Hog	5.85	117.00
16% Hog (40-125#)	6.20	124.00
16% Hog with SP-250	6.80	136,00
18% Pig Pusher pellets	8.05	181.00
Hamilton Hog Base Mix	12.75	255.00
Hog Concentrate	11.20	224.00
Pig Starter Pellets	9.65	193.00
Sow Concentrate	11.60	232.00
SP-250	2.65/1#	2.45/1# @ 50#
Tylan & Sulfa	1.75/1#	1.65/1# @ 50#

Source: Hamilton Farm Bureau Cooperative, Inc.
Date: June 3, 1980.

drugs for a ton of complete feed rose to $13.25 making it cheaper in terms of drug costs to purchase the feed ready mixed.

As shown by the co-op price list, Tylan-Sulfa undersold ASP-250 by 90¢ per pound (in small bags) and by 80¢ per pound in 50-pound papers. The co-op does not carry sulfathiazole products. Of the co-op's other swine products, "Pig Pusher" 18 percent complete feed also routinely contains ASP-250. This product sold for $9.05 per cwt on June 3, 1980, exceeding by $1.15 the 16 percent feed with identical medication. Included in the differential is the cost of pelleting and the added protein.

A second source of price data, the Michigan State University feed mill purchases and produces feed for the University's swine unit. The feed mill sometimes manufactures its own sulfa premixes and sometimes purchases ASP-250 already premixed. Relative prices of straight sulfamethazine and ASP-250 (in March of 1980) raise some questions regarding the margins incorporated in the premix. One pound (454 g) of sulfamethazine listed for $11.90 per pound. The cost of sulfamethazine required for one ton of complete feed, then, is $2.62 (for 100 g). The price of 100 g of sulfa purchased in ASP-250 was $10.20, a difference of $7.60, representing the cost of 50 g of penicillin, 100 g of chlortetracycline, premixing costs and margin.

One final view of pricing practices for sulfa products in the extended swine subsector is gained by comparing the market statistics of IMS America, Ltd. and those of Doanes Market Research. Recall that IMS figures present the value of purchases of ASP-250 and other combination premixes of the feed industry, the veterinary profession and large broiler integrators. Doanes, on the other hand, furnishes

estimates of the annual value of sulfa purchases by swine producers in the form of ASP-250, CSP-250 and Tylan-Sulfa.

In 1979, purchases of ASP-250 ($35.39 million), Tylan-Sulfa ($3.76 million), Chlorachel-250 ($5.96 million), Super Chlorachel-250 ($.29 million) and CSP-250 ($3.49 million) by the feed and veterinary industry totaled $48.89 million as estimated by IMS.[1] Doanes estimated that in the same year (1979), hog producers paid approximately $70 million for all sulfa combination feed additives.[2]

Although imprecise, these figures suggest that a ball park margin of 40 percent is added at the feed and veterinary level to the price of sulfa drugs.[3]

To summarize: aggregate market purchase information suggests that sulfa feed additives undergo an increase in value of approximately 40 percent in the hands of the feed and veterinary industries between the time they are purchased from the animal health industry and sold to hog producers. Additionally, examination of the pricing practices of one independent Michigan cooperative indicated that the cost differential per ton of complete 14 percent hog feed due to ASP-250 was $12. A hog producer could beat the cost of medication by on-farm mixing (assuming all other feed costs were equal) provided he purchased ASP-250 premix in a 50-pound bag (costing $122.50, June 3, 1980). Purchasing any smaller size bag of premix[4], he would have benefitted by buying medicated complete feed.

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[1]Data supplied by IMS.

[2]Interview with Holmes, Doanes.

[3]In 1979.

[4]Again, with all other costs equal.

This example corroborates statements of numerous feed industry experts who suggest that medications are priced very close to cost in high bulk (complete) feeds.[1] This practice encourages the purchase of complete feeds or supplements and provides a customer service. It is with the sale of more concentrated articles such as premixes--especially in smaller sizes--that the feed industry appears to make its margins.

4.2.2.2.3 A Summary of Some Non-pricing Strategies to Control Market Uncertainty

In addition to pricing practice, marketing strategies of the feed industry include advertising and promotional practices, decisions regarding sales and distribution, and long term investment decisions.

Advertising and promotional expenditures vary widely between companies and over time. Advertising and promotional activities represent one area of expenditures which may be curtailed or expanded in the short term. A 1981 survey of a national sample of the feed industry indicated that advertising and promotional expenditures fell sharply as the industry responded to cash flow problems, low profitability and rising costs in other areas.

Sales and distributional strategies also play an important role in feed industry performance. As the size and sophistication of agricultural production units have increased over the years, many feed companies are changing sales and distribution strategies moving to selective strategies of direct sales to large producers, upgrading of

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[1] Interviews with Boyd, AFMA; McElhiney, Kansas State University; Pfost, Feed Manufacturing Technology; Schoeff, Kansas State University.

the sales force, the provision of a wider variety of services linked with sale to these large units, greater use of the phone, and other measures directed toward achieving the greatest sales return with the least expenditure.[1]

Relationships with dealers involved in product distribution constitute another area with important ramifications for controlling costs and correctly anticipating demand as well as successful pricing strategies. A substantial factor in distribution costs, for example, is transportation; the location of dealerships influences transportation costs involved in moving a product efficiently. A dealer's inventory control, including an accurate knowledge of sales in an area, contributes to the ability of a feed company to anticipate demand and schedule production. Finally, price policies followed by a dealer with respect to the feed company's products play an important part in generating sales, building demand for the company's brand of product and in other ways meeting the competition in the area, thus guaranteeing the future market position of both the dealer and the feed company. (Purina, for example, has a reputation in the industry of rigorously policing dealers' pricing practices to ensure that they follow the company's recommended retail price lists.[2])

In the longer term, issues influencing the structure of demand carry with them important questions for the feed company formulating

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[1]Direct sales strategies of Moorman's Feeds and United Feeds (of Indiana) were repeatedly credited by customers and competitors as the key to these companies' sales success.

[2]Interview with Schoeff, Kansas State University.

long range investment strategies. Trends in demand for the broad range of livestock products manufactured by a feed company, as well as consideration of trends in the cost of energy of all forms, and replacement costs of plant and equipment, necessitate a careful balancing act regarding optimal plant location and capacity, product blend anticipated and arrangements for product sales and distribution and input procurement. As indicated, the feed industry began a marked transition in the past ten to fifteen years as energy costs[1] began to alter the general structure of agriculture. The most obvious manifestation of these changes in the derived demand for feedstuffs has been a shift in the structure of demand away from complete feeds and toward more concentrated feedstuffs in many agricultural industries. If a general trend for hog producers can be identified it is toward increased purchases of feed concentrates or super concentrates and the separate purchase or on-farm production of soybean meal, premixes and on-farm grinding, mixing and feed formulation.

Structural impacts in the feed industry have resulted in a reversal of the earlier trend toward large capacity mills serving a large market territory to more compact facilities located closer to the area of demand. Old line companies with facilities designed for production of large tonnages of complete feed have found themselves scrambling to compete with newer competitors handling concentrated base-mixes and without the heavy investment in large scale plants and

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[1]Transportation, fuel.

equipment. Excess capacity has become a serious dilemma for many of the older facilities. In addition, large multi-plant feed companies producing complete lines of products must balance the costs of maintaining specialized equipment in every plant: for example, that involved in manufacture of drug premixes; with the transportation costs involved in distribution from a centralized facility.

Another set of decisions confronting the long run strategic planner includes investment decisions with respect to input procurement, and product marketing and whether vertical integration or contractual arrangements can be exploited to reduce uncertainty and costs associated with obtaining necessary inputs (for example, soybean meal), and subsequently marketing feed products.

In summary, planners rely upon market research and knowledge of agriculture to detect broad-based, long run trends. Such information contributes to investment planning. The life of a feed mill is of such a duration at 25-30 years, however, that in initial feasibility planning risk management demands a certain respect for versatility. (One industry expert noted that livestock practices in an area can change relatively rapidly; Petaluma, north of San Francisco, used to call itself the layer capital of the world. "They still have a sign, but I don't think there's a single chicken in the area.") [1]

Investment planning, as well as other aspects of feed industry operation, are influenced by regulation and regulatory uncertainty. Discussion of these topics follows:

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[1] Interview with McElhiney, Kansas State University.

4.2.2.3 Sources of Institutional Uncertainty

The preeminent regulatory issue facing the commercial feed industry in the early 1980s is the proposed Food and Drug Administration policy to rationalize and restructure the manner in which the commercial feed industry, and the agency itself, handles animal drugs (and animal drug regulation). The policy proposal (introduced above) has been labeled the "Second Generation of Medicated Feeds." The Second Generation policy is designed to rationalize FDA animal drug policy by establishing new categories for drugs based on their potential human health risk, and new categories for feed based on drug type and concentration. Those firms wishing to handle concentrated or high risk drugs would have to undergo a "directed inspection" to establish compliance with a body of feed manufacturing practices. The policy is currently being promoted by regulators and many of the large firms within the industry as part of a national move toward deregulation. Many smaller firms entertain a different suspicion, perceiving the move as an effort to restructure the industry, removing smaller firms from the business of manufacturing drug premixes and other concentrated articles and forcing them, essentially, to purchase many medicated feed articles from former competitors. Judging from espoused aims of top FDA regulators, this perception, in fact, is true.[1] Regulators within FDA perceive that a majority of industry problems with contaminated feed originates in small firms

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[1] Interviews with William Bixler, Special Assistant to the Director of the Bureau of Veterinary Medicine, FDA, February 15, 1980; and Robert Schmidt, Bureau of Veterinary Medicine, FDA, Manhattan, KS, May 28, 1980.

without knowledge or resources for adequate quality control. The regulators believe that many large firms have the capacity to handle drugs carefully and maintain quality control systems which permit self-policing; they think these firms should be the ones handling concentrated and/or high risk drugs.[1]

A second major issue creating "institutional uncertainty" is the spectre of product liability for contaminated products. Labeled by one trade association representative, a "time bomb, a potentially horrendous problem,"[2] product liability claims have become, if not commonplace in recent years at least memorable and in certain cases, extremely costly. The case of PBB and Michigan's Farm Bureau Services was one frequently cited example of the potential problems attributable to chemical contamination.[3] PBB is a fire retardant accidentally mixed into dairy feed in Michigan in 1973, eventually contaminating a significant share of Michigan livestock products and resulting in lawsuits and damages in the trillions of dollars.[4] Subsequent

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[1] Ibid.

[2] Interview with Lee Boyd, Vice President, American Feed Manufacturers Association (AFMA), Washington, DC, February 19, 1980.

[3] Interview with Dr. Dale Olson, Nutritionist and Research Director, Central Laboratory, Research and Quality Control, Indiana Farm Bureau Services, Indianapolis, July 31, 1980.

[4] See Edwin Chen, PBB: An American Tragedy (Englewood Cliffs, NJ: Prentice-Hall, Inc. 1979), pp. 1-329; Frederic Halbert and Sandra Halbert, Bitter Harvest (Grand Rapids, Michigan: William B. Eerdmans Pub. Co., 1978) pp. 1-159.

cases of chemical or drug contamination have demonstrated that PBB in Michigan was not a completely unique and isolated incident but can happen repeatedly in various forms.[1]

The two issues cited here are not entirely independent. Rather, the proposed Second Generation policy represents FDA regulatory response to drug contamination problems within the feed industry. To a pronounced degree FDA regulators have expressed the belief that the majority of contamination problems are caused by small feed mills and elevators without sufficient resources or, in some cases, knowledge to manage adequate quality control, particularly with regard to drugs.[2] Regulators believe that restructuring the industry will improve the contamination situation.

An important distributional question arises, however, when current trends in the structure of demand are taken into account. Increasingly, demand for medicated feeds is turning toward base mixes with separate purchase of medicated pre-mixes. This practice accompanies on-farm mixing by livestock producers. If the Second Generation policy reduces the number of smaller firms eligible to manufacture medicated premixes and concentrates, then larger firms benefit by gaining a larger share of a shrinking (volume-wise) business. As a result, small firms may

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[1] In the spring of 1980, Montana hog producer, Dr. Bob Bryant, had several thousand hogs slaughtered after being declared unfit for human consumption due to dieldrin contamination. Bryant sued Cargill, Inc., for $25 million claiming Cargill sold him contaminated grain. Montana pork producers estimate additional damages of $500,000 in marketing penalties, delays and increased feed costs. "Chemical Contamination: Top-notch Management Can't Halt a Disaster," National Hog Farmer, May 15, 1980, pp. 8-10.

[2] Interview with Bixler, Bureau of Veterinary Medicine; and Dr. Robert Schmidt, Bureau of Veterinary Medicine; Food and Drug Administration, Washington, DC, September 25, 1979.

suffer from the worst of both worlds: a loss in complete feed, supplement business due to on-farm mixing; and a loss in premix, medicated concentrate business due to Second Generation prohibitions against mixing a number of drugs without suitable certification.

4.2.2.4 Organizational Quality Control

In addition to the market and the institutional structure, the third source of uncertainty facing the firm is the internal functioning of the organization. One pertinent example of this sort of uncertainty suggested by the product liability cases cited above is the firm's performance with respect to product quality control. In general, evidence appears to support the hypothesis that the marginal cost of removing the final units of contamination from feed articles increases sharply. Accordingly, the firm selects a level or range of acceptable quality control on the basis of a variety of factors summarized by the balancing of expected costs and benefits of particular levels of quality control.[1] For substandard firms, food safety regulation (by definition) provides quality control standards in excess of those levels selected by the firms in the absence of regulation. The issue of whether the establishment of new regulatory standards alters the substandard firm's quality control targets depends in part on the expected costs associated with the regulation. These expected costs depend in turn on the

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[1] Of course, the firm's assessment of expected costs and benefits is contingent upon the prevailing degree of uncertainty.

probability of getting caught by regulators or the public if in error and the loss associated with this possibility.

In relation to quality control, sulfa drugs contribute costs and uncertainty to the feed industry in their role as contaminants. On one hand are the costs to the feed firm of over-medicating, that is surpassing specifications for costly ingredients. On the other hand are the possible costs of product liability, if drug contamination of feed results in a livestock producer experiencing product condemnation, loss or marketing delay. Costs associated with contamination might include product liability insurance or settlements, loss of business or business reputation or regulatory sanction.

Costs of quality control are preventive investments taken by the firm to counter product risk. Costs of quality control associated with medications include (but are not limited to) regular drug assays, inventory control, production scheduling (sequencing, flushing) and cleaning of plant, equipment, trucks.

4.2.3 Feed Industry Decisions in the Sulfa Case

The previous section illustrates the complex manner in which animal drugs and the commercial feed industry interrelate in terms of costs and benefits associated with the multiple role of drugs as product, input and contaminant. Also mentioned in general terms were sources of uncertainty facing the industry (the market, the institutional arena and the firm's quality control performance) and the influence of animal drugs in either increasing or reducing uncertainty. Against this

backdrop, case evidence of industry and firm decision-making in the sulfa case is presented in order to demonstrate factors influential in altering the firm's balance between expected costs and benefits of handling sulfa drugs.

As an industry, commercial feed manufacturers are most broadly represented by two principal trade groups, the American Feed Manufacturers Association (AFMA) and the National Feed Ingredients Association (NFIA). The AFMA, particularly, has participated actively in various aspects of the sulfa case as well as broader issues relating to animal drugs and medicated feeds. The AFMA assisted the USDA in conducting research on sulfa cross-contamination in feed mills, contributing time, resources and moral suasion of industry members directed toward promoting cooperation. The trade association functioned as a clearinghouse for news of regulatory developments on the one hand and sulfa-related complaints, or requests from members, on the other. Officials of major feed trade groups communicate regularly with counterparts in other industry trade groups as well.

Regarding the AFMA position toward the sulfa problem, the AFMA adopted an official position that the FDA action level for sulfamethazine feed contamination set at 1 ppm constituted a level set too low for the state of feed mill technology.[1] The organization lobbied for an increase in residue tolerance levels in swine which it calculated would correspondingly increase the amount of sulfamethazine which could safely remain in feed to 8 ppm. Accordingly, the

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[1] Interview with Boyd, AFMA.

association supported the American Cyanamid and National Pork Producer's Council petitions to the FDA to raise sulfa tolerance levels. As one AFMA executive expressed his concern, "The Food and Drug Administration has got to make up its mind on this, either the substance is safe (as indicated by extensive approved therapeutic use at much higher levels) or it's not. If it is, then the agency must set reasonable levels that can be met; if not, FDA ought to take it (sulfa) off the market." [1]

Members of the feed manufacturing industry reacted with concern when USDA field representatives began advising hog producers to retain samples of commercially manufactured feed and feed components for reference in case of sulfa residue trouble.[2] Product liability threats were described by assorted feed industry participants as a potentially serious problem.

In light of the difficulties associated with handling sulfamethazine in feed mills in conformance with FDA standards, what sorts of decisions did feed companies make? The following presents case evidence of individual firm responses to quality control uncertainties in the sulfa case as each weighed the benefits of providing a popular product to hog producers against the costs associated with quality control, potential product liability problems and transactions and financial costs related to violation of FDA standards.

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[1] Ibid.

[2] This occurred during the 18 month period of the Sulfa Task Force in 1978 and 1979.

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4.2.3.1 Strategic Decisions: The Michigan Farm Bureau and Sulfamethazine

Michigan Farm Bureau Services is a federated farmers' cooperative organization supplying services and supplies (including manufactured feeds) to farmers throughout Michigan.[1] Headquartered in Lansing, Michigan, the co-op gained extensive and unwelcome national prominence after 1973 as a result of the tragedy associated with PBB, a fire retardant which was unintentionally mixed in Farm Bureau Services dairy feed (described above).

In general, the PBB incident resulted in a high level of concern over product contamination and liability among personnel at the Michigan Farm Bureau and associated companies. The company and its insurance carriers paid out hundreds of millions of dollars of PBB-related claims.

Despite the PBB experience, the Michigan Farm Bureau affiliated company, Farm Bureau Services, continued mixing sulfamethazine in its feed products. Farm Bureau Services owns a large feed plant at Climax, Michigan where Farm Bureau Services feeds are manufactured for distribution all over Michigan.

Why wasn't the Michigan co-op wary of potential new product liability problems after its experience with PBB? Basically, managers at

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[1]This section is based on interviews with Robert Braden, Executive Director, Michigan Farm Bureau, Lansing, Michigan, August 7, 1980; David Anderson, Commercial Underwriting, Farm Bureau Services Insurance Group, August 6, 1980; Bob Craig, Public Affairs, Michigan Farm Bureau, August 12, 1980; Rudy Yost, Head, Animal Products Group, Farm Bureau Services, August 7, 1980; Brian Gates, Director of Quality Control, Quality Assurance Lab., Climax Plant, August 13, 1980.

headquarters in Lansing and in charge of quality control at the Climax plant believe that their plant quality control capabilities are now such that Farm Bureau Services can adequately handle the drug. After the PBB incident, the already modern Climax facilities underwent extensive and repeated equipment modifications and cleanings. The mill is equipped with a variety of specially controlled devices permitting cleaning. Conventional elevator boots are replaced with contour boots. Steam cleaning is used and mixers are hand scraped. The quality control director at the Michigan Farm Bureau Climax laboratory believes that the mill does as well as possible on quality control. However, he also believes that assay test methodology used by government inspectors results in false positives. He stated that it is not possible for any in the feed industry to comply if current sulfa regulations are really enforced using current government assay methodology.[1]

An economic consideration also contributed to the decision to continue sulfamethazine mixing operations. Michigan Farm Bureau Services is one of approximately four companies in the U.S. which does batch work for American Cyanamid, manufacturing a concentrated cattle feed, AS-700 crumbles, and Aureo-50 crumbles.[2] Production of the Cyanamid products is scheduled once a month, usually on a Friday after which it takes between four and six people an eight-hour day at time and a half pay (average wage cited $8.00 per hour) to clean the plant

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[1] Interview with Gates, Michigan Farm Bureau Services. (Note: at the time of this interview, sulfa granulation had not been developed.)

[2] Interview with Gates, Michigan Farm Bureau Services.

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The head of the animal products group at Farm Bureau Services stated that he had not seen any adequate experimental evidence permitting him to conclude that either CSP-250 or ASP-250 is superior. Currently the co-op handles both products to satisfy producer requests.[1]

As in the animal health industry, large cooperatives and corporations in the feed industry maintain specialized regulatory affairs staffs. The example of Michigan Farm Bureau provides a glimpse of the sorts of specialized regulatory expertise that organizations of this size are willing and able to bring to bear on regulatory issues of concern to the company. In general, many large corporations in the feed industry began adapting organizationally to increased demands from the Food and Drug Administration in the early 1960s by adding regulatory compliance experts to their staffs.[2]

Many farmer co-ops operative in the feed industry link with the American Farm Bureau Association. This umbrella organization maintains a well articulated set of policy statements including positions on feed issues, legal counsel, and a computerized information service providing background research materials on a variety of particular issues for members. The Farm Bureau's membership is more broadly

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[1] Interview with Yost, Michigan Farm Bureau Services.

[2] Interview with McElhiney, Kansas State University.

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based than strict industry trade associations, however, and the organization does not maintain the narrow focus on feed issues of the feed industry trade groups. Affiliated with Michigan Farm Bureau, Farm Bureau Services, benefits from the public affairs activities of this organization and those of the American Farm Bureau Federation. At the Lansing office, the Administrative Director of Michigan Farm Bureau directs a public affairs staff of four full-time individuals, up from two in the early 1970s.[1] He attributes the increase to the growing importance of regulatory visa vis legislative issues. While duties of the staff are directed toward issues of local government in part, the bulk of effort of three of the four staff members is concentrated on national issues of import to co-op members.

4.2.3.2 Strategic Decisions: The Indiana Farm Bureau and Sulfamethazine

Indiana Farm Bureau is a federated farmer's cooperative serving Indiana principally but with limited product sales in Kentucky. The State organization owns and operates three mills in addition to supplying an assortment of products to approximately 71 local affiliated co-ops. Local co-ops typically operate their own feed mills and elevators, although the type and quality of these operations vary widely.[2] Indiana Farm Bureau has a market share of

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[1] Interview with Braden, Michigan Farm Bureau.

[2] Interview with Dr. Dale Olson, Nutritionist and Research Director, Indiana Farm Bureau Services, July 31, 1980.

approximately 20 percent in sales of swine feeds in Indiana. Swine feeds comprise from 40 to 45 percent of total sales and the co-op's most popular feed is a swine base mix.

In 1979 Indiana Farm Bureau decided to completely halt production of products containing sulfamethazine (including ASP-250) due to concerns over sulfamethazine residues, product liability risk and the belief that CSP-250 is an effective and safe substitute.[1] The co-op has replaced sulfamethazine with Diamond Shamrock's sulfathiazole product CSP-250.

In explaining the decision, the research director stated that the case of PBB and Michigan's Farm Bureau Services has created a memorable impression in the minds of many feed manufacturers and their insurance carriers. He credited the incident with stimulating a variety of quality control procedures at the Indiana firm and throughout the industry. At Indiana Farm Bureau Services, for example, each lot of micro ingredients purchased for use in feeds is shelved until samples can be analyzed.[2] Purchase orders are checked before going out and cross-checked when shipments arrive.

One aspect of marketing strategy followed by Indiana Farm Bureau involves feed articles for which the company does not wish to incur contamination risk or expense. Yet the cooperative wishes to satisfy customers by supplying a complete line of products. A remedy in such

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[1] Ibid.

[2] Ibid

cases is sometimes the decision to purchase for resale those items which are not sufficiently profitable, safe or convenient to manufacture.

In a related vein, the director of research commented favorably on the proposed Second Generation feed policy. He stated that the Indiana Farm Bureau Services state organization would probably not advise its locals to attempt to qualify as medicated feeds establishments under the new policy. Instead, he feels that the state is better equipped to manufacture high risk and highly concentrated articles for use and resale by local co-ops.

4.2.3.3 Strategic Decisions: Growmark of Illinois and Sulfamethazine

Growmark of Illinois (formerly FS Services) is allied with the Illinois Farm Bureau. The Growmark sales force covers Iowa and Wisconsin, in addition to Illinois,[1] selling approximately 157 different feed products. Growmark manufactures a complete line of swine feed, in all forms. The company began manufacturing highly concentrated premixes relatively early, in 1975. Illinois swine production has traditionally relied on farm-based grind and mix operations. The head of Growmark's feed division commented that the evolution of the feed industry has progressed rapidly in the past thirty years, "The bricks and mortar of 29 years ago--like Growmark's Mendota mill--were

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[1] Interview with Larry Toillion, Product Services Manager, Feed Division, Growmark, Bloomington, Illinois, August 8, 1980. The Growmark feed sales force consists of eight people.

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not built with any concerns about using drugs."[1] Neither were the old mills built in an era of high energy costs. For both of these reasons, companies with a significant number of old mills are faced with difficult management problems.

What steps did Growmark take regarding sulfa? In essence, Growmark decided to play it safe. As of the first of 1980, Growmark management pulled sulfamethazine products out of "line" manufacturing as well as largely out of sales. The company did continue to offer the five-pound micro-product ASP-250 manufactured by American Cyanamid, for resale. However, in the words of one salesperson, the sales force "discouraged the use of sulfamethazine products by its customers."[2] (Growmark primarily sells products wholesale; for instance, Growmark supplies local Farm Bureau co-ops and elevators throughout Illinois.)

Growmark implemented a switch to sulfathiazole products after dropping sulfamethazine from its line. Growmark's director of research conducted a series of feeding trials at Growmark's research farm which satisfied him that sulfathiazole's efficacy was as good as that of sulfamethazine.[3]

Summarizing, Growmark's decision to drop sulfamethazine was influenced by the head of the feed division who stated that the co-op's

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[1] Interview with James Ego, Head, Feed Division, Growmark, Bloomington, Illinois. August 15, 1980.

[2] Interview with Toillion, Growmark.

[3] Interview with Ego, Growmark. The Director of Research for Growmark is Dr. Gary Pearl.

management had felt threatened by "astronomical" product liability risk.[1] Many Illinois farmers with sulfamethazine citations were accustomed to regularly marketing 100 hogs per week. A marketing delay could severely disrupt marketing operations at great cost in terms of feed, facilities and other expenses. Since farmers were being counseled to retain feed samples which might be used to implicate feed suppliers, Growmark did not wish to incur the product liability risk associated with sulfamethazine. It switched to sulfathiazole and attempted to persuade its customers that the substitute was equally effective.

4.2.3.4 Strategic Decisions: Hamilton Farm Bureau Cooperative and Sulfamethazine

The Hamilton Co-op is the largest independent farmers co-op in Michigan. As indicated, the co-op is not affiliated with the Michigan Farm Bureau; neither is it a member of the American Feed Manufacturers Association. The co-op and its principal market area are located in and around Hamilton, Michigan, near Lake Michigan in the western part of the state.[2] Annually, the co-op markets approximately 60,000 tons of feed of which 45 percent is hog feed.

The Hamilton Co-op continues to mix sulfamethazine products although the plant was cited by FDA for a sulfamethazine violation in the summer of 1979. At that time FDA inspectors spent the better part of a week in the plant. A feed mill employee recalled that inspectors alienated

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[1] Ibid.

[2] More correctly, as any Michiganian knows, the western part of the lower peninsula.

mill employees by photographing their activities without providing any explanations (causing uncertainty over job security).[1] Although sulfamethazine residues provided the initial concern, once FDA inspectors were in the plant they found a number of drug-handling practices they didn't like. Of chief concern were record-keeping and inventory control procedures.

Following the investigation and a regulatory letter (a preliminary FDA sanction), the co-op's general manager initiated a number of changes in operation including an improvement of drug inventory procedures, the purchase of a new micro computer and printer capable of producing printouts of sales records, drug labels and use instructions and the decision to change the assignment of a plant employee to full-time director of quality control at the mill.[2] At the time of the investigation, the Hamilton Farm Bureau had two drug applications pending before the Food and Drug Administration. Although FDA powers of enforcement suffer from certain limitations, one power the Agency does enjoy is that of holding up new drug approvals until violations are corrected. The fact that the FDA could hold up approvals on new products added to the co-op's sense of urgency in correcting its problems.[3]

The general manager estimates costs of compliance to FDA drug regulations to contain the following components:

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[1] Interview with Matt Bowen, employee, Hamilton Farm Bureau Cooperative, East Lansing, Michigan,

[2] Interview with Henry DeWeerd, General Manager, Hamilton Co-op, Hamilton, MI, August, 1980; and Jerry DeSwaan, Quality Control, Hamilton Co-op, Hamilton, MI, August, 1980.

[3] Interview with Bowen, Hamilton Farm Bureau Co-op.

1) Director of Quality Control, manhours, $15,000/year.

2) Uncovered laboratory drug assays, $200-$300/year.

3) Computer costs of new equipment, $7,500 (one-time investment).

4) Extra time in the mill, no estimate.

5) Flushing, no estimate.

6) Programming time, no estimate.

7) Computer time, no estimate.[1]

As for sulfamethazine, the co-op continues to mix the drug upon the recommendation of Dawes Laboratories of Chicago with whom it contracts for feed formulation services; Dawes still considers sulfamethazine the drug of choice. And although the feed mill incurred a number of costs which were attributable to handling sulfamethazine and other drugs, management has not changed its pricing practices for medicated feeds. The drug handling improvements which were initiated were considered merely a general cost of doing business; no differentials in manufacturing costs have been calculated.[2]

As for the Hamilton Co-op, one year after initial inspection by FDA in summer of 1979, after undertaking substantial steps to bring the co-op into compliance and requesting notification of FDA approval, the general manager had not received any response from the agency.

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[1] Interview with DeWeerd, Hamilton Farm Bureau Co-op.

[2] Ibid.

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4.2.3.5 Strategic Decisions: Central Soya and Sulfamethazine

Central Soya is one of the top ten commercial feed manufacturers in the U.S. It is headquartered at Fort Wayne, Indiana, and supplies an international market with a line of agribusiness products consisting of livestock feed products, soybean products, broilers and other poultry products and assorted processed foods.

With regard to the sulfamethazine situation, company management has made the decision to continue production of sulfamethazine products. The Central Soya plant manager in Portland, Michigan, for example, reports that the company's two most popular hog starter foods, Primer I and Primer II, are both medicated with ASP-250.[1] The company has traditionally carried ASP-250 but had not carried sulfathiazole until demand for CSP-250 appeared to increase in the late 1970s. Central Soya made the decision to continue production of sulfamethazine products believing that sulfathiazole is not as effective as sulfamethazine in preventing disease and that substituting medication would be misleading to customers.[2] The company also demonstrates confidence in its ability to comply with FDA regulations although Central Soya through its Director of Regulatory Compliance did support American Cyanamid's petition to raise the tolerance levels for sulfamethazine residues in swine organ tissue and in feeds.

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[1] Interview with Roger Habegger, Plant Manager, Central Soya, Portland, Michigan, January 22, 1981.

[2] Interview with Chuck Klinger, Director of Regulatory Compliance, Central Soya, Inc., Ft. Wayne, Indiana, August 14, 1980.

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Central Soya represents an interesting case because of the active role its regulatory affairs staff has played in articulating and shaping the voice of the feed industry and ultimately the substance and philosophy of proposed FDA regulations.[1]

Central Soya's director of regulatory compliance (and staff) has responsibilities related to regulation for Central Soya's entire line of products. He devotes approximately fifty percent of his attention to medicated feeds policy and has been an influential architect of the FDA's Second Generation Policy through his position on the AFMA Feed Control Relations Committee. It was reported by many that early discussions between this individual, the FDA person in charge of medicated feeds policy and a representative of the Indiana Association of Chemists eventually grew into the comprehensive set of policies currently proposed by FDA.[2] Central Soya's director of regulatory compliance has provided a consistent sounding board during this process, attempting to advise, convince and ultimately obtain a set of regulations favorable to Central Soya and similar companies.

In comparing two organizations such as Central Soya and a large state co-op such as Michigan Farm Bureau or Indiana or Growmark, a contrast in the level of specialization of regulatory affairs personnel becomes apparent. The production and sale of medicated feeds is only one amony many concerns of a diversified farmer organization like the

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[1] Interview with Flick, Diamond Shamrock; Teague, USDA; Klinger, Central Soya.

[2] Ibid; interview with Olson, Indiana Farm Bureau.

Michigan Farm Bureau. Consequently, public affairs concentration is generally diffused over a substantial number of issues of potential import to the organization's members and affiliated companies. In a feed and agribusiness company like Central Soya, regulatory expertise focuses with greater intensity on specific issues affecting the feed industry and the company's own opportunities. The level of expertise and familiarity with the feed industry and its regulation appears to generally exceed that demonstrated by public affairs staff members of organizations with fewer resources (such as a Hamilton Co-op) or a broader commodity focus (Michigan Farm Bureau).

4.2.3.6 Strategic Decisions: Ralston Purina and Sulfamethazine

Ralston-Purina is the largest feed manufacturer in the country with approximately 22 primary mills and 19 distributor mills. The company manufactures literally hundreds of feed products as well as a complete line of animal health products. The company introduces its hog program as "the number one choice of hog producers throughout the United States and in 63 countries around the world. . .(Purina) the only national feed company that offers not only hog rations, but also health products, breeding stock and professional advice on hog management, nutrition, marketing, health and sanitation."[1] The company offers sulfamethazine in its Stimupak 50 pound drug additive pack in combination with chlortetracycline and penicillin as well as in its pig starter complete feeds. Purina's Stimupak(R) line of medications allows producers to

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[1]Ralston Purina Co., Purina Hog Programs, 1979.

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choose among a variety of medications. The pack is then substituted for 50 pounds of grain in mixing one ton of feed. Purina does not sell CSP-250.

The Purina quality assurance manager at the Lansing, Michigan Purina plant related that plant's experience with sulfamethazine, saying the plant has received numerous flyers and bulletins from company headquarters detailing procedures to be followed in handling sulfamethazine, including sequencing of feeds, flushing the equipment after mixing, cleaning equipment approximately once per month, flushing company contract trucks (although only a few of the trucks transporting Purina's feed are company contract) and following FDA procedures regarding sulfa feed assays (four times per year at Roltec, the company's lab) and record keeping.[1] Plant managers at the Purina Lansing plant reported that "rarely, if ever" has there been any problem with sulfa in the plant and that they could feel quite confident in certifying their feed sulfa-free. They reported that FDA had only come to the plant once, some years previously to establish jurisdiction in a case involving a dealer but had not had any complaints about the Purina plant.

4.2.4 The Feed Industry and the Regulatory Agencies in the Sulfa Case

The feed industry position in the sulfa case was that of an intermediary, positioned midway between the swine industry (bearing

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[1] Interview with Erin Lively, Manager of Quality Assurance, Ralston-Purina plant, Lansing, MI, January 23, 1981.

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the major brunt of regulatory concern) and the animal health industry (experiencing little direct regulatory intervention). As such, the industry's position was an ambiguous one: only gradually did regulators begin to focus on feed mills as a contributing source of the sulfa problem. When the USDA began to point fingers at the feed industry after identifying contaminated commercial finishing feeds on swine farms, the agency cautioned hog producers to retain samples of purchased feeds for their own protection. The feed industry then began to look around for a way out of what it saw as a potentially horrible product liability situation. The feed industry looked to USDA and received some limited assistance from SEA in the form of research into sources and frequency of drug carryover in the feed manufacturing process.[1] Clear advice on proper manufacturing practices did not come quickly, however, and many feed industry members expressed frustration with the FDA (which regulates feed mills) in this matter. Spokesmen for Kent Feeds, headquartered in Muscatine, Iowa, indicated at a feed industry conference that FDA inspectors had been in their plants frequently in the preceding months and they believed FDA policy was inconsistent regarding manufacturing practices for handling premixes and other drugs (between drugs and between inspectors).[2] Kent Feeds eventually stopped handling sulfamethazine in its feed.

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[1]Research conducted by Dr. Robert Wilcox, Department of Grain Science and Industry, Kansas State University, Manhattan, KS; USDA (SEA) and AFMA also carried out a feed mill survey.

[2]Interview with Dick Lister, Manager, Quality Control, Safety and Training, Kent Feeds, Manhattan, KS, May 28, 1980.

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FDA's attitude and performance toward the feed industry during the controversy over sulfa drug use in swine production was also ambiguous. Early blame for residues was directed at hog producers. Even after USDA efforts also implicated the feed industry, many FDA personnel still were saying privately that the major problem was with hog producers.[1] In 1979, however, the feed industry (through AFMA) and USDA (through SEA) cooperated on a feed mill survey to study frequency and extent of cross-contamination in various mills. The FDA at that point decided that it also needed to conduct a survey of feed mills. Persons within FDA stated privately that FDA wanted to have its own data in case USDA found strong evidence of feed industry contamination. Such FDA data, presumably, would provide a basis for policy recommendations concerning sulfamethazine.

The FDA feed mill study drew some private criticism from personnel at USDA on the basis of statistical design and from some members of the feed industry on the basis of its administration.[2] Most surprising of all, though, were the results. These were not widely publicized by FDA, probably because their meaning was unclear. In general, analysis of FDA feed mill inspection data failed to reveal significant correlation between the practice of commonly-recommended quality control procedures to eliminate drug cross-contamination and residue status of the

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[1] Interviews with Dr. George Graver, Director, Division of Animal Feeds, Bureau of Veterinary Medicine, Food and Drug Administration, Rockville, MD, September 25, 1979; Dr. Bob Schmidt, Bureau of Veterinary Medicine.

[2] Whereas USDA secured voluntary cooperation by working with AFMA (USDA has no jurisdiction in feed mills), FDA did not. Instead, FDA conducted the survey under the auspices of its regulatory jurisdiction.

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mill. Another hard to explain result (which appears to challenge some of the assumptions on which the Second Generation Policy was based) was the lack of correlation between feed mill size or type of operation and measure of drug contamination.[1] The implication of results such as these was clearly that sulfamethazine could not be handled with the then-current state of the art given the existing tolerance levels. The FDA did not proceed directly to ban or restrict the mixing or sale of sulfamethazine, however, realizing its popularity among hog producers and apparently willing to wait and see regarding potential public health dangers. Members of FDA also believed the proposed Second Generation Policy might improve the sulfa situation.[2]

What steps did the feed industry take in conjunction or relationship to the animal health or the swine industries? The feed industry supported the efforts of both groups to have the tolerance levels raised. Had this effort succeeded, no further moves would have been required. When attempts were unsuccessful and as pressure from hog producers began to increase, the feed industry reduced its purchases of sulfamethazine products. The pressure of the market finally stimulated some research into product granulation on the part of American Cyanamid and other sulfamethazine producers in the summer of 1980. In the words of a long-time American Cyanamid market research director, the effort was undertaken primarily to convince the feed industry some efforts were being undertaken in its behalf.[3]

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[1]This survey is discussed below (Chapter V, Section 4).

[2]Interview with Bixler, FDA.

[3]Interview with Jamison, Merck (formerly of American Cyanamid).

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4.2.5 Summary and Conclusions

This section examined characteristics of the relationship existing between the commercial feed industry, animal drugs, uncertainty and food safety/animal drug regulation, particularly in the sulfa case.

It was pointed out that a marriage of convenience has occurred between the animal drug and the commercial feed industries over the past thirty years. Sulfa and other animal drugs conferred benefits on the feed industry as they were employed to sell feed. Animal drugs must be considered in their triple role as product, input and contaminant, however. In recent years, increased realization of the potential of animal drugs to contaminate both feed and livestock has amplified risk associated with mixing animal drugs into feeds. As in the sulfa case, expanded regulatory emphasis on eliminating drug contamination can change (increase) costs associated with mixing drugs in feed and thus modify firm behavior.

Evidence of firm decision-making gathered in the course of this research suggested a number of possible firm responses to the sulfa situation:

1) management of all firms and co-ops interviewed was aware of sulfamethazine contamination problems;

2) two large midwestern state cooperative organizations (Indiana and Illinois) substituted sulfathiazole for sulfamethazine in their

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production and marketing strategies in order to reduce the risk of product liability associated with sulfa-contaminated feeds;[1]

3) even though the feed industry, as represented by the AFMA, voiced concern over sulfamethazine tolerance levels and the belief that these were beyond the state of feed-handling art to meet, major companies such as Ralston-Purina and Central Soya continued to mix sulfamethazine medicated feed. For these companies with well-established quality control procedures and the ability to centrally purchase and premix drugs, the benefits from being able to offer sulfamethazine medicated feed evidently outweigh the potential risk of a regulatory or product liability problem;[2]

4) many mills interviewed had initiated changes in operating procedures as a result of the sulfa problem and actual or potential FDA scrutiny. Hamilton Co-op in Michigan, for example, initiated a new computerized system of record keeping for drugs and medicated feeds as a result of a sulfa violation;

5) some members of the feed industry who had been cited for sulfamethazine violations by FDA and consequently scrutinized more broadly in regard to general drug handling practices expressed frustration over apparent inconsistencies in agency drug handling recommendations and in inspection procedures. Some members of the feed industry,

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[1] In both cases, the PBB contamination incident experienced by Michigan Farm Bureau Services was cited as an example of the potential expense of product liability problems.

[2] A factor here may be the companies' legal capacity in regard to either a product liability or a regulatory challenge.

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particularly small ones, express the fear that FDA Second Generation Policy will penalize small feed mills unduly even though many smaller mills are capable of good quality control.

With regard to this final point, one observation can be made and that is that the feed industry does not in general offer possibilities of rapid growth. Possibilities that exist come in part from industry cannibalization. To the extent that government policy is formulated to favor particular firms over others (for example, large over small), growth of particular industry segments is assisted by government regulation. In the case of the medicated feed industry, the wishes of government regulators and large regional or national feed companies may correspond. However, policy questions are raised when inspection surveys such as that of the FDA into feed mill sulfa contamination does not support the assumptions underlying a new policy proposal such as the Second Generation Policy.

4.3 Decision-making in the Swine Industry

Decision problems faced by hog producers with regard to sulfa drugs revolve around the dual roles of the drugs as valuable inputs on the one hand and potential contaminants, on the other. By the most conservative estimates, between 60 to 70 percent of starter hogs in the U.S. receive sulfa medication in feed. When subtherapeutic sulfa use in growers and finishers and additional therapeutic uses throughout the production cycle are added to this, the estimated percentage of hogs in the U.S. receiving sulfa drugs (primarily ASP-250 containing sulfamethazine) at some time in their lives climbs beyond the 70 percent range.

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Sulfa drugs are used by hog producers for two primary reasons: to reduce the production uncertainty associated with the threat or actuality of disease and/or to reduce unit costs of production by substitution of animal drugs for some other input, either feed, labor, veterinary services or management.

Against the profile of use, in recent years has been juxtaposed a different visage of sulfa drugs as a contaminant. As we have seen, detection rates for violative sulfamethazine residues climbed in the seventies to a high of approximately 15 percent (of hog livers sampled) in 1977, since then declining to approximately 5 percent in 1981.

This section describes and examines how hog producers make decisions regarding sulfa drugs and to what extent animal drug food safety regulation appears to influence these decisions. Also considered is the impact of uncertainty (related to the market, regulatory arena and production performance) on the producer's choice of sulfa handling strategies. Finally, producer strategies to increase control over animal drug/food safety regulation are examined.

4.3.1 The Economics of Feeding Animal Drugs

Whether and at what level the use of antibiotic feed additives would appear in a least cost feeding program depends upon a number of factors, including:

1) impacts on feed efficiency;

2) impacts on rate of gain;

3) impacts on animal morbidity and mortality;

4) price of the antibiotic;

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5) product price;

6) price of substitute inputs and/or substitute technology.

Over the past 30 years, the use of a relatively small number[1] of antibiotic and antibacterial agents at low levels in animal feeds has become standard procedure in the production of livestock products. The original inclusion of antibacterial drugs in livestock feeds represented the introduction of new technology in production as diagramatically depicted by the new production function, y_2 (Figure 4.3). In relation to the old production function y_1 (where $y_1 = f(x_1, \ldots, x_n)$ with inputs $x_1, \ldots, x_n$), $y_2 = f(x_1, \ldots x_{n+1})$ and is positioned to the left of the traditional one. Represented here are the favorable effects of low level antibiotic use on rates of livestock weight gain and feed efficiency, as well as reduced morbidity and mortality attributable to the disease preventive effects of antibiotics.

Exactly where the new production function falls to the left of the traditional one depends upon a number of factors. Numerous experiments have shown that the rate and magnitude of responsiveness to antibiotics in animal feeds varies in relation to the animal species and drug considered, the age, sex and health of the animal, the degree of stress imposed, the adequacy of diet, and the sanitary conditions of the animal's environment. In general, while antibiotic use provides some positive response in terms of increased feed efficiency and rate of gain in the vast majority of situations tested, the rate of responsiveness varies inversely with age, and directly with the degree of clinical

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[1]Approximately 14. See Hays, Effectiveness of Feed Additive Usage, p. 2.

FIGURE 4.3.

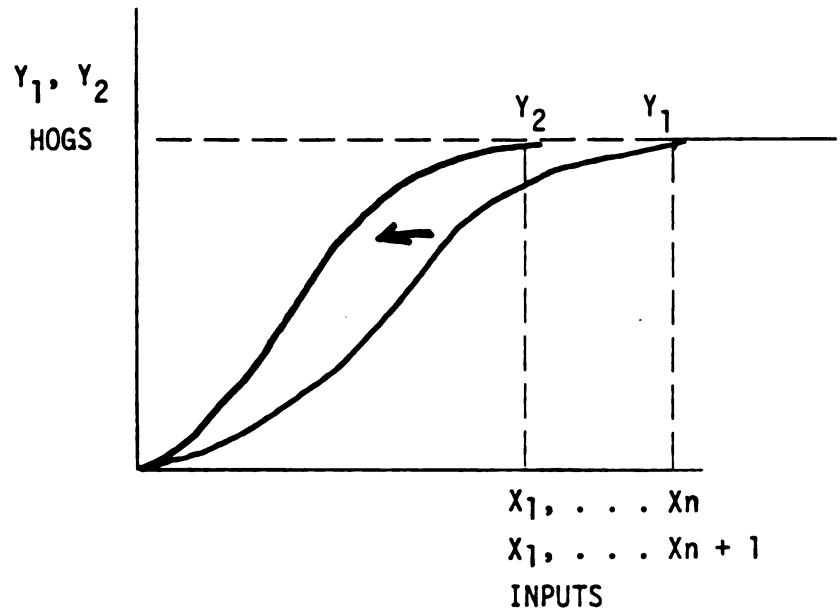


FIGURE 4.3. INTRODUCTION OF ANTIBIOTIC TECHNOLOGY: PRODUCTION FUNCTIONS Y_1 AND Y_2

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Other factors influencing where the new production function will lie (in Figure 4.3) include the complex of other inputs used in the production process. Production practices, including inputs, have changed substantially since the early 1950s when antibiotic drugs were introduced in feeds. Now, instead of comparing production functions $y_1 = f_1(x_1, \ldots, x_n)$ and $y_2 = f_2(x_1, \ldots x_n, x_{n+1})$ where all inputs except the antibiotic are identical in each case, substantially different input sets and technology exist in addition to the use of antibiotics in feed. Changes in production practices have developed in response to a number of factors. These include changes in relative prices of inputs, product and substitutes over time; changes in consumer product preferences; an improved understanding of nutrition, disease prevention and other production practices; incentives incorporated in the tax system and differences in the structure of agriculture. Increasing specialization in production, larger producing units, continued substitution of capital and embodied technology for labor and land have all influenced the way pork is produced in the U.S.

While antibiotic use has not in itself caused these developments, in many cases the technology has facilitated the use of closed confinement plants, large units, increased utilization of capacity and has permitted unit savings in the use of feed and other inputs (for example, veterinary services).

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Economically, the cost saving effect of the introduction of antibiotics in animal feed by the individual firm in the short term can be demonstrated (in Figure 4.4) by a downward shift of the firm's short run marginal cost curve. With the use of antibiotics, the firm is now able to supply the same number of units of output y at a lower cost per unit y. Alternatively, additional units of product can be supplied for the same cost as before. While the firm now includes the cost of antibiotics in its marginal cost calculations, this new cost is more than offset by savings in the use of other inputs. The profit-maximizing firm in a certain world employs a decision rule to use that amount of antibiotic in production of livestock that equates the marginal cost of the last unit purchased with its marginal value product in livestock production.

Over time use of the technology spreads as others recognize that profits can be made. Paradoxically, of course, in the end economic profits dissipate, the price is driven down and those who fail to adopt the new cost-saving technology find themselves eliminated from the market. Figure 4.5 depicts the process described. Firm A symbolizes the adopter firm, firm B represents late-comer firms which do not reap the initial adopter profits. With the introduction of antibiotics, Firm A has lower marginal costs and is rewarded with a per unit profit of $P_1 - MC_2$ (Figure 4.5, Panel 1). In succeeding periods, late-comers also adopt the use of medicated feed (Figure 4.5, Panel 2) until at some point a critical mass of firms exerts outward pressure on industry supply (Figure 4.5, Panel 3). At this point, the

FIGURE 4

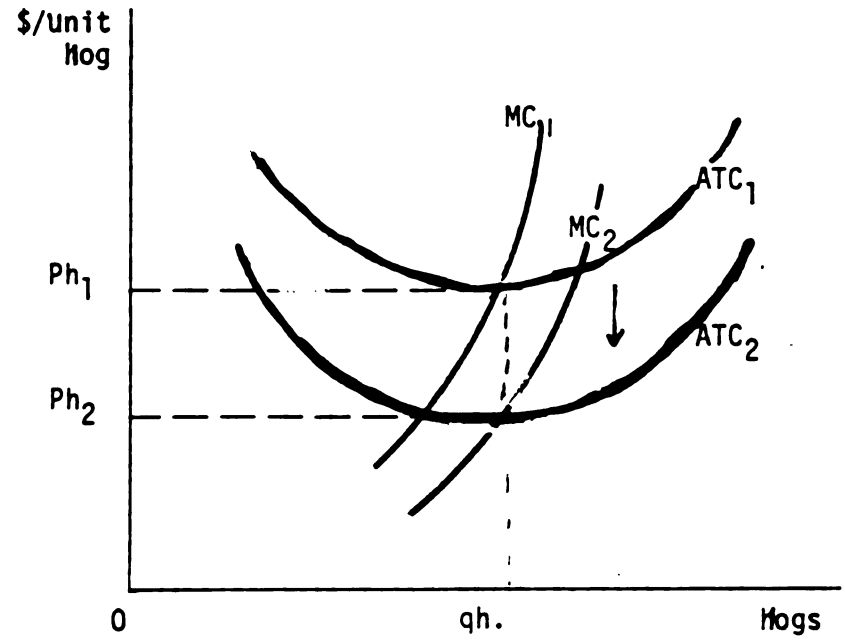


FIGURE 4.4. COST SAVING EFFECT OF ANTIBIOTICS

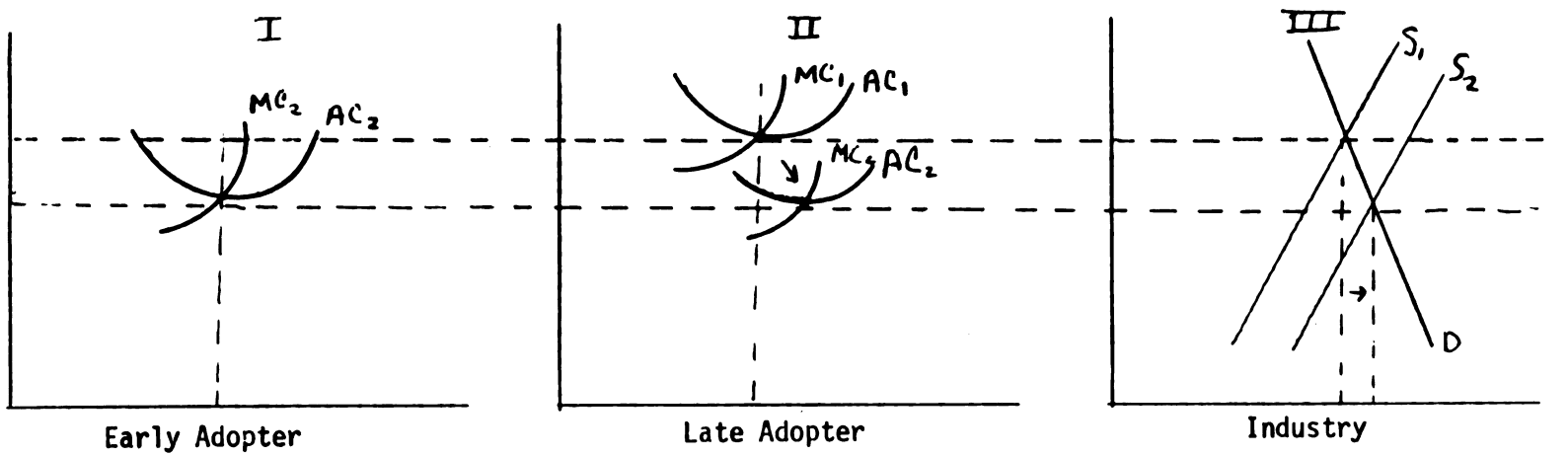


FIGURE 4.5. ANTIBIOTIC TECHNOLOGY SPREADS FROM EARLY TO LATE ADOPTERS EXPANDING INDUSTRY SUPPLY

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price of hogs falls (ceteris paribus) to P_2 and, given a demand of any elasticity, consumers purchase more product (increment $Q_2 - Q_1$).[1]

As stated, substitutability between antibiotic feed additives and other inputs over a certain range partially explains the potential cost savings obtainable from use of feed additives, provided that relative costs remain in line. Feed additives may substitute for feed (demonstrating their most pronounced effects when the diet is suboptimal), for plant and equipment (by speeding rate of gain), for management and labor time (again, antibiotics are most effective under imperfect hygienic and stress conditions) and in the case of disease preventive agents, for veterinary services or (higher) therapeutic doses. As the cost of feed represents between 65 and 80 percent of the production cost of a hog, significant savings of feed can easily represent the difference between profit and loss in a low margin industry. In periods of high interest rates, improved rate of gain can increase utilization of plant capacity, reducing fixed unit costs.

Economically speaking, much swine industry trade discussion and many of the advertisements for antibiotics are misleading to the extent that they advocate maximizing rate of gain or feed conversion or number of litters farrowed, baby pigs weaned, minimizing disease, or any other single measure of technical efficiency to the neglect

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[1]The analysis is similar to that found in both J. C. Headley, "Economic Aspects of Drug and Chemical Feed Additives," for the Office of Technology Assessment, U.S. Congress, 1978; and U.S. Department of Agriculture, Economic Effects of a Prohibition on the Use of Selected Animal Drugs, Agricultural Economics Report No. 414, NEAD/FSCS/USDA (Washington, DC: Government Printing Office, September, 1978).

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of economic consideration. A consulting veterinarian for Hastings Pork, producing 160,000 hogs per year in Hastings, Nebraska, explains the financial importance of calculating the economic contribution of an antibiotic:

> We calculated with one particular antibiotic recently that even if the (feed) conversion rate went up 2/10ths of a point, it was still uneconomical at the current price of hogs for us to put that antibiotic back into the feed. We've got to be able to say that it is economical to put this in and that we are getting this much good out of it. Too many people spend a buck and only get 50 cents back.[1]

Few dispute the value of feed additives, in general. However, many industry observers and participants interviewed in the course of this research concurred that antibiotic use in the past 25 years has been widespread, intensive and, in many cases, indiscriminate, although these generalities may be changing.[2] The reasons for extensive use of antibiotics were numerous. Scientific evidence for the most part encouraged use of antibiotics; the animal drug and feed industries became strong proponents of medicated feed additives and medicated feeds for purposes of their own sales, and, in short, very little reason existed not to use antibiotics. During the first twenty years of antibiotic use in feeds, animal drug regulation was relatively slack, and few major human health concerns surfaced. In this environment

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[1] Dr. Chuck Neumann, cited in National Hog Farmer, January 15, 1981.

[2] Interview with Holmes, Doanes Agricultural Services; Dr. Dave Ellis, Department of Veterinary Medicine, Michigan State University, E. Lansing, MI, September 10, 1979; Maynard Hogberg, Extension Swine Specialist, Michigan State University, E. Lansing, MI, May 1979.

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and in light of a prolonged general decrease in the average cost of antibiotics, use by producers increased dramatically (Figure 4.6).[1]

Many industry observers and participants agree that use of antibiotics in the past represented a cheap insurance policy for production uncertainty. Although indiscriminate or excessive use of antibiotics negates some of the economy associated with the insurance policy, many producers believed (and currently believe) in it nonetheless. Excessive reliance on use of antibiotics is counterproductive, however. This is because past some point, antibiotic use and other inputs (management, feed, etc.) cease operation as substitutes and enter a range of complementarity (see Figure 4.7). Swine specialists state that frequently producers operate beyond that point of substitutability, essentially throwing away money on antibiotics. Poor management practices include intentional or inadvertent double dosing which can result either from improper administration of the same drug by different routes (water, feed, boluses) or the simultaneous combination of redundant drugs. One veterinarian cautions:

> It's hard to know which additives are best since few research trials are done on a head-to-head basis. But there's no evidence from a rate-of-gain or feed efficiency standpoint that more than the approved level is better. And there's no evidence that putting in two or three additives in the starter or grower ration will pay for itself. . .many producers spend 4% to 5% of total production costs on additives.[2]

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[1] In recent years, however, many antibiotic prices have increased.

[2] Dr. Al Leman, veterinarian, University of Minnesota, cited in "Selected Use of Feed Additives Can Pay Off, National Hog Farmer, December 15, 1980, p. 65.

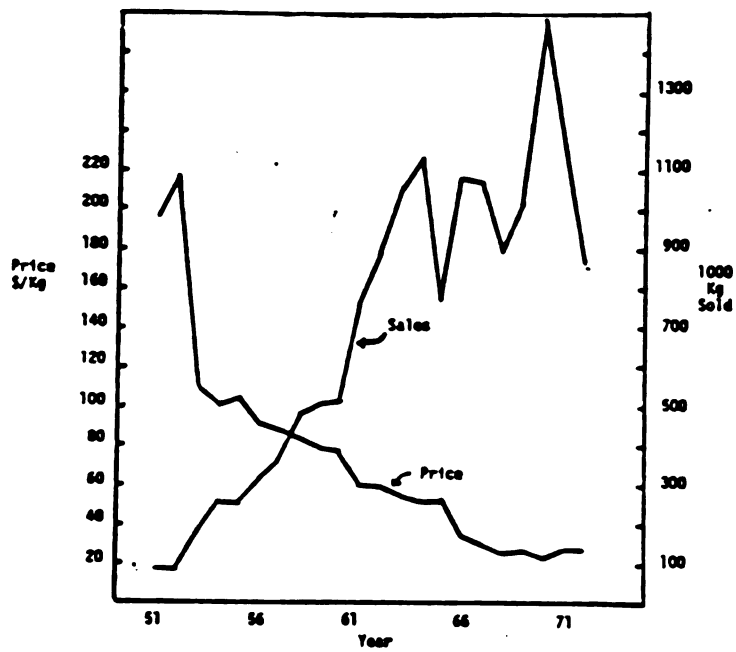


FIGURE 4.6. PRICE AND SALES VOLUME OF ANTIBIOTICS FOR NONMEDICINAL USES

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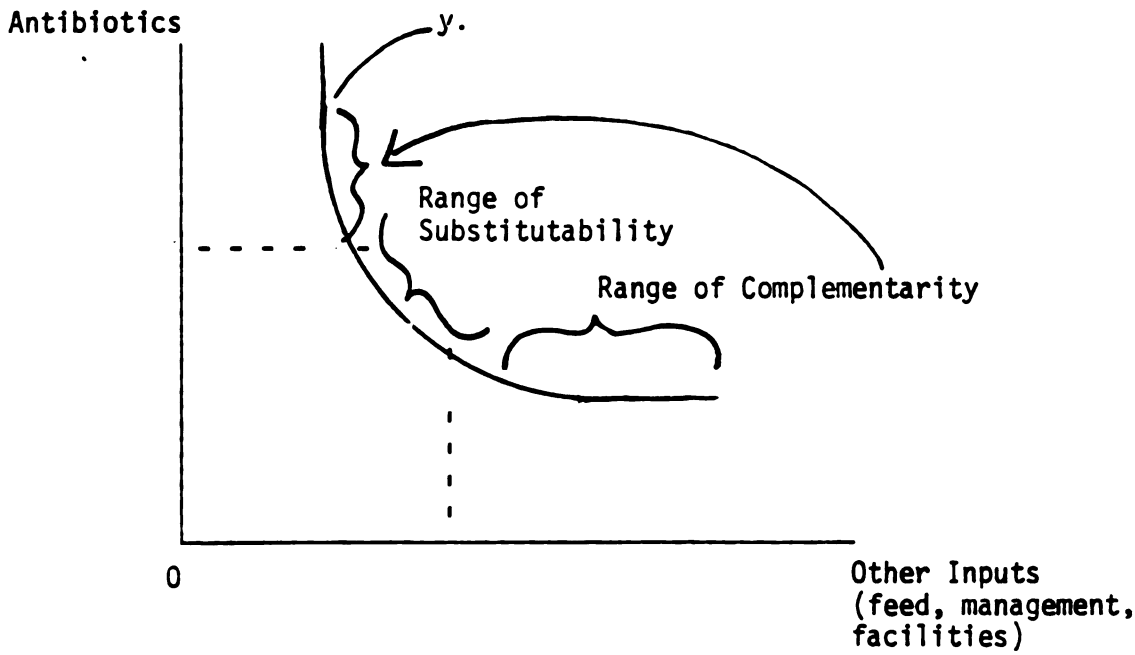


FIGURE 4.7. ISOQUANT DEMONSTRATING RANGE OF COMPLEMENTARITY AND SUBSTITUTION BETWEEN INPUTS

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4.3.2 Use of Swine Feed Additives by Hog Producers

The major source of statistics regarding actual use of swine feed additives at the farm level is Doanes Agricultural Services, Market Research.[1] Doanes confirms the fact that the three major drugs in the swine antibiotic feed additive market are ASP-250, CSP-250 and Tylan-Sulfa with combined retail sales of approximately $70 million in 1979.[2] Whereas a decline has been noted in farm use of the sulfa drugs, the market remains substantial. Doanes estimates that approximately one-half of all starter hogs (0-40 pounds) receives ASP-250 (the survey doesn't discriminate between ASP-250 and Chlorachel 250), and approximately 10 percent of starter hogs receives Tylan-Sulfa and CSP-250, respectively. Rates of use at the grower and later stages decline from these. Of the total swine antibiotic market (all ages) ASP-250 and CSP-250 comprise about 50 percent with the approximate breakdown in 1979 recorded at 44 percent for ASP-250 and roughly 6 percent for CSP-250 (the sulfathiazole product). Doanes did not detect any perceptible shift in use between sulfamethazine and sulfathiazole products; however, Doanes spokesmen had some question whether most hog producers discriminate between the products. Doanes stated that the animal drug companies attempting to sell their products are basically at the mercy of feed companies as pharmaceutical companies do not generally sell products direct to farms.

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[1] Interview with Holmes, Doanes Agricultural Services.

[2] Note the comparison between estimated retail sales value at the farm level of $70 million as compared to IMS estimates of purchases by the feed industry and veterinarians of $42.6 million.

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General trends noted by Doanes include a slight decline, on the order of 1-2 percent per year, in the use of antibiotics in feeds, a shift away from complete swine starter feeds to farm-mixed feeds in which hog producers incorporate commercial premixes and their own grain and protein source,[1] a shift from traditional use of sulfa drugs to newer feed additives such as neoteramycin, mecadox, lincomix, and the use of chortetracycline as a single drug. The spokesman for Doanes stated that the relative decline in the use of sulfa drugs in part reflects a feeling that sulfas are losing effectiveness against atrophic rhinitis (for which they have traditionally been used) as well as the introduction of a vaccine for atrophic rhinitis and the use of Specific Pathogen Free (SPF) hogs.

In addition, Doanes remarked a general trend toward more selective use of antibiotics with disease claims for periods of animal stress or for disease treatment and an increase in use for growth purposes of additives with growth promotant but no disease claims. Similar observations were echoed by others contacted during the course of this research.

To summarize market trends in the feed and swine industries, then, regarding sulfa feed additives, market information on purchase of sulfa feed additives by the commercial feed industry, veterinarians and others who subsequently sell them in some form to hog producers

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[1]Hog farmers have traditionally purchased complete starter feeds; grower and finishing feeds have been more frequently mixed in grind and mix operations on the farm.

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indicates that after a period of generally strong growth through the mid-seventies, purchases have fluctuated and in some cases slowed in the past two years. Some individual products including ASP-250, American Cyanamid's market leader, have lost ground while others have gained, specifically Rachelle's virtually identical product Chlora-chel-250 and Diamond Shamrock's sulfathiazole competitor CSP-250.

Doanes reports of farm level data regarding the use of these products by hog producers appears to bear out a slight over-all decline in the retail use of sulfa drugs in swine feeds. Doanes' market surveys did not record a perceptible shift in use between sulfamethazine and sulfathiazole products although there was serious question regarding the accuracy of producer discrimination between ASP-250 and CSP-250. The Doanes surveys were described as picking up a slight increase in the use of a number of non-sulfa additives, some of these growth promotants without any disease claims.

Available market statistics, then, paint a somewhat ambiguous picture of what has really occurred to patterns of sulfa feed additive use by swine producers. Doanes statistics do not reveal any shifts between sulfa feed additives although they do show a slight over-all decline in use of sulfa additives. Feed industry purchases of ASP-250, however, were down in 1979. One explanation supported by interview evidence is that feed companies have in some cases taken the initiative to switch products, in some cases without the awareness of hog producers. Reasons for product substitution include concern with residues.

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4.3.3 Case Evidence: Producer Use and Assessment of Sulfa Drugs

The following information regarding decision-making in the swine industry represents a composite of case evidence from hog producers, swine specialists and regulators. The central objective is to document empirical factors influencing producer decisions related to the use of sulfa drugs and some probable impacts of animal drug/food safety regulations on drug use decisions. Analysis and conclusions follow.

The case evidence presented here derives from a series of interviews conducted with approximately 20 hog producers in Michigan, Kansas and Illinois in 1979-80 as well as Extension swine specialists and agricultural economists in Michigan, Kansas and Indiana.[1] Included in the interview process was a uniform survey of ten Michigan hog producers.[2] The producers were selected for their diversity with respect to size of operation,[3] type of enterprise (farrow to finish or finishing), whether the producer had been identified through consultation with Extension and, if so, whether the Extension specialist had rated the producer a "good manager" or not. (See Table 4.4.)

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[1]A portion of the funding for this research was provided by the Michigan State University Toxicology Center for purposes of identifying impacts on Michigan producers of alternative proposals to control sulfa and other animal drugs.

[2]Ten of the Michigan producers surveyed were interviewed by research assistant Roberta Cook Villarreal of Michigan State University's Department of Agricultural Economics. The author appreciates her assistance in this task.

[3]Number of marketings ranged from 500 to 11,205 annually.

TABLE 4.4 CHARACTERISTICS OF TEN MICHIGAN HOG PRODUCERS AND SULFA DECISIONS

TABLE 4.4. CHARACTERISTICS OF TEN MICHIGAN HOG PRODUCERS AND SULFA DECISIONS

Producer	Type of Enterprise				Hogs Mktd. (per year)	Residue Trouble	Current Use	Experience with Sulfa Changes in Producer Sulfa Use	Source of Sulfa Information[1]	Consider Sulfa or Health Problems?
	Farrow	Finish	Corn	Soy-beans						
1	*		*		3,680	Feed	ASP-250 CSP-250 starters	Yes. Segregate hogs. More cleaning. Separate augers and feed tanks.	T, E, P, F	No
2	*		*		11,205	No	ASP-250 starters only. Sulfa in water for older pigs.	Not really. Has never fed to finishers.	T, E, P, F, FS	No
3	*		*		4,850	Feed Soybean Meal	ASP-250	Yes. Have always flushed. Changed feed supplier. Cut back sulfa use.	T, E, P, F	No
4	*		*		1,630	Feed Soybean Meal	ASP-250	Not really. Sequences with all drugs.	T, E, P, F, FS	Allergen
5		*	*		500	No	Extra sul water only	Yes. Has stopped feeding sulfa.	T, E, P, F	No
6		*	*	*	3,500	No	CSP-250	Yes. Separates starters from finishers. Separate feed equipment.	E, P, FS	No
7	*		*		3,550	No	ASP-250	Yes. Began flushing after mixing sulfa feed.	T, E, P	No
8	*		*		2,000	No	ASP-250	No.	T, E, P	No
9	*		*		9,050	Hogs Soybean Meal	CSP-250	Yes. Flushes. Keeps sulfa out of delivery trucks. Separate tanks and augers.	T, E, P, F	No
10	*		*		640	No	ASP-250	No.	T, E,	No

[1] T = Trade Press, E = Extension, P = Pork Producer's Council, F = Friends, FS = Feed Suppliers

Source: In-depth Interviews with Michigan Hog Producers, 1980

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Results of the survey and other interviews present a suggestive picture of one group of producers' attitudes regarding the value of sulfa drugs as an input, the alleged human health dangers of violative sulfa residues, producer experience with sulfa drugs, sources of producer information on these issues, and producer assessments of animal drug regulation in general, and the benefits and costs of specific regulatory proposals related to sulfa drugs in particular.

Of the ten Michigan producers surveyed, six reported some current use of ASP-250 and four, use of CSP-250. Only two producers of the 20 interviewed in all locations reported no sulfa use at all at the time of the interview. However, several producers mentioned that they had altered their own sulfa use patterns, most frequently restricting sulfa medications strictly to starter feeds or handling sulfa medications entirely in water to avoid contamination. When questioned regarding their primary reasons for using sulfa additives, all producers interviewed in all locations stated that disease prevention or treatment constituted the major benefit of sulfa additives although over half rated growth promotion as an important secondary impact. Fewer than half rated sulfa feed additives as having important impacts on feed efficiency; approximately half stated that sulfa additives are not important for this purpose, and one producer commented that several more economical drugs than the sulfas exist for purposes of growth promotion or improving feed conversion.[1] A number of producers

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[1] Interview with Barton, Homer, Michigan.

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reported that they had attempted to cut out the use of sulfa drugs entirely, but had been forced to resume use due to problems of disease.[1] Producers believe nearly unanimously that sulfa drugs are most useful against respiratory diseases and atrophic rhinitis, although they split down the middle in assessing the relative importance of the two diseases. The difference in producer ratings of sulfamethazine's most important disease-preventive impact appeared to be linked to individual experience: for example, many of the major hog producing counties in the state of Michigan are located in the southwestern portion where many hogs are still raised on land with farrowing in the fields.[2] With exposure to Michigan's rapidly fluctuating spring and fall temperatures goes an attendant risk of respiratory disease. Sulfa drugs assist in improving resistance to respiratory disease in such cases. Similarly, a hog and wheat producer in Green, Kansas mentioned that dust problems associated with grain production aggravate respiratory problems, particularly in years of drought. He felt sulfa medications to be useful in cases[3] like these.

On the other hand, large confinement operations with close body contact of thousands of animals sometimes aggravate herd problems of

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[1] Interview with Barton. Barton is one of Michigan's largest producers. He attributed his decision to halt use of sulfamethazine in ASP-250 in part to economics, stating that the price of the drug had increased over 500 percent in 10 years.

[2] Interview with Dale Purkhiser, Area Extension Swine Specialist, southwestern Michigan, Canopolis, Michigan, October 23, 1980.

[3] Interview with Dean Larson, Green, Kansas, November 13, 1980. Note that treatment of jowl abscesses is the only disease claim for sulfamethazine in the Code of Federal Regulations.

rhinitis. Producers with confinement facilities find sulfa drugs in general, particularly sulfamethazine, useful against this chronic disease. Sulfamethazine has traditionally been the drug of choice against atrophic rhinitis, but in recent years the veterinary profession has noted increasing resistance of some rhinitis strains to the sulfa drugs.[1] Additionally, a vaccine for atrophic rhinitis has been developed which some producers report to be effective, either alone or in conjunction with use of sulfa drugs at therapeutic levels.

One producer who experimented with a vaccine for atrophic rhinitis, however, illustrated some of the economic and management considerations associated with the decision to turn to substitutes.[2] He stated that a salesman persuaded him to invest in vaccinations for the sow herd (including a vaccination two weeks prior to farrowing) and for the baby pigs after farrowing (two more per baby pig, one at two weeks and again at six weeks). The producer concluded that this latter procedure was like throwing money away, in the amount of thousands of dollars. He invested in over 28,000 injections for the baby pigs (18 pigs/year x 800 sows x 2 vaccinations), after which he lost close to 1/4 of the baby pigs for normal reasons (such as mothers lying on them). Additionally, the vaccination of 28,000 baby pigs requires far more labor time than vaccinating only the sows or medicating in feed or water. The producer eventually settled on the use of a rhinitis vaccine for

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[1] Interview with Dr. Lowell Breeden, veterinarian, Extension Swine Specialist, Kansas State University, Manhattan, KS, November 1980.

[2] Interview with Barton, Homer, Michigan.

the sows only and medicating with sulfathiazole in the water in the event of disease outbreaks.[1]

4.3.3.1 Information Sources Regarding Sulfa Drug Problems

When questioned about various sources of information concerning problems associated with sulfa drugs, producers answered as follows:

1) all producers interviewed stated they had read about sulfa residue problems in trade magazines;
2) all producers interviewed said they had received advice or materials from Extension agents or state swine specialists;
3) seven of the ten Michigan producers surveyed stated that their feed suppliers had not mentioned anything about sulfa residue problems to them; one producer stated that a Moorman's salesman had advised him of potential problems and another said that his feed supplier (Ukeleys) had switched sulfa products from ASP-250 to CSP-250;
4) all but one of the Michigan producers surveyed stated that they had received notification from the Michigan Pork Producers Council regarding sulfa problems or possible solutions. Three of the ten mentioned the Farm Bureau

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[1] Ibid.

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as a source of information on the matter. Non-Michigan residents echoed the citations of the state Pork Producers Council as a principal information source regarding sulfa;

5) finally, when asked if they had learned about possible sulfa problems from friends, half of all producers interviewed responded that they had.

Producer response to interview questions regarding information sources tends to validate the hypothetical model of producer decision-making proposed in Chapter III above. It was suggested that producers seek information in order to reduce uncertainty originating in the market, the institutional arena and concerning their own production or organizational performance. The economic actor balances the costs of information search and utilization against expected benefits. Additionally, the available budget limits information expenditures.

These factors combine with the additional fact that expected benefits of information regarding sulfa depend upon the probability of undesirable sanctions befalling a producer. The fairly small number of producers experiencing problems probably minimizes the expected loss of any one producer. It then becomes rational to invest resources in relatively inexpensive sources of information such as spending the time to listen to an Extension presentation, belonging to the Pork Producers Council or reading a trade magazine. It is probable that budget constraints of most hog producers in a competitive market rule out the types of information strategies associated with large firms in the animal health and feed industries

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which maintain their own regulatory affairs staffs, frequently with Washington-based lobbyists. An appreciation of rational information strategies of this group of economic actors suggests possible means by which policy makers may subsidize information in order to influence swine producer decision-making.[1]

One further policy ramification is associated with the empirical finding that three-fourths of the Michigan producers surveyed said that they had not received any information from feed suppliers regarding potential sulfamethazine residue problems. Recall that this evidence tends to support the hypothesis that an economic transaction characterized by impacted information tends to encourage that party possessing detrimental information to withhold this in order to influence choice of the other party. The policy conclusion emerges in many similar situations that the government should step in and, in some manner, even the information odds. This belief has led to some of the policy proposals analyzed below in Chapter V.

4.3.3.2 Hog Producer Perceptions Regarding Human Health Impacts of Sulfa Residues

The following set of producer responses indicates producer perceptions regarding some potential human health hazards attributable to recent levels of sulfamethazine residues in swine. It was considered important to ascertain what persons actually using sulfamethazine thought about the possible risks because beliefs can influence behavior. In another context Hirschman discusses the concept of

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[1] As policy makers in fact did in activities of the Sulfa Task Force and in supporting the Cooperative Extension Service.

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loyalty.[1] Boulding speaks of love[2] and others describe altruism. The commonality in these conceptions is a concern with the impact which one's own actions might have on another's well-being. If altruism exists in conjunction with a belief that one's own actions might negatively affect another's health, then producers may exercise more care in their actions than that which would be expected solely from a decision rule calculating the expected loss from over-use or careless use of a drug such as sulfa to hog producers alone.

Accordingly, questioning centered on potential or alleged human health impacts associated with sulfa residues. When Michigan hog producers were asked if they could identify any human health impacts or allegations associated with sulfa drug residues, one producer volunteered the problem of allergic reactions upon ingestion of sulfa. The remainder of the sample did not identify health concerns or allegations. When the health subject was further pressed, producers were asked to comment on the allegation that sulfa drug residues can trigger an allergic response. Four-tenths of the Michigan producers surveyed stated they had not heard of this; six out of ten recalled hearing the allegation although one of these stated flatly that he didn't believe.

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[1]Albert O. Hirschman, Exit, Voice and Loyalty: Responses to Decline in Firms, Organizations and States (Cambridge: Harvard University Press, 1970).

[2]Kenneth Boulding and Martin Pfaff, eds. Redistribution to the Rich and the Poor; The Grants Economics of Income Distribution (Belmont, California: Wadsworth Publishing Co., 1972).

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Regarding sulfa drug residues being potentially carcinogenic, seventy percent stated they were unaware of this allegation,[1] while thirty percent said they recalled hearing the allegation, but didn't believe it.

The third allegation sometimes associated with sulfa drug residues is their potential contribution to an antibiotic-resistant gene pool common to livestock and humans and capable of compromising the effectiveness of animal and human disease treatment. Responding to this potential human health impact, half recalled hearing of the issue, two persons stated they recalled the allegation but felt there is no proof, and the last respondent offered a slightly rougher rendition of "poppycock!"

In summarizing their opinions as to whether sulfa residues pose a human health problem, seven of ten surveyed in Michigan stated uncategorically "no," two of ten believed possibly, but only at extremely high levels (one because of allergies, one because of resistance, none because of carcinogenesis) and one stated he had no reason to believe it wouldn't present problems if misused, but because he uses sulfa carefully, he has no concern.

The clear impression suggested by this set of producer opinions regarding sulfa, an alleged contaminant, is that a great majority does not believe sulfa residues pose any meaningful human health danger except (possibly) at extremely high levels, levels greatly

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[1] One who had not heard allegations regarding sulfa drugs being carcinogenic stated nonetheless he was not surprised, "What isn't these days!"

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exceeding those now considered violative or which have been reported in recent years.

With only one exception, producers were able to identify the Food and Drug Administration as the regulatory agency responsible for establishing tolerances for animal drug residues. Several producers stated they believed that the tolerances for sulfa in swine could reasonably be raised, but some stated that the FDA had an adversary relationship with producers and was difficult to influence.

Several policy questions are raised by producer answers to the questions of sulfa residue health impacts: does lack of producer awareness of, or belief in, possible adverse human health impacts of sulfa and other animal drug residues impair regulatory efforts? If so, can credible efforts be made to inform producers in this area? In situations where no indisputable proof, but only probabilistic evidence exists can reasonable explanations be developed of the conservative stance U.S. food and drug law requires? Can the nature of experimental evidence upon which food safety regulators are forced to rely in lieu of controlled human experiments be explained? Throughout the interview process producers repeatedly demonstrated both a lack of belief that sulfa drugs (or for that matter many other regulated substances utilized in agriculture) represent any significant danger to human health at current levels and a lack of <u>any</u> understanding of procedures of toxicological research in which the results of high dosage--small animal tests are statistically extrapolated to estimate risk to a human population. When the costs of attempting to effectively police

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an unpopular regulation are considered,[1] and in light of the number of potential applications of a basic food safety educational program, the regulatory economics involved appear to demand careful consideration.

4.3.3.3 Hog Producer Compliance Strategies

As previously indicated, Food and Drug Administration regulations set a tolerance level of .1 ppm for sulfamethazine or sulfathiazole residues in the organ and muscle tissues of swine. To attempt to ensure that the tolerance level is reached, producers must adhere to a mandatory sulfamethazine withdrawal time of 15 days (seven days for sulfathiazole). In the late 1970s, some producers claimed, despite precautions, swine were contaminated with sulfa (usually sulfamethazine) at market. Discovery of contamination by USDA and/or FDA can result in marketing delay and additional expenses.[2]

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[1]The case of DES provides an example of how regulatory enforcement problems related to one drug can tie up a substantial portion of the FDA's compliance budget when producers chose to ignore the regulation.

[2]One Michigan producer experiencing difficulties with sulfamethazine contamination in market hogs spent six weeks off of the market. During that period he had a first lot of five hogs sampled for analysis. After two-three weeks, results were reported as three hogs violative. The producer questioned test accuracy as he had made every effort to handle the swine identically. He then needed to slaughter and sample a second lot of five hogs. He sent these samples to a different laboratory. Results came back negative after two additional weeks. The producer was fortunate in the timing of his violation as it came during summer at a point when he had just finished clearing out a confinement area, and he didn't have new marketings planned for 50-60 days. Because he could afford to wait, monetary costs were largely limited to the cost of the three contaminated hogs (he did not pay for the costs of sampling). However, he did invest substantial management time in discovering the contamination cause. Interview with Bill White, hog producer, Jones, Michigan, October 21, 1980.

Given these factors, what types of decisions did hog producers make regarding sulfamethazine and sulfathiazole? Evidence in Michigan, Kansas, and Illinois indicated that while the vast majority of producers interviewed had not eliminated the use of sulfamethazine entirely--only two out of the ten Michigan producers surveyed said they had eliminated sulfamethazine in all forms--still, all said they had modified previous practices to some degree. In some instances, changes were marginal: for example, producers exercising greater care in following withdrawal time. In others, the drug was still administered but using different technical procedures. A number of producers had eliminated sulfamethazine use in feed additives at subtherapeutic levels. These procedures frequently adopted a strategy of substituting either sulfathiazole or sulfamethazine as a water medicant or another non-sulfa feed additive. Survey responses of ten Michigan producers are indicated in Table 4.4.

In summary, interview evidence indicates that adverse publicity surrounding sulfamethazine has caused some changes in producer behavior. While producers continue to use sulfa drugs, particularly sulfamethazine, they evince a high degree of awareness of its potential as a contaminant and have adapted some limited changes to protect against contamination. Adaptations which were made were not in general sufficient to eliminate all possibilities of contamination according to what is known about sulfamethazine contamination potential. However, for the most part, producers interviewed did not reveal the conviction that they needed to eliminate all potential for contamination--only control it.

4.3.3.4 Strategies to Reduce Uncertainty and Shape Policy

Chapter III identified the regulatory arena as a source of uncertainty for economic actors, in general, and hog producers, particularly. The model developed there suggested that rational self-interested producers attempt to influence regulation in their favor when expected benefits outweigh costs. Further, imperfect markets and economic power frequently provide large organizations opportunities to adapt organizationally to regulatory demands by exploiting economies of size. The fact that an industry has a relatively small number of firms--for example the animal health industry as compared to the feed or swine industries--may make the organizational transactions costs required to influence regulation relatively smaller than in more competitive industries.

How do producers in the swine industry evaluate their influence upon animal drug regulation? What regulatory control strategies are viewed as most effective? Hog producers in Michigan were asked to assess the effectiveness of alternative procedures for communicating their opinions and having an impact on regulatory policy concerning hog production and marketing rules (see Table 4.5). The strategy judged most effective by these producers in influencing regulation was participation through membership in a trade organization, especially the Pork Producers Council. A general farm organization such as the Farm Bureau was evaluated as less effective, yet still more valuable than individual action. Personal communication with a U.S.

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TABLE 4.5. HOG PRODUCER RATINGS OF ALTERNATIVE MEANS TO INFLUENCE REGULATORY POLICIES

Methods to Influence Regulation	Rating: Very Effective	Rating: Moderately Effective	Rating: No Impact
1. Belong to general farm organization (e.g., Farm Bureau)	4	3	3
2. Belong to a trade or industry organization (e.g., NPPC)	8	1	1
3. Personal communication with state representative or senator	3	2	4
4. Personal communication with federal represenative or senator	3	3	4
5. Personal communication with state or federal regulatory agency		3	5
6. Participation in heating	3	3	3
7. Other			

Source: Interviews with 10 Michigan hog producers, 1980-81

representative or senator and participation in a hearing ranked next in line. Trailing the list of possible strategies to influence regulation regarding hog production was personal communication with a regulatory agency. This judgment was qualified in two cases, one producer commented on his close working relationship with the Michigan Department of Agriculture and USDA but said he is "antagonistic" toward FDA. Another producer stated it is necessary to exert pressure on FDA through an organization such as the Pork Producers Council or Extension because "FDA won't deal with individuals." Another producer mentioned the necessity of influencing consumer opinions in food safety issues and clarifying hog producers' positions.

In general, producers expressed optimism about the recent direction of the National Pork Producers Council with respect to having an impact on public policy issues affecting pork production and marketing. They indicated progress in this area was symbolized by the organization bringing lawsuits against USDA in cases concerning nitrites in pork products and turkey ham labeling.

4.3.4 Decision-making in the Swine Industry: Summary

Swine producers have traditionally viewed sulfa drugs as inputs; in the late 1970s, contamination potential surfaced as an important concern. It is conservatively estimated that over 70 percent of swine marketed in the U.S. receive sulfa products at some point in the production cycle, either for purposes of health insurance, to speed growth or to save on feed.

Whether sulfa or any other drug additive appears in a least cost feed or input solution depends on a number of factors including drug cost, price of hogs, contribution to output and prices of substitutes in production.

Interviews of a small sample of Michigan hog producers permitted an in-depth look at factors influencing their decision-making regarding sulfa drugs. It was found that eight out of ten continued to use ASP-250 in some form in late 1980; four of the ten also used CSP-250 as a management tool; two reported no current use of a sulfa drug. Most producers claimed they had made some changes in the way they handled sulfa drugs, including restriction to starter feeds, switching to water medications, using only for disease treatment, eliminating use. All producers valued sulfamethazine for disease treatment and prevention effects. Atrophic rhinitis and pneumonia were mentioned equally in this regard.

Producers interviewed concurred that the most useful information sources for information about sulfa were the Cooperative Extension Service, the trade press and various State Pork Producers Council groups. Few producers had learned of problems from feed suppliers.

Producers interviewed were unconvinced of any human health dangers associated with sulfamethazine residues. Seven (of ten) did not believe sulfa posed any dangers; two thought at high doses sulfa conceivably represents a risk of allergic reaction or drug resistance. None believed any cancer link was meaningful.

Producers interviewed believed membership in the Pork Producers Council was the most viable means for them to have an impact on public policy.

4.4 Aspects of the Sulfa Case Relevant to Decision-making of Meat Packers and Hog Buyers

Hog buyers and meat packers relate to sulfa drugs primarily as contaminants. The hypothetical model of Chapter III suggests that hog buyers and meat packers may have an interest in avoiding sulfa contaminants, but rational decision-making on their part demands consideration of the costs and benefits associated with sulfa. If hog buyers or meat packers experience product liability risk and are forced to bear losses associated with product condemnations, then self-interest and rationality imply a different set of actions than if the processing and marketing of sulfa-contaminated products is not associated with costs to them.

With respect to meat packer interests in meat inspection program design, then, meat packers can be expected to favor regulatory efforts causing the least disruption of kill lines and other activities associated with meat packing along with those institutional arrangements minimizing hog buyer or meat packer liability for contaminated products and minimizing financial charges associated with support of inspection activities.

4.4.1 Case Evidence: Frederick-Harrads of Detroit*

Frederick-Harrads, the largest hog packing plant in Michigan and throughout the Midwest, slaughters 14,000 hogs daily. Much of this number is trucked in from out of state resulting in a typical queque of waiting trucks which stretches for miles.[1] Frederick-Harrads markets products under "Thorn Apple Valley" and "Harrads" labels.

The principal hog purchaser for Frederick-Harrads stated that, in the three year period of his employment at the plant, no hogs had ever been condemned for violative sulfa levels.[2] Frederick's ships meat in interstate commerce and is federally inspected, a process which includes USDA inspectors sampling two or three times per week for sulfa. On days when USDA samples, inspectors select two hogs from two to four loads per day resulting in a total sample ranging from four to eight animals. Samples are frozen and shipped airmail to a USDA regional lab for sulfonamide assay work. Because the USDA has no legal authority to retain carcasses without cause, the meat enters the food supply before determination of its contamination status.[3] The USDA makes no efforts

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*The assistance of Roberta Cook Villarreal in conducting interviews reported in this section is appreciated.

[1] Interview with Estes Reynolds, Department of Animal Husbandry, Michigan State University, April 27, 1979.

[2] Interview with Gary Nelson, Hog Buyer, Frederick-Harrads, Detroit, Michigan, December 15, 1980.

[3] A GAO reports documents a "typical" 1977 timetable for sulfa sampling in plants and subsequent sample analysis at a regional lab: April 7, 1977, sample collected at slaughterhouse; April 11, 1977, sample mailed to laboratory; April 13, 1977, sample received at

to recall meat products for sulfa contamination, an achievement which, in any case, would be virtually impossible after the animal has lost any external identification in the slaughter process and has been disassembled into wholesale cuts in the breaking room.

At the time of the interview at Frederick-Harrads[1], the supervising USDA veterinarian at the plant reported that no sulfa violations had been found in the previous six month period. If a positive sulfa result is reported, the USDA lab informs Fredericks and then attempts to trace the violative carcass back to the producer. Frederick-Harrads' personnel report identification of producers is difficult from their plant because few swine are purchased direct from producers, meat moving instead through terminal markets or buying stations. At these markets, assembly procedures imply that each truck load generally contains swine from two or three producers. The only steps Frederick-Harrads takes in cases when it receives information of violative swine is to notify the people it bought from. The plant itself has very limited contact with individual producers for any purpose. Due to the lack of incentives in the current meat inspection program, neither

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laboratory; April 22, 1977, residue analysis begun; April 27, 1977, residue analysis completed. Total time elapsed, 20 days; with marketing probably occurring 18 days before. U.S. General Accounting Office, Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues. Report to the Congress by the Comptroller General of the United States (Washington, DC: April 17, 1979).

[2]Interview with Dr. Clark, Frederick-Harrads Packing Plant, Detroit, Michigan, December 15, 1980.

the plant nor the hog buyer at an intermediate market has any significant interest in attempting to prevent purchase of sulfa-contaminated hogs.

By contrast, the plant's liability and defensive strategies with respect to disease bear noting. The USDA meat and poultry inspection programs have traditionally emphasized eliminating diseased animals from the food supply. All meat inspectors are supervised by veterinarians who finalize decisions on product dispensation. USDA inspectors conduct both ante- and post-mortem examinations for disease. Because disease frequently results in visible signs, inspectors condemn violative products and Harrads bears the cost of the condemned carcass or organ. Major disease losses in swine stem from arthritis, pneumonia, and septicemia[1]; one USDA veterinarian estimates that approximately 40 (out of a daily kill of 14,000) animals are condemned for disease each day.[2]

Frederick-Harrads attempts to reduce its liability for diseased animals by having government inspectors conduct ante-mortem examinations on arriving trucks prior to unloading. Using this examination as a screening device, the plant can then refuse to accept questionable animals. The seller runs the risk at this point of having suspicious animals retained by the inspector.

Because chemical contamination frequently cannot be detected as easily as disease, would not packing plants benefit from an animal

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[1] Interview with Mike Mayer, Plant Manager, Frederick-Harrads, Detroit, Michigan, December 19, 1981.

[2] Interview with Dr. Jablonski, Frederick-Harrads: Frederick-Harrads requires an inspection force of 39 USDA inspectors and five supervising veterinarians.

identification system? The Frederick-Harrads hog buyer responded to questions regarding the desirability of an animal identification program by stating the plant would favor a program submitting identification of the final seller in order to reduce liability for condemnation of diseased animals. It should be noted that many packing plants buying on a grade and yield basis direct from producers are able to identify producers. Farmland Industries pays a premium per cwt. for high quality hogs sold grade and yield and mails a computer printout to growers explaining payment per animal.[1]

As for reducing sulfa contamination by installing an in-plant monitoring system, as expected, the personnel contacted at Frederick-Harrads did not favor any procedures to institute in-plant sulfa testing as this could easily extend the plant's liability.

4.4.2 Case Evidence: Peets Packing Plant, Chesaning, Michigan

Peets Packing Plant is the third largest in Michigan with a reported average kill of 1,700 per day. Products are marketed under the Farmer Peets label. Plant procurement practices divide by thirds into purchases at the door direct from growers (identity retained), purchases at sales out in the state (no producer identity), and out of state purchases (not easily identified).

The Meat Inspection Service has five inspectors at the plant with one supervising veterinarian. The supervisor estimated his crew samples

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[1] Interview with Larson, Manhattan.

for sulfa eight to ten times per month taking samples from one hog each time. From 1978-1980, the USDA inspector estimated that violative sulfa samples were only identified two or three times. He reported that no other positive tests for chemical residues had come back during that time.

Peets Packing Plant management expressed concern at one point that USDA inspectors were sampling a higher percentage of hogs purchased direct and identified than those from other sources. Management argued that the practice discriminated against direct sales customers and damaged the plant's reputation. Inspectors subsequently agreed to select only one-third of their samples from the identified hogs.[1]

The purchaser notes an increasing trend toward direct sales. Five years ago this plant purchased only 10 percent of its hogs on a direct sale basis; now it purchases one-third by direct sale. Even some out-of-state hogs now come in on a direct sale basis (from Indiana and Illinois). When hogs are bought direct, producers are not paid until after hogs are slaughtered and tested; thus, the producer bears or shares losses if animals are condemned.

Peets currently operates a stockyards in the same manner it has for the past 40-50 years, purchasing from two to 200 hogs at a time. According to Peets' purchaser, the packing plant is unique in Michigan with respect to its stockyard with a holding area for 2,000 hogs (this is larger than at Frederick-Harrads). As at Frederick-Harrads, spokesmen at Peets favored the concept of an animal identification system,

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[1] Interview with Tom Gross, Assistant Livestock Buyer, Peets Packing Plant, Chesaning, Michigan, December 16, 1980.

particularly as it would find application in selective breeding programs to help producers meet Peets' specifications and in disease detection. Plant interests do not favor in-plant sulfa screening, however.

4.4.3 Summary

This section stated briefly that meat packers consider sulfa drugs as contaminants. However, concern about avoidance of contamination depends upon the perceived necessity as well as the costs. Currently, marketing rules and inspection arrangements minimize inconvenience and liability to packers due to sulfa contamination. At Frederick-Harrads in Detroit, violations were reported as negligible; in any case the meat is marketed by the time results are known. In addition, the source of violative swine cannot be traced beyond the buyer.

At Farmer Peets in Michigan, a packing plant which purchases one-third of the hogs direct from producers (identity can be traced in these cases), the sulfa testing program caused some inconvenience. The plant felt direct sale customers were being penalized because they could be identified by USDA and thus were sampled more often.

Personnel at both packing plants favored the concept of an identification system which would permit the plant to trace diseased animals back to the source and for breeding improvement purposes.

An in-plant sulfa screening test which might increase plant liability for drug contamination or impede plant production was not favored by those interviewed.

4.5 Decision-making Within the United States Department of Agriculture and the Food and Drug Administration in the Sulfa Case

The final focus of this chapter is upon decisions made within USDA and FDA which relate to the sulfa case. Indirect evidence of these decisions has colored the examination of the various subsector industries thus far. Here the sequence of administrative decisions and supporting reasons are discussed explicitly, paving the way for analysis of administrative decision-making in future food safety cases.

In the conceptual model developed above, policy decisions represent the aggregate outcome of the decisions of numerous individuals within agencies (and outside, as well). These individuals tend to satisfice, that is, to seek satisfactory solutions to policy problems. Individuals' decisions are based upon a number of factors including the agency's legislative mandate, available policy variables, standard operating procedures, individual job descriptions within the agency and individual personalities. Finally, two general problem-solving paradigms characterize agency decision-making: a routine problem-solving paradigm reflects established organizational problem-solving processes; a political problem-solving paradigm emerges upon the failure of routine procedures. This section 1) describes what occurred in the sulfa case; 2) analyzes factors contributing to the status of the sulfa problem as "non-routine" and not amenable to routine problem-solving techniques; 3) analyzes various non-routine administrative steps which were followed to alleviate the problem. The section concludes with an evaluation of major strategies followed by USDA and FDA in the sulfa case with conclusions pertinent to administrative handling of future food safety cases.

4.5.1 Summary of Administrative Decisions in the Sulfa Case

As previously stated, FDA responsibility includes animal drug safety evaluation as well as establishing tolerance levels for animal drug residues in edible meat. Agency authority permits establishment of mandatory withdrawal times for animal drugs in order to provide for drug depletion from the livestock system. USDA, on the other hand, has responsibility for inspecting the major portion of the nation's meat supply (that part moving in inter-state commerce) to enforce compliance to FDA regulations for drugs and other chemicals.

After USDA established its chemical residue monitoring program and began to record a high incidence of sulfa violations in swine, the FDA adopted a policy extending the withdrawal time for sulfamethazine to 15 days, believing that a longer withdrawal time would correct for hog producers who prematurely marketing medicated swine. (The withdrawal period was extended to 15 days in 1978.)

Another step had been taken by public officials within FSQS at USDA who decided to increase the sampling rate for sulfa in swine. As indicated above, the monitoring program is not designed for enforcement purposes. From an average rate of approximately 300 samples per year, swine sampled for sulfa drugs (including sulfamethazine) were increased in 1977 to 7,434 livers per year. The stated motivation for the sampling increase was two-fold: personnel within FSQS wished to verify that the high rate of violations was not solely a result of a

small sample size (this was in fact verified) and the agency wished to apply some pressure to hog producers by increasing their probability of being caught.[1] The increase in sampling rates revealed a violation rate of between 10 and 15 percent in 1977 and also succeeded in creating an awareness of the problem of sulfa residues among members of the swine industry.

It is important to note that an initial assumption of nearly all public personnel involved with the sulfa problem associated the problem of residues principally with hog producers. Producers were believed to exercise insufficient care in administering, withdrawing and in other ways handling the animal drug.

Many in the swine industry believed otherwise, however. Producers frequently maintained that they had not used the drug recently, or that they had used the drug properly, following label instructions. At the same time, sulfamethazine continued to be a highly valued drug for its disease prevention effects. Hog producers did not wish to see the drug banned from the market. Controversy mounted in 1977 and 1978 affecting both FDA and USDA and leading ultimately to formation of the Sulfa Task Force within USDA.

What factors led to USDA agency response expressing itself in formation of a task force? What was the role of the FDA in this process? Why did USDA take this action in the sulfa case and not in other cases, for example that of DES? What advantages does a task force approach have? How could it be further improved?

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[1]Interview with Dr. Grace Clark, U.S. Department of Agriculture.

The situation existing within USDA directly prior to formation of the Sulfa Task Force sheds some light on factors influencing the decision to initiate a task force in this case. Structurally, FSQS and the Federal Meat Inspection Program were positioned organizationally under the Assistant Secretary of Agriculture for Food and Consumer Services, Carol Tucker Foreman. Foreman appointed Robert J. Angelotti as Administrator of the Food Safety Quality Service. Angelotti's former tenure had been with the Food and Drug Administration. In both positions his reputation was that of a strong consumer advocate.

Perceptions among some members of USDA were that neither Angelotti nor Foreman entertained much initial sympathy for the swine producers, believing that sulfa residues were primarily due to mismanagement by producers.[1] At the same time, discussion within FDA began to touch upon withdrawing sulfamethazine from the swine feed additive market if residue rates did not drop. In the midst of controversy over residues and potential regulatory response, Assistant Secretary of Agriculture for Food and Nutrition Carol Tucker Foreman was invited by the National Pork Producers Council (NPPC) to attend an industry meeting at which producers aired their concerns. In January of 1978, USDA sponsored a public meeting with members of the swine industry and other government agencies to identify key questions and issues of concern regarding various aspects of the sulfa residue problem. A follow-up meeting in February 1978 was chaired by Food Safety Quality Service Administrator

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[1]Based on private interview with USDA employee.

Robert Angelotti in which officials of a number of USDA agencies were asked to cooperate in finding a solution to the sulfa residue problem in swine.

Eventually the Secretary of Agriculture Bob Bergland designated the Assistant Secretary of Agriculture for Marketing Services, P. R. "Bobby" Smith, as overall coordinator of the Sulfa Task Force Program. He, in turn, named the Administrator of the Animal Plant Health Inspection Service (APHIS), Dr. Frank Mulhern, to direct the program. Dr. Mulhern and others at APHIS determined to apply an approach similar to those utilized in livestock disease eradication campaigns to the residue problem. Specific activities of the Task Force program are examined below.

The decision to adopt a task force approach reflected a growing awareness on the part of policymakers that the problem was more complex (both physically and politically) than originally supposed and that many questions required answers regarding physical characteristics of the drug, the quantity necessary to cause problems, management practices causing problems. The popularity of the drug among producers was well noted.

It should be noted that major participation in the Sulfa Task Force within USDA was contributed by the Animal Plant Health Inspection Service (APHIS) rather than FSQS. Several factors help explain this fact. APHIS was positioned in USDA during the Carter Administration under a different Assistant Secretary than FSQS.[1] APHIS had an

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[1]Before appointment by Secretary Bob Bergland to the position of Assistant Secretary for Food and Consumer Services, Carol Tucker Foreman had been a highly visible and outspoken advocate of "consumer

institutional history of administering national or regional animal disease eradication campaigns which typically combined services of multi-disciplinary personnel and utilized services of the Cooperative Extension Service. Finally, the head of APHIS, Frank Mulhern, was recognized as an extremely able administrator experienced in managing similar campaigns. He was named to oversee the administration of the 18 month Sulfa Task Force.

In many respects the Sulfa Task Force grew most directly out of a previous task force, the Secretary's Task Force on Animal Feed Additives formed in 1977.[1] This latter functioned to formulate USDA policy responses to FDA policy proposals regarding antibiotics used in animal feeds. As a result of this previous experience, many members of the Sulfa Task Force had some prior experience in working together and combining efforts of individuals within APHIS, ESS and other branches.

In terms of administrative responsibility within USDA, the Sulfa Task Force activities were conducted by:

1. Animal and Plant Health Inspection Service (APHIS): responsible for overall program administration, coordination of field activities, sharing in training, laboratory assistance and information.

2. Food Safety Quality Service (FSQS): participant in planning and primary responsibilities for information and education program and laboratory support and training.

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interests" in many different issues. She has been credited by spokesmen for the swine industry as being the most influential factor behind growing political activism of the industry. During her tenure several issues grew into lawsuits involving the swine industry including turkey ham and nitrites.

[1] Interview with Clark Burbee, Food Group, National Economics Division, Economic, Cooperative, Statistical Services, USDA, Washington, DC, July, 1981.

3. Economics, Statistics and Cooperative Service (ESCS): responsible for providing economic analysis of regulatory control alternatives for sulfa.

4. Science and Education Administration (SEA): SEA scientists from Agricultural Research (AR) and Cooperative Research (CR) assumed primary responsibility for the research component of the sulfa program participating in planning, supervisory or direct research capacities. Extension (E) conducted Extension activities.

5. Office of the General Counsel (OGC): this office arranged for transfer of authority for the sulfa residue program to Assistant Secretary P. R. "Bobby" Smith with concommitant publishing of the authority in the Federal Register.

6. Office of Budget, Planning and Evaluation secured Congressional approval to re-program funds for the sulfa project.

7. Agricultural Marketing Service provided information to contacts in various marketing channels.

At the Food and Drug Administration, responsibility broke down so that the Bureau of Veterinary Medicine:

1. suspended for 18 months regulatory actions against swine producers identified as producing violative swine;

2. conducted a feed mill survey of 200 mills to identify procedures followed by those firms mixing sulfa and to assess which operating procedures and structural characteristics of mills appeared most problematic in terms of sulfa.

3. furnished at least one regular representative to all meetings of the Sulfa Task Force;

4. followed up on USDA reports of contaminated finishing feeds by investigating 42 mills.

The Bureau of Foods (responsible for setting animal drug tolerance levels and safety assessments) determined that it could not raise tolerance levels without new toxicity test data; petitions submitted by American Cyanamid were twice denied. The Bureau of Foods agreed to undertake long-term toxicity testing of sulfamethazine in order to reassess the appropriate safety factor to be used in establishing sulfamethazine tolerances. As indicated earlier, this policy decision was somewhat unusual, because generally research of this nature is supplied by the private sector.

As a final comment upon FDA activities related to sulfa, the Bureau of Veterinary Medicine's efforts to propose and implememt the Second Generation Feed Policy should again be noted. Major emphasis was accorded this effort in the late 1970s and many top policy-makers believed implementation of the policy would directly improve the sulfa problem along with a host of other Agency problems associated with feeds. It can be argued that efforts to install this broader policy superseded any aimed at sulfa residues alone.

4.5.2 Analysis of Administrative Decisions in the Sulfa Case

A number of factors contributed to the non-routine character of the sulfa problem, one leading in turn to a need for extraordinary agency response: 1) violation rates for sulfamethazine in hogs exceeded those for any other known substance; 2) the drug's popularity extended to its use in over 70 percent of all swine; 3) the public health impacts of human low-level exposure to sulfa residues are unclear and controversial with many reputable authorities stating the health danger is negligible or non-existent.

These factors, coupled with the indisputable illegality of residues over .1 ppm, posed problems for the FDA. Within the Bureau of Foods was a reluctance to "cave in" to pressure from producers and users of sulfamethazine and raise this single tolerance level, thereby setting a precedent. Derivative costs in terms of other appeals could be high.

The popularity of the drug with hog producers created substantial pressure from hog producers, related industries and from parts of USDA upon FDA to seek a solution short of withdrawing approval for sulfamethazine.

Within FDA itself, backgrounds and professional status of personnel lend different perspectives to a problem such as the sulfa problem. Bureau of Veterinary Medicine personnel, many of them professional veterinarians or animal scientists, have experience and training creating an understanding of livestock health problems and an appreciation of effective medicinals; an agricultural background

is probably less characteristic in the Bureau of Foods, where human health skills predominate.

Short of the polar moves of banning the drug or raising tolerance levels, FDA initially did not have many intermediate control strategies available. This fact necessitated an improvisational approach and undoubtedly contributed to some successful cooperation between FDA and USDA. FDA did not have direct control over hog producers or meat packers. It fell to USDA to enforce FDA rules. (At first, the feed industry had not been implicated as a problem source.) For a while, FDA resorted to rumblings about a sulfa ban.

At one early point, an intermediate measure of restricting sulfa use to starter feeds was also considered briefly by some FDA personnel. Eventually, scepticism about the success of this measure predominated.

When USDA research began to indicate a sulfa contamination problem in feed mills, FDA was faced with a new dilemma. Now it appeared that a major source of the sulfa problem extended directly within FDA jurisdictional boundaries. This fact placed a new onus upon FDA to implement a policy to control sulfa residues but not solely at the expense of hog producers. In other words, FDA incurred increasing pressure to deal with the feed industry and finally the animal health industry.

As indicated above, a good share of that pressure originated at USDA. Sampling of finishing feed and components on hog farms suggested to USDA that hog farmers were taking the heat for the feed

industry.[1] USDA recommended hog producers sample purchased feed. At the same time, USDA referred names of mills suspected of cross-contamination to FDA.

In 1978, USDA and AFMA cooperated in conducting a major survey of feed mills producing swine feeds in states with major sulfa problems. FDA responded to the USDA effort by launching its own feed mill survey. The sentiment was voiced privately within both agencies that FDA felt it needed to have its own feed mill data to be able to respond from a position of some strength to any USDA conclusions. As it turned out, the FDA results could only be described as confusing.[2]

In the end, circumstances and decision-making within the FDA resulted in the agency refraining from any clear cut moves with respect to sulfa. As indicated earlier, by adopting decisions to conduct a battery of long term toxicity studies under the proposed Sensitivity of Method policy, the agency delayed having to make any drastic decisions for a number of years. By emphasizing in the late 1970s and 1980 the Second Generation of Medicated Feeds policy rather than direct measures to correct sulfa contamination, the agency was able to diffuse controversy concentrated on the sulfa issue, and at the same time claim to be working toward implementation of a feed policy which could alleviate sulfa problems.[3] It should be noted that neither FDA policy

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[1] And the USDA was doing the same for FDA.

[2] Discussed below.

[3] The correspondence between adoption of the Second Generation Policy and reduced sulfa residue rates is not straightforward, however. This is discussed below.

move aimed directly at the animal health industry or the problem of electrostaticity.

At the USDA the sulfa problem was non-routine for reasons already indicated: violation rates were higher than for any other substance--creating what one FSQS administrator termed in 1978 "my number one headache."[1] USDA as a consumer protection agency in its role as meat inspector was sensitive to not doing its job[2] when over 10 and up to 15 percent of swine contained illegal residues.

USDA as an agency serving agricultural producers, on the other hand, demonstrates sensitivity to the needs and desires of this clientele group as well. Hence, the agency sought around for a solution which would: 1) control sulfamethazine residues at some "satisfactory" level; 2) assist swine producers experiencing difficulties attributable to sulfa; and 3) appease the FDA, thereby preventing any unwanted policy moves. An educational approach was chosen utilizing the sizable institutional research, education and Extension capacity of USDA.

The political pressures incumbent on each agency--including in each agency counterveiling representatives of consumer and producer interests--and the fact that sulfa health hazards were not considered of the carcenogenic variety combined to encourage a certain improvisational ingenuity. Decision-makers were encouraged to avoid extreme

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[1] Interview with Dr. R. E. Engel, Acting Deputy Administrator, Science, Food Safety Quality Service, U.S. Department of Agriculture, Washington, DC, May 14, 1979.

[2] Carol Tucker Foreman and Robert Angelloti owed their considerable reputation to their stands on issues of consumer protection.

solutions and seek a mutually advantageous level of cooperation between agencies. Sulfa Task Force Administrator Frank J. Mulhern commented that he could not recall a case of closer cooperation between USDA and FDA than the sulfa case. Evidence raises the question whether "cooperation" may not represent a partial euphemism for competition tempered by political reality.

Finally, the question again surfaces--why wasn't more effective pressure brought to bear upon the animal health industry from the outset to force the three companies producing sulfamethazine feed additives to eliminate electrostaticity? The answer to this problem contains a number of parts: 1) the problem was not initially conceptualized or defined as a systems problem flowing throughout an extended subsector; 2) USDA has no jurisdictional authority over this industry; 3) FDA does have ostensible authority over this industry through the Federal Food Drug and Cosmetic Act. However, the law as written does not easily permit the FDA to withdraw approval on grounds of electrostaticity for a drug it has previously approved. Additionally, as indicated previously, resources within the animal health industry were directed toward a goal of increasing tolerance levels rather than decreasing electrostaticity. This action by American Cyanamid and other industry supporters had the not unusual impact of placing the regulatory agency on the defensive for a significant period of time. The sulfa case thus provides some insights to decision-makers faced with food system contamination incidents in the future.[1]

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[1]Explicit policy conclusions constitute much of Chapter VI below.

The problem may be more effectively and rapidly approached if viewed from a systems perspective from the outset. Such an approach in the sulfa case would have more rapidly pinpointed the animal health industry as a focus of attention.

The political nature of the sulfa problem--stemming in part from the drug's popularity with hog producers--encouraged USDA attempts to control rather than eliminate all illegal residues. This position at USDA probably had a moderating influence upon FDA. However, cases such as that of DES suggest that the carcinogenicity factor severely limits any room for compromise.

4.6 Decision-making in the Sulfa Case: Conclusions and Implications for Policy Analysis

This section presents major conclusions emerging from the data collection and analysis process represented above. Specific empirical conclusions concerning each industry and agency are not repeated here. (Individual summaries conclude each industry section above). Instead, more general observations relating to the interactions between participant decision-making procedures and regulation lend credence to the use of a decision-making model for systematic diagnostic analysis of policy alternatives. Such an analysis of policy alternatives follows in Chapter V.

This research methodology employed a subsectoral approach on the premise that many food safety problems characterized by contamination can be most profitably addressed in a systemic manner due to the nature

of potential contamination flow through the relevant value-added system and due to the diversity of potential "control" points in a marketing system.

After identification of the system, the research sought to model decision-making procedures of various system participants. It was hypothesized, and evidence supported the hypothesis, that decision-making in different industries would reflect basic conditions in the industry as well as features of market structure. The conceptual model of the firm which supports the research posits that an economic entity acting in a rational, self-interested manner, but under conditions of uncertainty, costly information and, frequently, economic power adopts satisticing strategies to reduce uncertainty and increase control, while conserving scarce firm resources. In relation to regulation the firm makes three distinct sets of decisions: decisions related to the acquisition and use of costly information, decisions related to choice of strategies to influence the design or enforcement of regulation, and decisions related to developing a compliance strategy for those regulations judged desirable or inevitable or unescapable. Empirical evidence in the sulfa case supports the conclusion that economic power encourages organizational adaptation to cope with regulation and that functionally specialized regulatory affairs personnel select strategies in relation to regulation which at worst tend to subvert or counter the intent of the regulations and at best tend to shape the regulation to the firm's interests.

Firms operating in a competitive industry such as the swine industry have neither the resources nor the organizational incentives to attempt to individually and directly influence regulatory design. These producers appear more likely to make marginal adjustments in operating procedures depending on expected necessity and costs and to employ relatively inexpensive methods such as Pork Producers' Council membership to influence policy.

Those strategies adopted by a firm reflect the nature and magnitude of that firm's interest in the chemical substance in question. If, as in the case of sulfamethazine additive manufacturers, a firm's interest is in sulfa as a significant product generating substantial revenue, then a decision process which balances expected benefits and costs of regulatory compliance implies that regulators trying to change performance of firms in this industry have a choice of: 1) substantially raising the costs of producing a product with undesirable characteristics (such as electrostaticity) or 2) substantially increasing the net benefits from producing an improved non-electrostatic product. Potential mechanisms for accomplishing these objectives are suggested in Chapters V and VI.

In industries such as the swine industry where producer interests in sulfamethazine as product, input and contaminant are more nearly balanced, a regulatory policy which slightly modifies relative costs and benefits associated with use of the drug (including information costs) can marginally alter producers' decision-making regarding animal drug use. The appropriateness of any policy selected depends

upon whether the policy objective is one of residue elimination or control. These decision-making and policy issues are integrated into the analysis of policy options which follows.

CHAPTER V

ECONOMIC ANALYSIS OF FIVE FOOD SAFETY POLICY SCENARIOS DIRECTED AT CONTROL OF SULFA RESIDUES IN SWINE

Sulfa feed additives generated revenues of approximately $50 million to the animal health industry, and $70 million for the commercial feed industry.[1] Primary benefits from sulfa additives for the swine industry include improvements in feed efficiency, growth promotion and disease control. Hays estimated on the basis of 658 experiments that sulfa feed additives outperformed substitutes in starting and growing pigs.[2] His figures imply that average daily gain would have been decreased by 6.5 and 4.07 percent in starting and growing pigs, respectively, had sulfa additives been replaced by other available antibiotics. The decrease in contribution to feed efficiency between sulfa and substitutes was 1.57 percent for starting pigs and 1.04 percent for growing pigs. In 1979 percentages like these might have translated into an increase in aggregate costs of feeding the 89 million hogs slaughtered that year of an estimated $52 million[3] had sulfa feed additives not been used.

Against this backdrop and considering the diverse interests in sulfa products documented above, this chapter analyzes the economic

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[1] IMS America, Ltd. Personal correspondence; and interview with Holmes, Doanes Market Research.

[2] Hays, "Effectiveness of Feed Additive Usage of Antibacterial Agents in Swine and Poultry Production." See Table 5.2 below.

[3] Based on a 1% reduction in feed efficiency. See assumptions and discussion below. Control of jowl abscesses is the only disease claim legally made for sulfamethazine alone.

impacts of five food safety policy scenarios with potential application to the sulfa case using the analytical model developed above. The policies are:

1) Ban or restrict use of sulfa drugs at subtherapeutic levels in livestock feeds.

2) Raise the tolerance level for sulfa drugs in swine.

3) Follow the set of procedures undertaken by the Sulfa Task Force.

4) Institute policy measures to eliminate sulfa residues in commercial feeds.

5) Adopt changes in inspection procedures and marketing rules to eliminate sulfa residues in swine.

The policy scenarios were identified in conjunction with decision-makers responsible for resolving the sulfa problem. Each alternative received specific consideration in the sulfa case (or a similar case) or is a broader policy which will have an impact on the sulfa problem if implemented. Sulfa Task Force activities were actually implemented and the analysis below assesses their impacts.

The policies differ slightly in problem definition; fundamental assumptions about problem causes and appropriate regulatory philosophies; and in estimates of program cost-effectiveness. The policies cover a range of institutional alternatives and each will yield a different pattern of benefits, costs and distributional impacts if implemented.

Dependent variables considered in the analysis include:

1) impact on sulfa residue rates in pork products at the consumer level;

2) impact on consumption and price of pork products at the comsumer level;

3) impact on costs, income, output, sales and price at the four industry levels: animal health industry, commercial feed industry, swine industry, livestock marketing and meat packing industry;

4) structural impacts;

5) public program costs.

5.1 Ban or Restrict Subtherapeutic Sulfa Use in Swine (Three Variants)

This section examines three versions of a ban or restriction on the use of sulfa feed additives. The policies vary in severity; the most extreme encompasses a complete ban on sulfonamide swine feed additives except by prescription; the second a ban of sulfamethazine feed additives alone; the third a restriction of subtherapeutic use of sulfa drugs to the starter phase of hog production. The general rationale behind all these policies is that violative levels of sulfa in swine are unacceptable and necessitate a ban or restriction for correction. The policies focus upon removing opportunity for error by rescinding or circumscribing opportunities for sulfa use by producers and manufacturers throughout the system.

Specific rationale behind the different versions of a sulfa restriction indicate differences in policy makers' assessments of problem causes and potential solutions: 1) the rationale for a ban is that sulfa residues in pork are of sufficient concern that opportunity for use in swine must be eliminated because evidence indicates

that sulfa cannot be handled in the hog production system without some contamination; 2) restricting the ban to sulfamethazine alone incorporates the previous judgment but recognizes that sulfamethazine is the largest problem cause--a ban of this compound alone could accomplish the desired policy purpose without jeopardizing hog producer use of the one other approved sulfonamide, sulfathiazole; 3) restricting sulfa use to starter phases of swine production reflects a judgment that sulfa residues do present a concern, but probably not a public health threat of the calibre implied by 1) and 2). Accordingly, residues can be most effectively controlled without sacrificing beneficial effects by restricting sulfa use to starter rations. Evidence shows that sulfa feed additives are most effective in disease prevention, maintenance of rate of gain and improvement of feed efficiency at the start of the production cycle. Therefore, proponents of the policy believe that such a restriction permits realization of major economic benefits of antibacterial use at the most critical stage in the production cycle, but then provides for a sufficiently long withdrawal period for swine to deplete the drug from their systems.

5.1.1 Economic Impacts of a Sulfa Ban: Sulfa as Product, Sulfa as Input

Reduced to its simplest form, a ban on the production, sale and use of sulfa feed additives constitutes a regulatory ban on 1) the sale of a product and 2) the use of an input in production.[1] The

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[1]This section begins with cases of sulfa as input and product. Sections 5.1.1.1 through 5.1.1.4 expand the analysis to incorporate the decision-making model and empirical analysis presented in Chapter IV.

consequences of such a ban depend upon the contribution of sulfa the product to animal health (or feed) firm profits and sulfa the input to hog production (its technical efficiency), the availability of substitutes in swine production and relative costs and prices of inputs, substitutes and final product. Under the usual competitive assumptions of perfect information and profit maximization,[1] pre-ban equilibrium production and sales patterns reflect optimal sale and use of sulfa drugs. Institution of a sulfa ban, then, necessarily reduces profits of the sulfa manufacturer or raises costs of production for the sulfa user in the short term (and lacking a perfect substitute) because it forces drug sellers and swine producers away from maximum profit (or least cost) situations.

The measurement of ban impacts on the aggregate supply of swine requires estimation of the contribution of sulfa to swine production (of all enterprise types) and the existence and cost of substitute inputs. In the case of a ban, producers will adopt new decision strategies. To a degree an analysis of the impacts of a ban depends upon behavioral assumptions regarding the management strategies producers follow under conditions of reduced feed efficiency and rate of gain and increased incidence of disease (for example, whether they attempt to finish the previous number of animals, but at lighter weights, or a smaller number of animals at former weights).

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[1] In a framework of partial equilibrium analysis.

The panels of Figure 5.1 depict the relationships between an individual firm's production functions, before and after a ban (Panel A), the firm's initial and subsequent cost curves (Panel B), initial and subsequent aggregate supply (Panel C), and aggregate demand which is assumed to remain stationary. Following assumptions of no perfect substitutes for the banned input, the analysis suggests impacts in most normal cases consisting of higher consumer prices, smaller quantities taken, increased costs of production and increased total revenue;[1] presumably the ban would also result in a product uncontaminated with sulfa residues.

The economic models of Figures 5.2-5.4 illustrate some of the impacts of improvements in production efficiency and/or increased yield per animal from the use of an animal drug on equilibrium value (prices and quantities) in both the markets for hogs and for pork.

Figure 5.2 demonstrates the impacts of a change in production efficacy resulting from an improvement in feed efficiency and growth rates. In this case, the shift is to an additive producing efficiency gains which are more than sufficient to compensate for the higher unit feed cost. Increased feed efficiency and improved growth rates result in a larger supply of hogs which then translates into a larger quantity of pork at retail levels. Given stable demand in both markets, larger supplies imply unit prices paid for hogs and for pork decline.

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[1] Price elasticities of demand for pork are generally estimated to be inelastic.

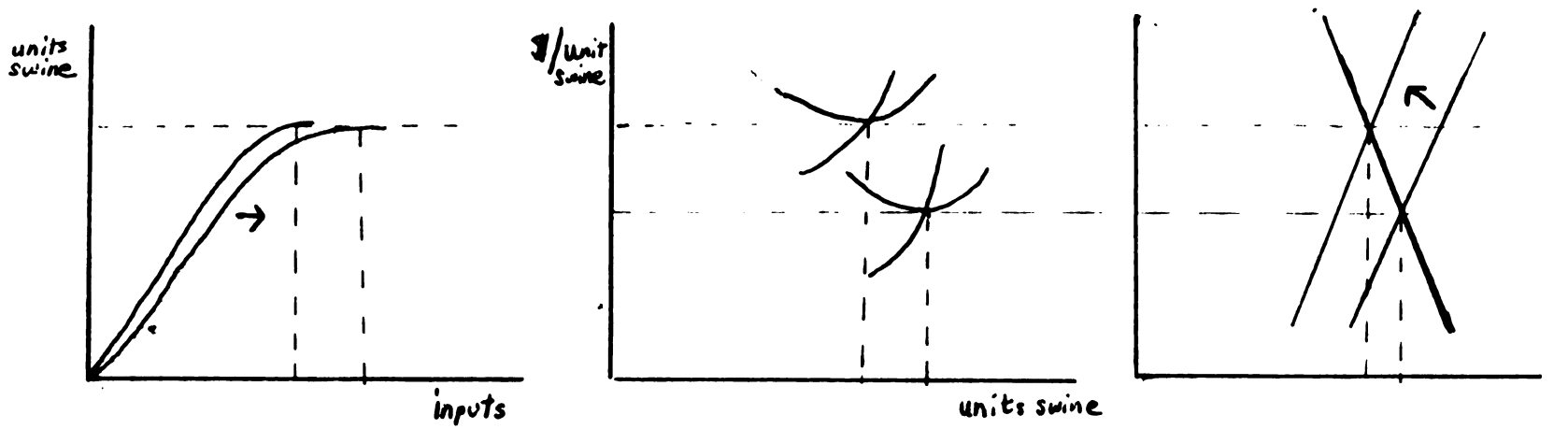


FIGURE 5.1. ECONOMIC IMPACTS ON SWINE PRODUCTION OF A DRUG BAN

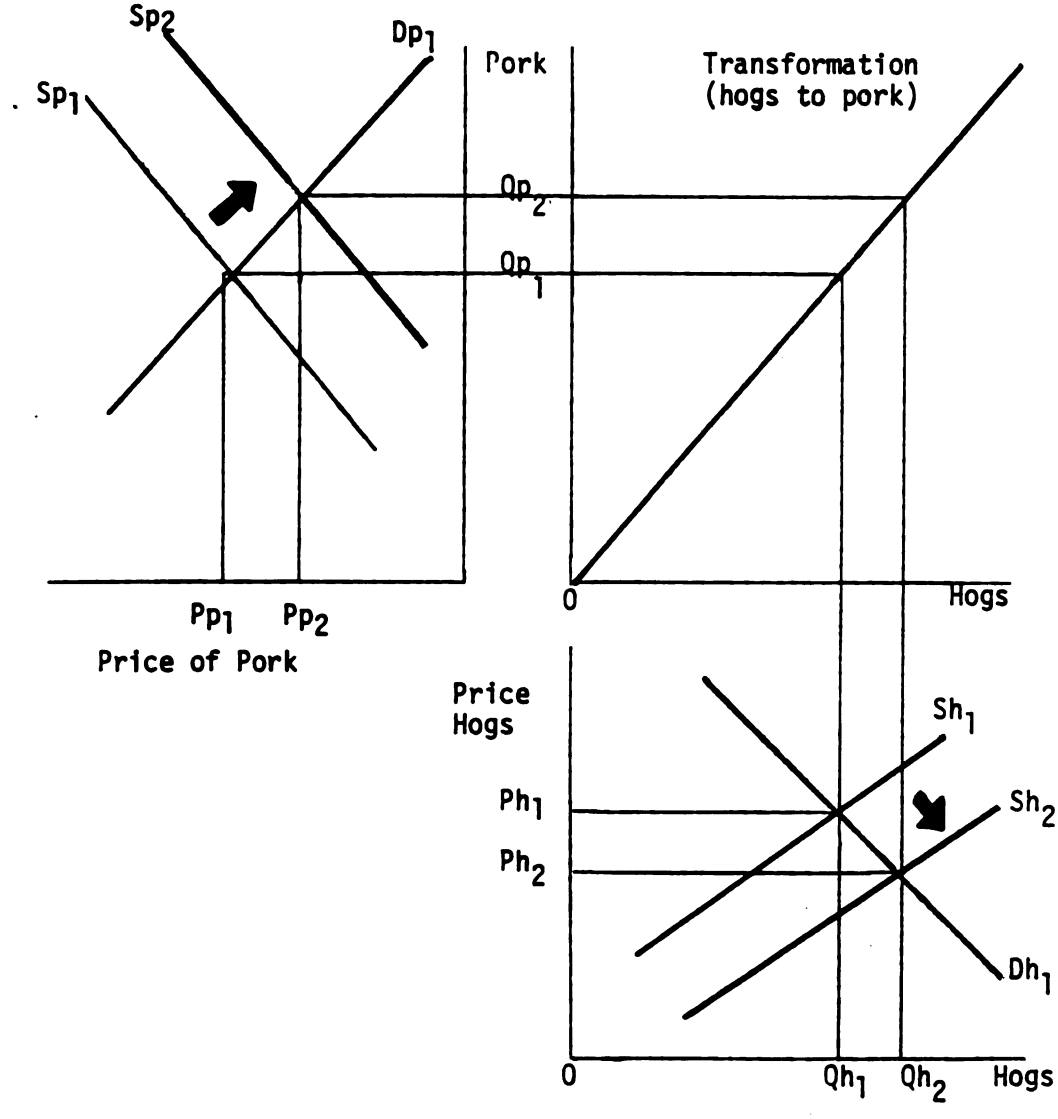


FIGURE 5.2. IMPACTS OF A CHANGE IN PRODUCTION EFFICIENCY ON EQUILIBRIUM VALUES (Model 1)

Figure 5.3 illustrates the impacts of a change in yield (increased yield of meat per animal) on equilibrium values as fewer animals or less meat are condemned at the packer level as a result of the use of a drug at the producer level. In the case of sulfamethazine, for example, jowl abscesses, are reduced. The consumer pays a lower price while the price spread is reduced. Consumers consume more pork and total pounds produced (both edible and inedible) is lower.

Figure 5.4 combines the impacts of a change in production efficiency and yield per animal on market equilibrium conditions. More hogs produced, more pork consumed, lower prices per period result, likely impacts with the addition of sulfa to feed.

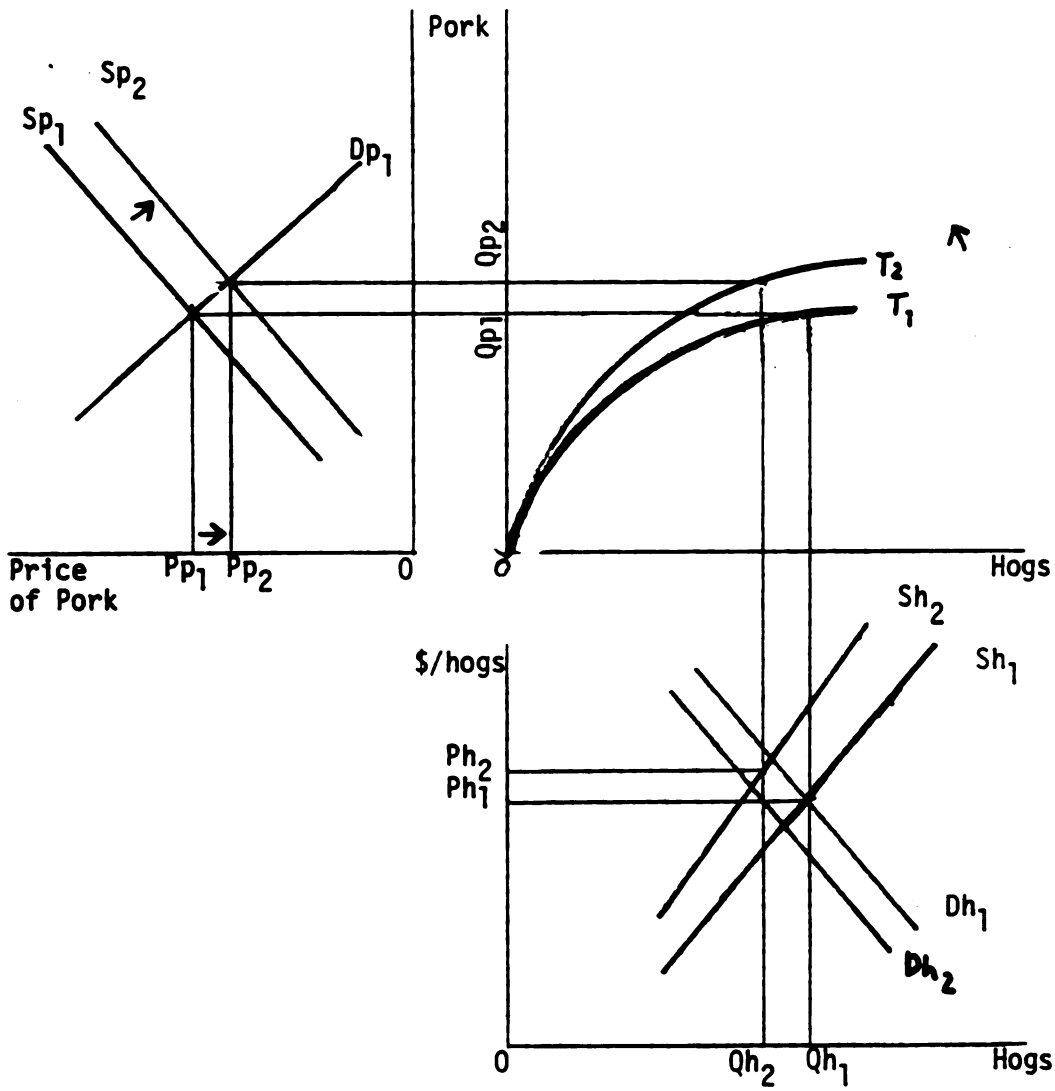
5.1.1.1 Impacts of a Sulfa Feed Additive Ban on the Animal Health Industry

As reported above, four firms in the animal health industry received approximately $50 million from the sale of sulfa combination feed additives in 1979. Sales estimated for the years 1973 through 1980 are presented in Table 4.2.[1]

A ban of the products shown would initially reduce sales, revenue and profit of the animal health manufacturers of these products. Whereas, the sales figures shown in Table 4.2 provide a benchmark, several factors with potential influence on the economic position of these firms and the industry in both the short and longer term should be considered:

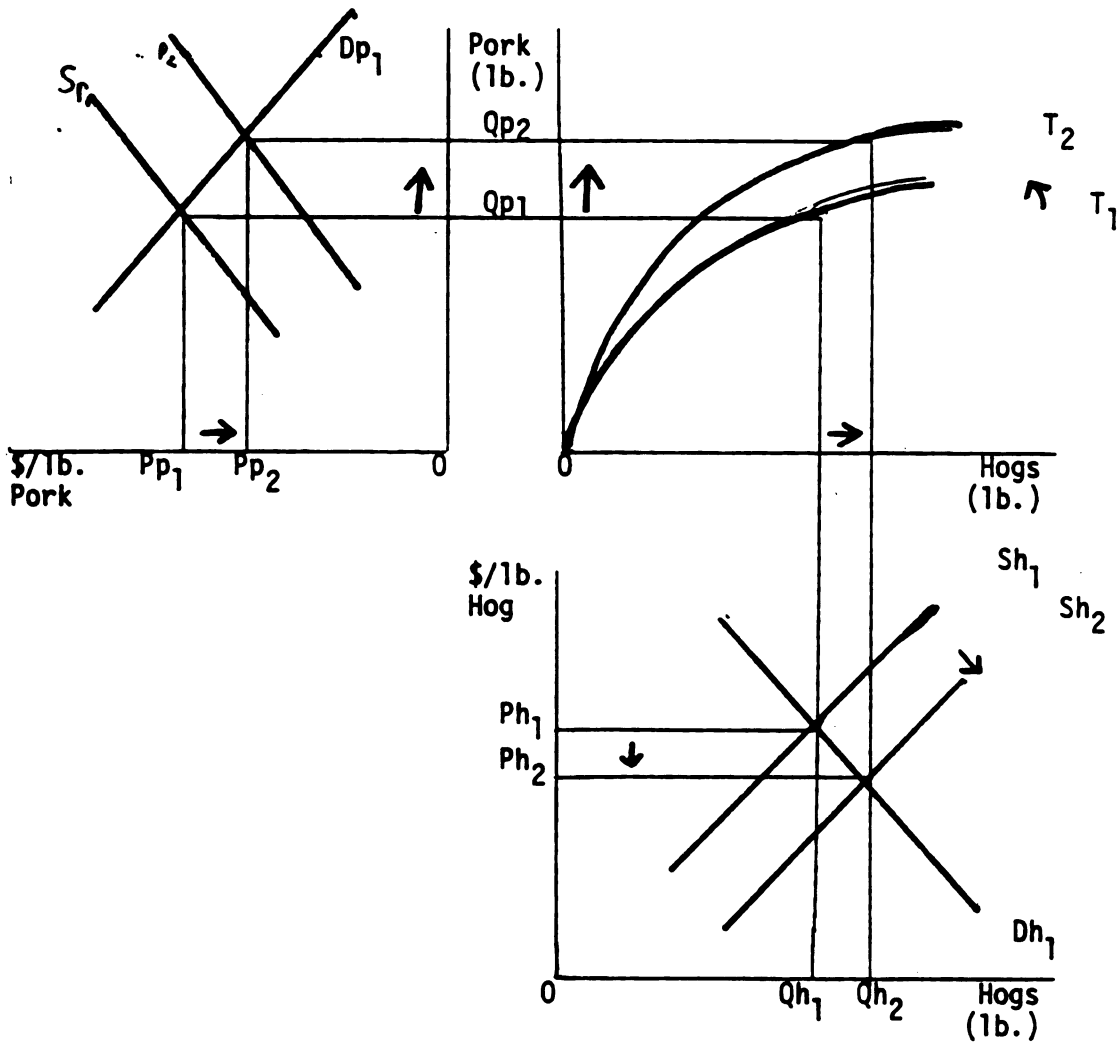
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[1]This figure overstates the quantities received at the manufacturers' level to the extent distributor or dealers' margins have been included.



Source: Clark Burbee, USDA

FIGURE 5.3. IMPACTS OF AN INCREASING IN YIELD/ANIMAL ON HOG AND PORK MARKETS (Model 2)



Source: Clark Burbee, USDA

FIGURE 5.4. IMPACTS OF CHANGES IN YIELD/ANIMAL AND PRODUCITON EFFICIENCY ON MARKET EQUILIBRIUM CONDITIONS. (Model 3)

1) A ban on sulfa feed additives in swine, if based on emergent experimental evidence indicating carcinogenicity, might preface more widespread sulfa bans in the future. If all sulfonamides were completely banned from livestock use, manufacturers' economic loss would substantially exceed the loss of sulfa swine feed additives alone.

2) Several industry strategies in the event of a sulfa feed additive ban might be anticipated on the basis of the analysis of Chapter IV. To recall, Chapter IV indicated that a complex, economically powerful pharmaceutical firm frequently responds to incentives to:

1) Define and exploit multiple market outlets for its products.

2) Use measures of price and non-price competition in order to expand sales.

3) Employ specialized public affairs and legal staff to anticipate and influence regulatory and legislative developments.

4) Invest heavily in research &nd development.

These factors suggest that firms confronting a ban of sulfa swine feed additives could be expected to expand markets for all sulfa drug articles not banned including water medicants, boluses, and injectables. The firms might also market or seek approval to market the remaining drug components of the sulfa combination drugs which were not implicated.

Animal health firms could be expected to invest in advertising and promotional activities informing customers of available alternatives to sulfa feed additibes in the event of a ban.[1] Before a ban were

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[1]Another strategy might result in increased promotional activities encouraging veterinarians to prescribe sulfa.

finalized, however, industry firms might predictably mount public relations campaigns enlisting support of livestock producers and the feed industry to prevent regulators from instituting a ban. Similarly, sulfa manufacturers will employ regulatory expertise to prevent or impede a drug ban.[1]

A ban on use of sulfa feed additives would open up a market segment for substitutes toward which research and development efforts within the industry would likely be directed. (The ban of DES led to development of alternative hormone implant growth promotant products.) To the extent new products are priced higher than old products, buyers will face higher costs and adjust their drug use accordingly.

In summary, a proposed or actual ban on the manufacture and sale of sulfa swine feed additives by the animal health industry would result in a short term decrease in sales, but economic incentives and standard operating procedures within the industry combine to suggest that a ban proposal would be tenaciously resisted and that sulfa manufacturers and competitors would mobilize economic resources to develop and explore alternative products. Over the medium and longer term, these factors suggest sulfa manufacturers would be fairly resilient to a sulfa feed additive ban.

5.1.1.2 Impacts of a Sulfa Feed Additive Ban on the Commercial Feed Industry

The feed industry, in losing sulfa feed additives, would lose a product, an input and a contaminant. Chapter IV analyzed the nature

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[1]The DES ban came about only after years of counter-maneuvers.

of the feed industry's economic interests in sulfamethazine and sulfathiazole feed additives. Summarizing briefly, as a product, sulfa feed additives and sulfa medicated feeds confer benefits on the industry as they afford feed manufacturers an effective means of differentiating products in order to expand demand among livestock producers and make this demand less elastic. Doanes Market Research estimates hog producers spent approximately $70 million in 1979 on ASP-250, CSP-250, Chlorachel-250, and Tylan-Sulfa.[1] As inputs, sulfa feed additives represent costs to the industry. Purchase figures for 1979 were about $50 million.[2] As contaminants, sulfa feed additives impose costs on the industry associated with extra quality control expenses (required to combat sulfamethazine carry-over), the risk of regulatory intervention, the risk of product liability suits, or loss of feed sales due to contamination fears of hog producers.

The feed industry began mixing sulfa feeds in a period when fear of contamination was negligible, thus eliminating this expected cost to the industry. In the latter 1970s, awareness of sulfamethazine contamination had increased in the feed industry, the swine industry and regulatory agencies, contributing to higher expected industry costs associated with sulfa contamination and a decrease in sulfamethazine sales. Many feed manufacturers (including some large Midwestern state co-ops) elected not to mix sulfamethazine. These decisions reflected

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[1] Interview with Holmes, Doanes Market Research.

[2] IMS America, Ltd. Personal correspondence.

a shift in the relative balance of expected costs and benefits associated with sulfamethazine.

A ban of both sulfa swine feed additives would eliminate the benefit attributable to sulfa as a product (opportunity to mix this drug as a service, advertise this drug, increase the margin on sulfa drug articles, et cetera); it would also eliminate costs associated with the purchase of sulfa drugs from the animal health industry and costs associated with sulfa contamination (expected costs of regulatory interventions or sanctions, costs of sulfa quality control and expected costs of product liability due to sulfa).

Whether firms in the industry benefit or lose from a sulfa ban depends upon the availability, the popularity, costs, prices and contamination potential of substitute products. Because sulfa drugs are "old" and because the patent on ASP-250 expires in 1982, it is likely a replacement drug (if newly patented and approved) would be more costly.

5.1.1.3 Impacts of a Sulfa Ban on the Swine Industry

Impacts of a sulfa ban on the swine industry depend on the economic value of sulfa relative to alternative drugs. Because sulfamethazine and sulfathiazole are generally used in combination with penicillin and chlortetracycline or, in the case of sulfamethazine, with tylosin, very little research is available on the individual merits of either drug. As stated above, the only disease claim noted in the Code of Federal Regulations for sulfamethazine is the control of jowl abscesses.

The Hays analysis of existing experimental evidence on the effectiveness of antibiotic-antibacterial usage in swine production (cited above) compared a number of antibacterials including ASP-250, CSP-250 and Tylan-Sulfa. Table 5.1 summarizes experimental data comparing the performance of sulfa additives to other antibacterials and to controls (receiving no antibacterials). As indicated, sulfa additives demonstrate the greatest impact upon young pigs (19 to 57 pounds) and with respect to rate of gain, showing a 21.3 percent improvement over control pigs given no other antibacterials. Other antibiotic additives resulted in a 13.7 percent improvement over controls.

The sulfa additives improved feed efficiency 8.2 percent over control pigs during the starter phase (compared to 6.5 percent improvement over control or substitute products).

Corresponding figures for growing pigs (37 to 109 pounds) are shown in Table 5.1. Impacts of sulfa drugs and other antibiotics on growth and feed conversion drop as the pigs grow, but remain important.

The economic value of sulfa feed additives to swine producers depends upon their contribution to both the mean and variance of swine producer profits over time. Hog producer profits reflect differences between total revenue from sales and total costs. Impacts on feed efficiency, rate of gain, morbidity and mortality[1] influence the determinants of profit for individual producers. Recall the producer

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[1]Herd feed efficiency figures should capture a large component of the impacts of morbidity and mortality exclusive of veterinary costs and some replacement costs.

TABLE 5.1. COMPARISON OF ANTIBACTERIALS AS GROWTH PROMOTANTS FOR YOUNG PIGS[1]

Additives	No. Exp.	Percent Improvement Over Control Pigs	
		Avg. daily gain	Feed/gain
Starting Pigs (19 to 57 lb.)[2]			
ASP-250, CSP-250, Tylan-Sulfa	104	21.7	8.2
Other Antibiotics	274	13.7	6.5
Growing Pigs (37 to 109 lb.)[3]			
ASP-250, CSP-250, Tylan-Sulfa	32	15.4	5.7
Other Antibiotics	248	10.7	4.6

[1]Hays, University of Kentucky
[2]Data from 378 experiments, 10,023 pigs
[3]Data from 280 experiments, 5,783 pigs

Source: Virgil W. Hays, "Effectiveness of Feed Additive Usage of Antibacterial Agents in Swine and Poultry Production," 1978.

has no control over competitive market prices. Increases in feed efficiency exert impacts on two factors influencing profit. An increase in feed efficiency means a reduction in the unit cost of hogs--in other words, equal production is achieved using less feed (reducing total variable costs) or, alternatively, increased production is achieved with the same amount of feed (increasing total revenue).

An increased rate of gain implies increased quantity of pork produced per unit time. This phenomenon represents a savings in per hog fixed costs because the total costs of such fixed items as depreciation, interest, taxes, repairs and insurance are spread over increased production.

In the aggregate, of course, increases in supply decrease prices. Decreased prices decrease producer profit as they decrease individual producer's total revenue. The amount prices and total revenue fall due to an increase in supply depends on the price elasticity of the aggregate demand relationship for pork. If, as frequently reported, this demand relationship is slightly inelastic,[1] total revenue to the hog industry declines as supplies increase, ceteris paribus.

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[1]U.S. Department of Agriculture, Economic Research Service, Price-Quantity Relationships for Selected Retail Cuts of Pork, Agricultural Economic Report No. 245 (Washington, DC: NG, pp. 37-45). See Appendix B, "Theory of Pork Demand, Alternative Approaches and Elasticity Estimates." Specifically, retail pork elasticities: Brandon (-0.75 in 1961); Trierweiler and Hassler (-0.84 in 1970); Myers, Havlicek and Henderson (-.734 in 1970).

In order to place economic value on the contribution of sulfa feed additives to swine production in terms of impacts on feed efficiency, assume that sulfa feed additives improve lifetime feed conversion between 1 and 5 percent over pigs receiving no sulfa. (It seems likely that over a lifetime the difference in feed conversion would settle at the low end of the range.[1]) Then the savings in feed costs attributable to use of sulfa additives constitutes one partial measure of economic value.

Table 5.2 indicates the average total receipts, feed and total costs of producing hogs in the United States, all types and all enterprises for 1978.[2] Because a vast majority of swine receive sulfa additives at early stages of growth, for purposes of discussion the average costs shown in Table 5.2 will be assumed to include the use of sulfa additives. Then, with a ban it is assumed feed efficiency declines and feed costs rise between 1 and 5 percent over 1978 figures. Table 5.3 indicates the increase in average feed costs attributable to a ban of sulfa additives given a contribution to feed efficiency of, alternatively, 1 or 5 percent. Summed across the number of swine marketed in 1978, a ban of ASP-250

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[1]USDA estimates medium and high efficacy levels of sulfa combination drug performance in a 1979 report. Assuming high efficacy, a ban would have decreased supplies by 2.2 percent; medium, by 1.5 percent. See below.

[2]U.S. Department of Agriculture, Economics, Statistics and Cooperatives Service, Costs of Producing Hogs in the United States--Final 1978, Preliminary 1979, and Projections for 1980, Committee on Agriculture, Nutrition and Forestry, U.S. Senate (Washington, DC: U.S. Government Printing Office, July, 1980).

TABLE 5.2. COSTS AND RETURNS FROM PRODUCING HOGS BY TYPE AND SIZE OF ENTERPRISE, ALL REGIONS

Type of Enterprise and Annual Sales (head)	Receipts	Total Cash Costs	Feed Cost	Feed Cost + 1%	Feed Cost + 5%	Total Costs	Total Costs (at Feed Costs + 1%)	Total Costs (at Feed Costs + 5%)
Farrow-to-finish:								
All sizes	47.11	33.77	23.88	24.19	25.07	48.84	49.15	50.03
40	46.89	36.34	24.18	24.42	25.34	62.43	62.67	63.59
140	47.05	35.45	24.00	24.24	25.20	58.82	59.06	60.02
300	47.44	33.05	23.93	24.17	25.13	49.60	49.84	50.80
650	47.47	32.58	23.78	24.02	24.97	46.16	46.40	47.35
1,600	47.26	33.36	23.92	24.16	25.12	46.60	46.84	47.80
5,000	45.86	32.04	23.67	23.91	24.85	42.06	42.20	43.24
Feeder pig production:								
All sizes	87.61	52.97	31.91	32.23	33.50	91.65	91.97	93.24
	86.80	55.24	33.72	34.05	35.41	111.79	112.12	113.48
	94.93	53.24	31.15	31.46	32.71	95.09	95.40	96.96
	85.34	52.42	31.44	31.75	33.01	93.27	93.58	94.84
	84.26	49.33	32.36	32.68	33.98	76.03	76.35	77.65
Feeder pig finishing:								
All sizes	47.82	44.09	18.55	18.73	19.48	52.39	52.57	53.32
140	48.02	45.46	18.02	18.20	18.92	60.37	60.55	61.27
300	47.27	42.62	18.34	18.52	19.26	51.94	52.12	52.86
650	48.10	43.86	19.05	19.24	20.00	52.58	52.77	53.53
1,600	47.94	44.09	18.44	18.62	19.36	49.96	50.14	50.88
5,000	48.36	45.86	18.42	18.60	19.34	50.76	50.98	51.68

TABLE 5.3. COST INCREASE PER HOG AND FOR TOTAL U.S. HOG SLAUGHTER ATTRIBUTABLE TO SULFA BAN

	1978 $	1979 $	1980 $
Cost of Production per 220 lb. Market Hog			
Feed	52.51	58.76	57.18
Total Direct Costs	73.06	83.63	86.04
Total Nonland Costs[2]	89.43	100.94	105.53
Gross Return	103.64	90.46	76.56
Net Margin	14.21	(-10.48)	(-28.97)
Cost Increase per Hog of Sulfa Ban Assuming:			
1% increase in feed costs	.53	.59	.57
5% increase in feed costs	2.63	2.94	2.86
Total U.S. Hog Slaughter			
numbers (1,000)	77,315	89,099	96,074
value ($)	4,059,810,650	5,235,457,240	5,493,511,320
Total Cost Increase of Sulfa Ban Assuming:			
1% increase in feed costs ($)	40,598,106	52,354,572	54,935,113
5% increase in feed costs ($)	202,990,530	261,772,862	274,675,566

[1] Cost estimates from U.S. Department of Agriculture, Costs of Producing Hogs, 1978.

[2] Includes costs that need to be covered to justify operation in the situation.

translates into an increase in costs of production attributable to feed of $40.6 or $203 million (see Table 5.3). Corresponding figures for 1979 were $52.3 and $261.7 million.[1]

As suggested in Chapter IV, a major reason for swine producer use of sulfa drugs is disease prevention and control. Antibacterials function as an insurance policy against catastrophic loss from disease which might destroy a herd. Finally, sulfa drugs enhance growth promotion or rapidity of gain, another measure which has economic ramifications for reducing unit costs associated with use of plant, equipment and management but which is not reflected in a measure of feed conversion. To summarize the economic importance of sulfa drugs to the swine industry:

1) approximately $70 million was spent on sulfa combination feed additives in 1979;

2) assuming a 1 percent reduction in feed efficiency attributable to a ban of sulfa drugs, a ban of these drugs would have cost the swine industry $52.3 million in increased feed costs in 1979. While a ban would have prevented producers spending the $70 million on sulfa, presumably many would have turned to substitute products with that money. The feed efficiency calculation does not capture economic benefits of growth promotion or the insurance factor, both of which are probably substantial;

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[1]This estimate does not net out the costs of sulfa drugs. If substitutes are considered, the 1 percent figure is probably more accurate. If no substitutes were available, the 5 percent figure would appear to be closer to the truth.

3) If a sulfa ban caused a 5 percent reduction in feed efficiency and a 5 percent increase in feed costs, 1979 increases in feed costs alone would have approached $261.8 million.

Two recent studies analyze economic impacts of broad-based bans of a variety of animal drugs, including sulfonamides.[1] Results of these studies assist in establishing benchmarks for assessing economic and exposure impacts of policies concerning only sulfa drugs. The impacts of a ban of several different antibacterial drugs, especially applied to multiple livestock species, will probably overstate the impacts of either a complete or a partial ban of sulfonamides in swine alone. This overstatement becomes more likely if alternative conduits for sulfa administration remain legal or if possible problems of enforcing producer compliance are considered.

The USDA and OTA studies employed similar analysis and virtually identical economic modeling but drew somewhat different conclusions due to differences in assumptions. The USDA study analyzes a ban on the use of sulfonamides and tetracyclines at subtherapeutic levels in swine feed.[2] Study conclusions do not isolate the effects of

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[1]U.S. Department of Agriculture, Economic Effects of a Prohibition on the Use of Selected Animal Drugs, Agricultural Economics Report No. 414 prepared by William J. Boehm, Clark Burbee and William Gallimore (Washington, DC: 1978); J. C. Headley, "Economic Aspects of Drug and Chemical Feed Additives," report prepared for the U.S. Congress, Office of Technology Assessment, 1978.

[2]First the report examines isolated one-year market effects of antibiotic bans in single species and then the cross-species market effects of various drug bans over a period of five years. A recursive econometric model linking livestock, wheat and feed grains sectors is used. Reductions in feed efficiency and increases in mortality and

banning only sulfonamides. The authors note it is difficult to isolate responses of swine to individual drugs due to the widespread use of combination drugs. They estimate the percentage reduction in swine output from banning sulfa drugs in swine feed at 1.5 percent annually under a medium efficacy assumption and a 2.2 percent reduction under a high efficacy assumption.

USDA estimates that banning the subtherapeutic use of all drugs from hog feed (this includes bans on tetracyclines, sulfas, nitrofurans, and penicillins) would have reduced 1976 hog production by 600 million pounds carcass weight (a 5 percent drop) under the moderate efficacy assumption and by 2,270 million pounds (an 18 percent reduction) under the high efficacy assumption.

Other one-year impacts noted for the swine subsector:

1) hogs would be marketed at lower weights (by assumption);

2) reduced total feed usage by hog producers would reduce total costs (assuming effect of lower marketing weights swamps feed conversion impacts);

3) producers would pay slightly higher feed costs per pound gain (due to reduced feed efficiency);

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condemnations attributable to cessation of use of the various antibiotics are estimated to modify production coefficients in order to reflect the ban. Two alternative efficacy levels are used to bracket probable actual levels. Additional assumptions include: 1) no substitutes for the banned antibiotics exist; 2) effects from banning each drug are additive; 3) commercial animals react in the same manner as test animals; 4) no new technologies become available in the time period; and 5) livestock producees react to a drug ban by maintaining pre-ban feeding schedules in order to exploit fixed plant and equipment.

4) total revenue of hog producers would be unchanged to slightly higher. Any increase in net revenue could be expected to result in expanded capital investment leading to an increase in future production;

5) consumer price increases on the order of 5 percent (assuming medium efficacy) would result as customers bid up the price of a reduced supply.

Conclusions from the five-year cross-commodity model indicate:

1) banning all drugs from all species results in a first year increase in barrow and gilt prices of 5 percent ($2.32 per hundredweight);[1]

2) by the fifth year, barrow and gilt production adjustments would have narrowed the gap between prices (with the ban) and a baseline projection (without ban) to a rise of 1.14 percent ($0.54 per hundredweight);[2]

3) the across-species effect of a ban on sulfa use in swine production would cause a slight increase in broiler prices because of the cross effects between commodities.

The Office of Technology Assessment study concluded with more extreme results. The scenario including a ban of nitrofurans and sulfa drugs in swine, chickens and turkeys resulted in supply shifts

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[1] At 1976 prices.

[2] At 1976 prices.

of -2.5 percent for the pork industry and -12 percent for the broiler and turkey industries. The difference in price elasticity of demand and coupling the effects of nitrofurans and sulfa drugs on the pork and poultry sectors over a longer period results in more extreme impacts in the OTA study. Pork consumption falls by 2.5 percent over an 11-year period while barrow and gilt prices increase approximately 10 percent due to decreased supplies of chickens and turkeys. Since many of the results depend on supply impacts within the poultry industry due to drug bans there, results are not strictly applicable to the current study.

In summary, the USDA and OTA studies provide similar conclusions regarding qualitative effects of broad-based drug bans over multi-year periods and when combinations of drugs are banned affecting several species. Quantitative estimates of economic impacts differ in some respects due to assumptions employed in the studies.

For our purposes, the studies provide a means of bracketing the expected economic impacts of any restrictions on sulfonamides or sulfamethazine alone. The USDA study demonstrates that a total ban of a variety of major drugs in hog feeds would have reduced supplies 5 percent and increased consumer prices for pork 5 percent in the first year but in the cross-commodity, five-year model, by the fifth year pork price differentials with and without a ban would have dropped to approximately 1 percent. Headley's results of a multi-species, multi-drug ban predict a drop of pork consumption of 2.5 percent over an 11-year period with a rise in barrow and gilt prices of approximately 10 percent.

A total ban of only sulfonamides in swine production would be expected to create a smaller impact than a ban on these drugs plus the chlortetracyclines, penicillins, and nitrofurans. Once again, however, a lack of experimental data on the sulfonamides alone prevents empirical assessment of the specific impact of a ban on this single antibacterial.

Similarly, a restriction on only sulfamethazine (while continuing approved uses of sulfathiazole) would create even smaller aggregate impacts than a restriction on both sulfonamides because these drugs are considered fairly close substitutes.

Finally, a restriction of sulfonamides to starter feeds would be expected to have the least adverse economic impact of any of the variants. The sulfa combination drugs are most valuable in terms of growth promotion, feed efficiency and disease prevention at early stages in the production cycle. Therefore, their restriction to the starter stage would not sacrifice important early impacts. For disease treatment at later stages, veterinary recommendations call for heavier doses than present in feed additives and these can be administered in water or by alternative means.

5.1.2 Effectiveness of Banning or Restricting Sulfa

This section turns from a review of the economic impacts associated with sulfa bans in swine feed to an examination of the potential effectiveness of the three sulfa policy variants in reducing population exposure to sulfa-contaminated swine. The analysis of potential program

effectiveness builds upon a conceptual model of producer decision-making in which expected benefits and costs of regulations influence compliance. It considers the incentives present in policy measures which would ban all sulfa drugs in swine feeds, restrict the ban to sulfamethazine or finally, restrict sulfa use to starter feeds.

5.1.2.1 Ban of Subtherapeutic Feed Additive Use of the Sulfa Drugs

A general ban of sulfa drugs for purposes of subtherapeutic use in swine feeds would eliminate the use of ASP-250, CSP-250, Chlorachel-250 and Tylan-Sulfa (except, perhaps, under veterinary prescription).

Producers wishing to continue use of sulfa medications would then have basically two options: obtaining a veterinary prescription for therapeutic use of sulfa, or purchase of sulfa drugs for use as water medicants.

Interviews conducted with Michigan hog producers indicated that several producers had switched to the use of sulfa water medicants for a combination of economic reasons, disease management factors and concern over potential residue problems. If a sulfa feed additive ban were effected, it is likely producers would consider therapeutic use alternatives for sulfa along with the use of non-restricted growth promotant feed additives, and vaccination for atrophic rhinitis.

The effectiveness of the policy in reducing public exposure to sulfa-contaminated swine would depend upon producers exercising proper

care in their use of sulfa drugs at therapeutic levels. Producers would still face the necessity of segregating finishing hogs from those on medication, and of following withdrawal times. However, the policy measure would eliminate problems stemming from contaminated feeds and the necessity of cleaning feed equipment.

5.1.2.2 Banning Subtherapeutic Use of Sulfamethazine Only

Banning sulfamethazine but not sulfathiazole would almost certainly induce a switch to this close substitute on the part of many producers. Research has shown that sulfathiazole is eliminated more rapidly from the swine's system, is less electrostatic and, consequently, less liable to hang up in feed equipment. FSQS monitoring statistics confirm the fact that almost all sulfa residue violations are attributable to sulfamethazine; less than one percent is caused by sulfathiazole even though CSP-250 (containing sulfathiazole) is estimated to have a market share of approximately 10 percent of the swine combination feed additive market.

Exposure to sulfa residues in pork, therefore, would probably be significantly reduced through institution of this measure.

A restriction on the subtherapeutic use of sulfamethazine alone or of both currently used sulfonamides would exert several distributional impacts which should be noted. As producers lose access to one input, they seek substitutes. Banning only sulfamethazine would benefit the one U.S. producer of CSP-250 containing sulfathiazole.[1]

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[1] Diamond Shamrock.

Banning both sulfonamide feed additives would be expected to benefit producers of substitute drugs, sulfa water medicants, sulfa therapeutic drugs and, to the extent veterinary prescriptions are required, the veterinary profession.

5.1.2.3 Restriction to Starter Feeds, The Canadian Experience

This policy would permit the addition of currently approved sulfa drugs to swine feeds fed up to a designated weight. Canadians adopted such a policy and claim success for the measure. Technically, a pre-starter feed is fed up to about 6 weeks post-weaning and a starter feed up to about 40-50 pound body weight. (Terminology for various types of feeds differs in usage.) Restriction of sulfa drugs to starter feeds would apply to both commercial and on-farm mixers.

The rationale for this policy is based on the assumption that hog producers continue to feed medicated feed too close to slaughter time for clearance. As such, the policy represents an extension of current withdrawal requirements of 15 days. Support for this policy was premised on early belief that intentional misuse or sloppy sulfa use by hog producers was the primary cause of sulfa violations.

Some aspects of the Canadian experience relating to use and regulation of sulfa medications in hog feeds bear mention at this point.[1]

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[1] Information for this section was provided by officials from industry and government: C. L. Friend, Executive Secretary, and Jay Johnston, Technical Director, Canadian Feed Industry Association; Dr.

Sulfamethazine is permitted for use in swine feed in the chlortetracycline-sulfamethazine-penicillin combination produced by American Cyanamid and legal in the U.S. Because Canadians consider their market for swine products to extend throughout North America (with some exports to Japan) concern mounted in 1978 when U.S. meat inspection of swine product imports from Canada began to indicate violative sulfonamide residues. Canadians feared that sulfa residues might be used as a non-tariff barrier to restrict pork exports to U.S. and to Japan.[1] Canada's meat inspection program has sampled for sulfa residues since the mid 70s. However, sulfa testing by Canadians was intensified as a response to the U.S. experience.

Canadian response to the sulfa problem[2] was an administrative action restricting the use of sulfamethazine to hog starter feeds, defined in the policy as feeds fed to swine up to a weight of 80 pounds. This restriction translates into a withdrawal period of approximately 80 days.

As explained by Canadian officials, the Canadian policy of restricting sulfa to starter feeds addresses the problem of negligent

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M. G. Morissette, Meat Hygiene, Meat Inspection Service, Agriculture Canada; Mr. McKay, Bureau of Veterinary Medicine, Department of Health and Welfare, Ottawa, Canada, February 20, 1981.

[1] Interview with Johnston, Canadian Feed Industry Association.

[2] Estimates of violation rates reached 14-15 percent. By 1981, rates had been halved.

use of sulfa feeds by providing an economic disincentive for producers to extend the use of sulfa drugs past eighty pounds. Starting rations are conventionally formulated at higher protein levels than finishing feeds thus costing relatively more. A producee wishing to feed sulfa-medicated feed past eighty pounds is required to bear additional costs associated with higher protein levels in starter rations (unless he dilutes).

A second reason this policy was considered desirable by Canadians was its supposed compatibility with a fairly typical physical layout for Canadian hog production management. If farrowing units and nursery are physically separate from finishing barns along with separate feeding set-ups (including bins, sugars and mixers) then exposure to sulfa-medicated feeds by finishing hogs due to accidental contact should be reduced.

Canadian officials interviewed expressed the opinion that the policy decision has succeeded in bringing down sulfa violations although several qualifications were offered. One concerned the representativeness and overall accuracy of residue monitoring. Another person commented on alternative marketing factors contributing to the sulfa policy's apparent success. The Canadian marketing system for hogs employs a system of marketing boards. These boards do not directly manage supplies (e.g., setting quotas as in the case of poultry), but do administer a nationwide grading program and handle hog sales.

The current marketing system had its origins in the war years of the early 1940s when concern about the overall quality of the Canadian hog herd led to initiation of a program to improve the quality of the

herd. Goals were set regarding such characteristics as lean/fat ratios and bonuses were paid to farmers for achieving them. During this time, a tatoo system for animal identification was initiated indicating lot numbers and producer origin. Dealers did not take title of the product under this system; the producer received payment directly.

Currently hogs are sold by marketing boards instead of producers. In some provinces, use of computerized systems has been instituted. A farmer with hogs available for sale advises his marketing board of the number, weight and grade. The board flashes information on a telex, packing plants make bids and the sale price is flashed and therefore publicly available. Some of the ramifications of a marketing board system combined with a system of animal identification are that sulfa or other chemical residues can be controlled through the marketing board. In cases of violation, both producers and marketing board receive notification of problems. Agriculture Canada required submission of five market hogs for sulfa testing prior to clearance for the producer to resume marketing (as did the U.S.).[1]

Canadian officials interviewed believed that a combination of policies including information and education aimed at producers, the restriction of sulfa medications to starter feed and the cooperation of marketing boards which could pressure hog producers to clean up their acts or lose marketing privileges, succeeded in reducing violation rates to current levels.

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[1]As in the U.S., the producer also had the option of marketing a lot of hogs without clearance so long as these carcasses were held pending clearance.

In the U.S. the success of a policy restricting sulfa to starter feeds depends upon its probability of effectively addressing all major causes of sulfa contamination in swine carcasses:

1) improper withdrawal of medicated feeds;

2) therapeutic doses to finishing animals prior to slaughter;

3) accidental exposure of hogs to contaminated finishing feed, feed ingredients, water or environmental contamination including urine or fecal material;

4) exposure of hogs to contamination from any of the above sources at holding stations, during transport or elsewhere in the assembly or marketing process.

The restriction of sulfa medications to hog starter feeds addresses the problem of feeding medicated feed to finishing hogs only imperfectly. It provides an economic disincentive to feed sulfa to finishers to the extent sulfa cannot be obtained except in high-protein (and more costly) starter feeds. Then the rational producer must weigh these incremental costs against the expected costs of loss from disease.

In the U.S. at present, sulfamethazine can be legally obtained without any permit in several levels of concentration ranging from a five pound bag of pre-mix containing 100 grams of sulfamethazine to sulfa-medicated complete feed. Several persons interviewed indicated that straight sulfamethazine is also readily available. Factors influencing compliance, then, include expected costs of non-compliance versus expected costs of compliance. Regulatory enforcement procedures and sanctions affect producer calculations.

Canadians were able to utilize this policy fairly successfully because of the existence of an animal identification system which increases the expected costs of non-compliance for producers. However, the policy does not explicitly address the problem of cross-contamination of feeds in commercial feed mills or on farms. Starter, grower and finisher feeds are all customarily mixed in the same commercial feed plants in the U.S. and Canada and unless special precautions are taken, contaminated finishing feeds can result from carryover of medicated starter feeds. The same holds true on farms.

A final argument for a policy measure of this sort is that limiting sulfa medications to starter feeds reduces the total quantity of sulfa drugs in the system, lessening the extent of sulfa residue problems. The accuracy of such a conclusion depends upon two major assumptions:

1) that in fact the total quantity of sulfa in the system would be reduced when all potential substitute sources (feed stores, veterinarians, etc.) are considered;

2) that a meaningful correlation exists between the vastly different orders of magnitude represented by total sulfa tonnage added to the system annually and the violative parts per million detected in swine carcasses.

Both assumptions appear dubious suggesting that this policy should not be considered effective enough to rely upon if exposure to sulfamethazine is considered a serious health hazard.

5.2 Raise the Tolerance Level for Sulfamethazine Residues in Swine

This section examines the proposal made in a petition to the Food and Drug Administration by industry groups to raise the tolerance levels for sulfamethazine residues in raw pork organs (liver and kidney) to .3 and .4 ppm, respectively.[1] The stated rationale for this proposal includes the assertion that conformance to current tolerance levels is impossible and that human safety would not be impaired by such a move. In fact, the petition argues, exposure to current levels has occurred for many years with no adverse effects, although increased monitoring and altered analytical techniques on the part of regulatory agencies have fostered the misleading perception that violation rates suddenly reached crisis proportions in the latter 1970s.[2]

The analysis does not deal with the evaluation of human health impacts potentially attributable to such a policy change. It does assess potential impacts upon human exposure to sulfamethazine residues along with probable economic impacts upon the four major industries in the sulfa case.

5.2.1 Economic Impacts of an Increase in Sulfa Tolerance Levels on the Animal Health Industry

At the animal health industry level, an increase in tolerance levels for sulfamethazine would benefit producers of sulfamethazine products,

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[1]These organs retain sulfamethazine and generally demonstrate higher levels than muscle and fat tissues.

[2]Arguments cited in American Cyanamid's "Petition to Increase Tolerance of Sulfamethazine."

namely, American Cyanamid, Rachelle Laboratories and Elanco, possibly at the expense of competitors. An increase in tolerance levels would reduce much of the stigma which has become associated with sulfamethazine and which appears to have cut into the market share of American Cyanamid and sulfa products, generally.[1]

An FDA action to increase the sulfamethazine tolerance level would be viewed as a victory by American Cyanamid and other manufacturers of sulfamethazine products. Such an action would probably similarly reduce uncertainty for manufacturers of other sulfonamides, although Diamond Shamrock could be expected to lose some sales as a result of such a development. An FDA action to increase tolerances would certainly be very carefully scrutinized by other firms in the animal health industry in attempts to learn from the successful American Cyanamid regulatory strategy. Lawyers and regulatory affairs personnel in this industry would probably cite an FDA action increasing tolerances in the sulfamethazine case as precedent for similar agency action in future cases.[2]

In the event of an increase in tolerances, manufacturers of sulfamethazine products would likely invest resources in advertising and promotional campaigns to regain market share. If the propensity of a feed additive to cause a violative residue is considered a negative product attribute, then advertising efforts would probably be directed at accentuating the change in the regulatory assessment of this attribute. In an industry with administered prices in which costs are only

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[1] IMS, America, Ltd., personal correspondence.

[2] A large part of the (as yet) unsuccessful argument in the American Cyanamid petition to FDA rested upon an earlier FDA action which raised tolerances for arsenic.

one among many factors entering into a pricing decision, it is not necessary that any increased costs of advertising sulfamethazine products would be reflected in their price, particularly if a pricing goal concerned regaining market share. When prices fail to reflect costs, consumers of other products subsidize these costs.

At this juncture, the impact of a change in tolerance levels is probably somewhat of a moot point due to alterations in the physical form of sulfamethazine feed additives announced in early 1981. The move to a granulated product appears to hold promise of greatly reducing sulfamethazine cross-contamination within mills, a major factor in violative residue rates.

With respect to the modification in technology represented by granulation, it appears relevant to ask whether or not incentives favoring its development might have been eliminated had the tolerance been raised initially.

Summarizing impacts of an increase in tolerance levels upon the animal health industry reveals:

1) distributional benefits to manufacturers of sulfamethazine products and distributional costs to competitors;

2) likely advertising and promotional campaigns to regain lost market share;

3) probable animal health industry perception of an FDA sulfamethazine decision as a "victory" which establishes a precedent for future animal drug or agricultural chemical cases. Potential increase in petitions to FDA;

4) an increase in the tolerance level might have eliminated incentives encouraging technological processing modifications resulting in granulation had it been enacted.

5.2.2 Economic Impacts of an Increase in Tolerance Levels on the Commercial Feed Industry

Chapter IV analyzed the nature of the feed industry's economic interests in sulfamethazine feed additives as a balancing of economic benefits associated with sulfa feeds as products and costs associated with the drug as inputs (purchase price) as well as expected costs of sulfa connected with its contamination potential. The strategies which various firms have chosen with regard to sulfamethazine reflect the manner in which these intendedly (although imperfectly) rational firms have balanced expected costs and benefits.

The previous chapter presented case evidence indicating that firms have adopted a variety of actions with respect to sulfamethazine:

1) two large midwestern state co-ops suspended manufacture of sulfamethazine feeds and substituted sulfathiazole instead[1] due to perceived product liability risk;

2) many large firms with national market areas continued to carry sulfamethazine products believing their quality assurance to be adequate to handle the drugs and believing in the superiority of sulfamethazine products;

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[1] Interviews with Olson, Indiana Farm Bureau Services, and Ego, GrowMark.

3) other non-cooperative firms, citing trouble with FDA, ceased manufacture of many sulfamethazine products;[1]

4) one smaller, independent co-op which was cited by FDA for a sulfamethazine violation, installed numerous quality control procedures in order to facilitate FDA approval of pending medicated feed applications;[2]

5) a small local elevator in Michigan instituted a policy of custom mixing sulfamethazine feed only if the customer supplied his own flush.[3]

A policy increasing tolerance and action levels for sulfamethazine in feeds would probably marginally alter the feed firm's balance of expected benefits and costs of mixing sulfamethazine feeds. Such an action would improve the product's popularity with hog producers; policy impacts upon the price of sulfamethazine and sulfa combination drugs are indeterminate in an imperfectly competitive market; however, the increase in tolerance levels would probably decrease the firm's expected costs associated with sulfamethazine contamination potential--both regulatory costs and product liability costs. Thus, benefits from sulfa the product increase while expected costs of sulfa the contaminant decrease. If the price of sulfa the input remains constant, then the feed industry will increase its manufacture of

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[1]Kent Feeds, Muscatine, Iowa.

[2]Hamilton Cooperative, Hamilton, Michigan.

[3]Mason County Elevator, Mason, Michigan.

sulfamethazine products. Spokesmen for members of the feed industry have announced that they could live with an action level of 8 ppm. Presumably, some companies (such as the Illinois and Indiana Farm Bureau) would reconsider their decisions to cease manufacture of sulfamethazine products. Other feed companies which have carried and mixed sulfamethazine products all along would presumably maintain or expand operations. Changing incentives could imply a marginal relaxation in quality control procedures although this result is necessarily speculative.

5.2.3 Economic Impacts of an Increased Sulfamethazine Tolerance Level on the Swine Industry

Economic impacts of an increased sulfa tolerance level on members of the swine industry depend upon producer expectations regarding monitoring rates (and actual monitoring rates) and on producer compliance with voluntary pre-market testing requirements (the producer must have the next lot of hogs cleared after an identified violation). The future number of violations falling between .1 and .3 ppm, management practices adopted by hog producers (including use of sulfa) in the case of a higher tolerance level and assorted prices and costs also influence impacts on the swine industry.

The (satisficing) swine producer decides to use sulfamethazine products on the basis of expected net benefits (including the insurance aspect of using sulfa to control disease and reducing the risk of catastrophic loss). Expected costs stem from the price of sulfa and sulfa medicated feeds and the expected costs of a sulfa violation.

A number of components contribute to the potential total cost of a sulfa violation:

1) costs of required pre-market testing of hogs;

2) transactions costs associated with dealing with FDA inspectors--for example, time, information costs, loss of autonomy;

3) transactions and monetary costs associated with determination of the cause of sulfa violation (perhaps including the necessity to assay feed samples, change feed suppliers, negotiate compensation, or purchase new equipment);

4) costs associated with marketing delays including (a) increased feed costs (due to a longer feeding period); (b) increased physical plant costs (per hog); (c) adverse changes in price;

5) costs of condemnation of an organ or animal if the pre-test lot is violative;

6) in addition, the hog producer may forfeit sulfa feeding benefits if he stops feeding sulfa drugs for fear of contamination problems.

Many of these cost components are difficult to value in monetary terms. However, examination of the USDA sulfa monitoring program suggests some probable determinants of a swine producer's expectations regarding costs.[1] If 1977 is chosen for purposes of analysis, sulfa sampling levels and detected violations were at an all-time high. This fact could be expected to increase the well-informed producer's

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[1] If expected benefits are a function of the expected value of the marginal product of sulfa, these remain unchanged at constant use but possibly decrease when sulfa use is restricted. An increased tolerance level, by this reasoning, might influence a producer to increase use of sulfa due to perceptions of safety and increased expected benefits.

expectation of sulfa contamination costs. A total of 7,434 liver samples was taken, with 935 of these assessed violative by a USDA regional laboratory. After the USDA determines a sample is violative, it notifies the Food and Drug Administration for follow up. FDA contacts producers to ascertain cause. In many cases producers cannot be traced because of loss of animal identity in marketing channels. Estimates of the percentage of swine which can be traced vary some. USDA-APHIS estimated that 75 percent of violative swine could be traced to a producer during the sulfa campaign.[1] Earlier, an official of FSQS stated that only 50 percent of violative swine could be traced back to a producer.[2]

The General Accounting Office (GAO) determined that in a four-year period ending in December 1976, FDA district offices investigated only 37 percent of the cases referred by USDA.[3] Reasons for not investigating included identification problems and loss of timeliness.

If this rate of FDA follow up had been applied to sulfa violations, then a mere 346 producers (.37 percent x 935 sulfa villations) would have been routinely identified and contacted out of a national population of hog producers numbering well over 400,000.[4]

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[1]USDA-APHIS, Sulfa Task Force unpublished paper.

[2]Thomas Grumbley, Associate Administrator of Food Safety Quality Service cited in "USDA Pushes for Mandatory Identification," National Hog Farmer, November 15, 1979.

[3]U.S. General Accounting Office, Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues, Report to the Congress by the Comptroller General of the U.S. (Washington, DC: Government Printing Office, 1979).

[4]During Phase II of the sulfa campaign, all producers identified as marketing violative hogs were contacted by USDA field representatives.

If a producer of violative hogs can be traced, he is asked to submit five animals for further sulfa testing before shipping additional animals for slaughter. The USDA operates a testing program for these animals (under their surveillance program) or the producer may submit samples to an approved lab.

Participation in the program, however, is voluntary. GAO found in interviews with three USDA offices that 600 out of 1,100 growers asked to submit animals for pretesting between 1974 and 1976 did not comply, a percentage somewhat over 50 percent. Assuming a 50 percent pretest compliance rate, then only 173 (= 346 x .50) producers would have suffered either inconvenience or expense from submitting animals for pretesting (including marketing delay). If USDA performs the tests, there is no charge; if the producer sends samples to a private lab, he bears charges. If animals from test lots are violative, then the organ or carcass is condemned; if below tolerances, they may be marketed. (Having an animal tested for sulfa cost approximately $300-$400 per lot of five animals in 1978).[1]

Summarizing to this point: given a tolerance level of .1 ppm in 1977 and assuming 935 violations with a FDA follow up of 37% and producer pre-test compliance of 50%, then 173 producers would have been expected to bear costs or inconvenience associated with pre-testing or marketing. If sulfa assays cost approximately $400 per sample lot of five hogs, then maximum costs attributable to pre-testing were $44,000 in 1977.

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[1] C. D. Van Houwelling (National Pork Producers Council) formerly Director of the Bureau of Veterinary Medicine, quoted in Food Chemical News, July 28, 1980, p. 7.

As stated above, this figure is only a partial indication of costs associated with sulfa contamination. It does not include possible increases in feed costs (if sulfa is not used), medical expenses, investigation into sulfa contamination causes or other.

A rough estimate of some of the impacts of an increase in tolerance levels on one of the costs enumerated above can be achieved by calculating the proportion of violations falling between .1 and .3 ppm. These violations would then be removed from follow-up compliance activities if the violation tolerance level were increased. As an example, in 1977, approximately 50 percent of all violations were between .1 and .3 ppm. An increased tolerance level in that year would have saved producers approximately $34,600 in testing costs to get back on the market.

Note, this ignores aggregate changes in growth rates, feed efficiency and disease attributable to changes in management practices if producers begin to use more or less sulfa as a result of changes in policy.

Producers would benefit from reduced anxiety presumably, particularly those producers experiencing problems attributable to finishing feed contaminated at low levels. Additionally, producers making an effort to follow correct withdrawals and to segregate growers on sulfa medication from finishers not on sulfa would benefit from an increased margin for error.

Regarding other management cost differentials, survey results of a USDA study conducted to differentiate between management practices followed by producers who had been identified as marketing violative swine and those who had been checked but never been cited, reported

no significant differences in feed handling, waste disposal or other practices. Rather, the results of the survey seemed to suggest that both groups of producers could have marketed swine with violative residues.[1] This conclusion makes estimation of cost differentials between management set-ups and practices producing swine with a difference of .3 ppm sulfa (implied by the increase in tolerance to .3 ppm) extremely problematic.

The history of residue rates from 1977-1980 raises some interesting questions regarding the relative percentages of violative rates below and above .3 ppm. As stated above, in 1977 statistics indicate a roughly even breakdown between the two categories. Over the four years 1977-80, total violation rates have fallen from over 13 percent in 1977 to 4.4 percent in 1980. However, the percentage of violations over .3 ppm has increased (Table 5.4). This implies that the program and producers have had greatest success eliminating low level violations.

Responsible personnel within the USDA residue monitoring program have expressed the judgment that the combination of activities carried out by the Sulfa Task Force--as well as increased monitoring--has greatly reduced the incidence of low level violations because many producers have exercised increased care. USDA figures indicate that remaining violations are associated to a rather large degree with hogs being marketed through auction markets. The area with the highest

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[1] U.S. Department of Agriculture, Sulfa Task Force, Surveys of Violative and Non-violative Hog Producers (D. Hubbard, SEA, and R. Brown, APHIS).

TABLE 5.4. HISTORY OF VIOLATION RATES, 1977-1980

Year	Violative Sulfamethazine Residues						
	Livers			Total Sulfonamide Sample Units			
	Total sampled	Total violative	%	Total sampled	% violative	.1 - .3 ppm	$\geq$ .3 ppm
1977	7,434	935	12.6	9,411	13.19	601	660
1978	6,679	642	9.6	6,682	9.4	297	345
1979	5,985	384	6.4	5,991	6.4	125	260
1980	4,602	202	4.3	4,622	4.4	56	147

Source: U.S. Department of Agriculture, FSQS, National Residue Monitoring Program.

violation rates is the southeastern part of the U.S. In early 1981, for example, monitoring program statistics for Georgia indicated that while the violation rate on hogs marketed direct to packers was 3.5 percent, for those moving through markets, the corresponding rate was 10 percent.[1] These statistics suggest some producers may intentionally circumvent markets which could lead to producer identification.

5.2.4 Economic Impacts of an Increased Tolerance Level on the Meatpacking Industry

Currently, hogs sampled for sulfa residues are not retained in packing plants but instead enter the food distribution system. A policy merely raising tolerance levels (without changes in sulfa assay methodology or the institution of an animal identification system) would not have significant impacts upon this industry because packers do not currently bear liability for sulfa contamination.

5.2.5 Impacts Upon Human Exposure

Industry argues that an increase in the sulfamethazine tolerance level in swine from .1 ppm to .3 ppm would have negligible impact upon human exposure to sulfa: this because low level exposure is occurring and has for the past 25 years due to conditions of use.

If the behavioral assumption is made that hog producers, feed manufacturers and government regulators maintain current management or sampling practices, then:

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[1] Interview with Dr. Harold Trabosh, Food Safety Quality Service, Washington, DC, 1981.

1) hog producers would continue current practices related to sulfa, feeding neither more nor less and maintaining current levels of care;

2) feed manufacturers would produce feed of unchanged quality;

3) regulators would maintain current inspection procedures, including sampling rates and follow-up.

Given these assumptions, an increase in tolerance levels would have no increase on human exposure to violative swine under the monitoring program as results are known only after sampled livestock have already entered the food chain. Exposure increases could result under the surveillance program in those cases in which violations are traced back to producers who must then submit five animals in their next market lots for sulfa testing in order to regain marketing privilege. With an increase in tolerance levels, these hogs could then be marketed with the higher level.

If any of the groups mentioned above altered its behavior, then changes in human exposure could result:

1) if hog producers reacted to an increased tolerance by increasing sulfa use or exercising less care, increase in exposure to sulfa could result;

2) the same is true if feed manufacturers increase use or reduce care;

3) if regulators modify procedures or reallocate resources to concentrate on high level violations (and can trace them), overall exposure to sulfa could decrease.

5.2.6 Impact on Program Costs

With an increased sulfamethazine tolerance level, total costs of sulfamethazine monitoring and surveillance programs would be reduced due to the decreased violation rates. Even if the monitoring sampling rate remained constant, assay results would produce fewer violative reports necessitating follow-up action and USDA would finance fewer pre-tests under the surveillance program.

Prospects for implementation of this proposal appear unlikely in 1982, however. As explained above, the Food and Drug Administration has concluded that insufficient evidence from controlled experiments presently exists to either permit the agency to raise the tolerance level or to conclude that impacts upon the public health would be acceptably safe. The agency has undertaken the responsibility of furnishing the evidence it desires itself and appears to favor post-poning action until test results become available.

5.3 The Sulfa Task Force Approach

Section 3 examines the combination of activities associated with the government-industry Sulfa Task Force which was initiated by the USDA in 1978 and terminated 18 months later at the close of 1979. The Secretary of Agriculture defined two major objectives for the task force: to aid swine producers with violative sulfa residue problems and to significantly reduce the percentage of violative swine carcasses. Essentially, the Sulfa Program represented an agency decision to attempt to change both producer behavior and system performance through the provision

of various types of information, while at the same time upping inspection rates, thereby increasing the probability a producer failing to utilize the information would be detected with a violative animal.

5.3.1 Description of the Sulfa Task Force Program

The Sulfa Residue Task Force directed or sponsored three phases of activities: Phase I consisted of field surveys to assist in identifying sources of sulfa residues; Phase II included additional field activity and an expanded information-education campaign carried out by USDA agencies, FDA, State Extension Services, State Department of Agriculture, producers' organizations, feed manufacturers, drug companies, marketing agencies and veterinarians;[1] Phase III involved scientific research into various questions surrounding sulfa use, depletion, electrostaticity, assay methodology, and other issues. Specific activities in each of the three phases can be identified as follows.

5.3.1.1 Phase I: Field Surveys and Activities

1) A survey of 112 swine producers was conducted in Illinois, Iowa, Indiana, Missouri, Nebraska and Georgia. Seventy-nine of the producers had marketed violative hogs; 33 other producers fed sulfa routinely but had not been identified as producing violative hogs. The objective of the survey was to collect information on sources of the sulfa problem and to differentiate management practices of the two groups in order to

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[1] USDA, FSQS, SEA, APHIS, "Facts About Sulfonamide (Sulfa)," November 1978.

be able to recommend those practices which might be effective in eliminating sulfa contamination. As part of the survey, Extension personnel collected samples of finishing feed and components for analysis.

2) A complementary collection of 100 environmental samples from farms, buying stations, holding pens at slaughter plants and trucks used to transport swine was conducted by Extension personnel in order to identify additional sources of contamination.

Results of Phase I surveys yielded some important conclusions:

1) Management practices of "violative" and "non-violative" producers were not significantly different. Rather, both groups of producers exhibited deficiencies in feed handling, waste disposal and other management techniques which could lead to sulfa contamination of finishing hogs;

2) The analysis of supposedly non-medicated feed samples collected on swine farms demonstrated that both violative and non-violative farms and both commercially mixed and farm-mixed finishing feeds contained detectable levels of sulfa over 50 percent of the time.

Specifically, 14 percent of the 77 samples contained residue levels of 2 ppm (that concentration in feed which produces a 90 to 95 percent probability that a swine consuming the feed directly prior to slaughter will be violative at the time of slaughter). In addition to complete finishing feeds, components were also analyzed if the complete feed revealed detectable sulfonamides. Sulfonamide contamination was found in soybean meal, vitamin premixes and finishing supplements, leading policy makers to the conclusion that feed mixing and handling practices in commercial mills and on farms were major contributants to the problem.

5.3.1.2 Phase II: Field Activities and Information Campaign

Phase II activities built upon survey results and data analysis of Phase I. The objective of this portion of the Sulfa Campaign was to assist hog producers with residue troubles to determine and solve their problems. In order to accomplish this objective, USDA personnel linked into the normal functioning of the FSQS monitoring system. When FSQS assays identify violative swine, lab personnel telephone the FSQS regional office which then contacts the producer by registered letter, also informing FDA, State regulatory personnel and the area FSQS office. During the Phase II field activities, USDA-designated "field representatives" were added to the list of people contacted.[1] These representatives telephoned producers of violative swine to offer assistance which producers were free to accept or decline. For those producers participating in the self-help program, FDA agreed to suspend any potential regulatory actions. USDA field representatives administered a questionnaire to cooperating producers and pulled feed samples for sulfa analysis. In a return trip to the farm they presented conclusions and offered recommendations.

Some of the tabulated results of the field investigations conducted from September 1978 through August 1979 include: sulfonamide residues detected by the Meat and Poultry Inspection Program in various states (Table 5.5); the number of field investigations conducted during the

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[1] Field representatives were APHIS employees, or worked for the Extension Service or the States.

TABLE 5.5. SULFONAMIDE RESIDUE VIOLATIONS REPORTED BY MPIP DURING PHASE II OF THE SULFA RESIDUE PROGRAM

September	- 51	March	- 38
October	- 45	April	- 34
November	- 22	May	- 33
December	- 42	June	- 20
January	- 44	July	- 17
February	- 25		371

STATE	NUMBER	STATE	NUMBER
Iowa	89	Wisconsin	5
Minnesota	38	Texas	5
Illinois	33	Colorado	5
Ohio	25	California	4
Nebraska	21	Florida	3
Indiana	21	Mississippi	3
Virginia	21	Michigan	3
North Carolina	19	Oregon	1
Tennessee	17	Louisiana	1
Missouri	14	Oklahoma	1
South Dakota	10	Montana	1
Kansas	10	Pennsylvania	1
Georgia	10	Alabama	1
Kentucky	9		

period and the number and percentage of producers accepting assistance (Table 5.6); results of the laboratory assays of feeds and feed components collected upon farms linked with violative swine (Table 5.7) and a summary of laboratory assays of finishing feeds, both mill-mixed and farm-mixed (Table 5.8).

Important results of this phase of Task Force activities include:

1) the report by field representatives that 100 percent of those producers accepting assistance were able to "clean up" their premises;[1]

2) only 43 percent of the "violative" producers identified accepted USDA assistance;

3) USDA personnel were able to trace 24 percent of the violative hogs (84 swine) back to the market but not to the original herd; 76 percent were traced back to the herd of origin and the producer;

4) of the 57 percent of producers declining assistance, approximately half gave no reason; others reported they knew the reasons for the violations, or had gone out of business, or had eliminated the problem, or had stopped using sulfa or had mixed up hogs when feeding;

5) of farms accepting assistance, 82 percent of the finishing-withdrawal feed samples collected demonstrated detectable levels of sulfa;

6) 46 percent of the mill-mixed finishing-withdrawal feed and 26 percent of the farm-mixed finishing-withdrawal feed samples collected in Phase II contained residues greater than or equal to 1 ppm. Over

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[1]Producers marketing violative swine must normally establish that subsequent market lots are sulfa-free in order to resume marketing.

TABLE 5.6. NUMBER AND PERCENTAGE OF PRODUCERS REQUESTING ASSISTANCE (SEPTEMBER - JULY 31, 1979)

	Assistance Requested		Assistance Declined		
	Number	Percent	Number	Percent	Total
Northern Region					
Illinois	11	68.7%	5	31.3%	16
Indiana	4	44.4	5	55.6	9
Michigan	0	0.0	1	100.0	1
Minnesota	9	30.0	21	70.0	30
Ohio	3	20.0	12	80.0	15
Wisconsin	2	40.0	3	60.0	5
Subtotal	29	38.2	47	61.8	76
Southeastern Region					
Georgia	2	66.7%	1	33.3%	3
Kentucky	0	0.0	3	100.0	3
Mississippi	0	0.0	2	100.0	2
North Carolina	16	84.2	3	15.8	19
Tennessee	0	0.0	14	100.0	14
Virginia	19	100.0	0	0.0	19
Subtotal	37	61.7	23	38.3	60
North Central Region					
Colorado	2	66.7%	1	33.3%	3
Iowa	30	39.5	46	60.5	76
Kansas	3	33.3	6	66.7	9
Missouri	2	33.3	4	66.7	6
Montana	9	0.0	1	100.0	1
Nebraska	2	15.4	11	84.6	13
South Dakota	4	44.4	5	55.6	9
Subtotal	43	36.8	74	63.2	117
South Central Region					
Louisiana	1	100.0%	0	0.0%	1
Oklahoma	0	0.0	1	100.0	1
Subtotal	1	50.0	1	50.0	2
Western Region					
California	0	0.0%	2	100.0%	2
Subtotal	0	0.0	2	100.0	2
National Total	110	42.8%	147	57.2%	257

Source: USDA Sulfa Task Force, August 10, 1979.

TABLE 5.7. LABORATORY ANALYSIS OF FINISHING-WITHDRAWAL FEEDS AND FEED COMPONENTS COLLECTED DURING PHASE II OF THE SULFA RESIDUE PROGRAM [1]

DETECTABLE LEVEL (PPM)	FINISHING-WITHDRAWAL FEED		SOYBEAN OIL MEAL	OTHER PROTEIN	VITAMIN MINERAL PREMIX	GRAIN	OTHER
	MILL MIXED[2]	FARM MIXED					
0	10	23	10	4	12	24	24
0.01-0.9	24	52	8	18	9	4	8
1.0-1.9	10	6	1	5	4	0	2
2.0-2.9	4	3	1	4	1	2	3
3.0-4.9	7	3	0	5	0	0	3
5.0-9.9	2	2	0	0	0	0	5
10.0-19/9	4	8	0	2	0	0	7
20.0-29.9	2	2	0	0	0	0	3
30.0 & over	0	3	0	0	0	0	3
TOTAL	63	102	20	38	26	30	58

[1] Feed components are tested only if the finishing/withdrawal feed was found to contain sulfonamides.

[2] Samples were collected from a feeder whenever possible. Contamination of mill-mixed feeds could have occurred enroute to or on the farm or enroute to or at the mill

Source: USDA Sulfa Task Force, August 10, 1979.

TABLE 5.8. SUMMARY OF LABORATORY ANALYSIS OF FINISHING-WITHDRAWAL FEEDS

Type of Feed	Samples Collected	Free of Sulfa	Contained Detectable Levels	Contained 1 PPM. and Over
Mill-Mixed	63	10 (16%)	53 (84%)	29 (46%)
Farm-Mixed	102	23 (23%)	79 (77%)	27 (26%)
Total	165	33 (20%)	132 (80%)	56 (34%)

Source: USDA Sulfa Task Force, August 10, 1979.

half of the soybean meal samples contained sulfa levels ranging from .1 to 2.9 ppm. Approximately one-third of the grain samples analyzed contained detectable levels of sulfa ranging from .1 to 19.9 ppm, slightly over one-half of the vitamin premix samples contained levels ranging from .1 to 2.9 ppm and of 39 remaining samples of other forms of protein only 4 were sulfa-free while 35 contained levels ranging from .1 to 19.9 ppm.

The final major Phase II field activity involved a program for non-violative producers in which Extension specialists and agents tested feed samples from the farms of more than 1200 volunteer producers. Results of sulfa assays of feed from "non-violative" farms indicated that 18.5 percent of the farm-mixed withdrawal feed samples and 25 percent of the commercially mixed samples contained sulfa levels of at least 1 ppm.[1]

In addition to field activities (Phases I and II), the Sulfa Task Force coordinated an information-education campaign. The purpose of the information campaign was to offer practical suggestions to all concerned segments of the pork industry (and to a more limited extent the feed industry) for reducing residues. The information campaign used various media, USDA, industry and land grant universities to reach the desired audience. Information "outputs" included sulfa information kits, several slide shows available through the Extension service, a

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[1]Frank J. Mulhern, "Report For Secretary Bergland on Sulfonamide Residues in Swine," February 29, 1980. Note, because USDA field representatives sampled commercially mixed feeds from the bottom of on-farm mixers or feeders, the possibility of on-farm contamination of these feeds cannot be excluded.

series of newsletters, radio and magazine announcements and USDA and Extension presentations at producer meetings.

5.3.1.3 Phase III: Research Activities

One of the early factors leading to USDA formation of the Sulfa Task Force was the realization that many answers to questions regarding sulfa drugs were unknown. Research projects sponsored by USDA in connection with the Sulfa Task Force include the following:

1) "Effects of Level of Sulfamethazine in the Feed on Sulfamethazine Residue in Tissues of Pigs."

2) "The Effect of Various Levels of Sulfamethazine in Swine Rations on Residues of Sulfamethazine in Edible Swine Tissues."

3) "Sulfonamides in Swine Urine and Feces as a Factor Contributing to the Incidence of Violative Sulfonamide Residues in the Tissues of Swine."

4) "USDA-sponsored Feed Mill Sulfamethazine Carryover Study."

5) "Metabolism of Sulfas."

6) Workshop on "Evaluation of Chemical Methods of Analysis for Sulfas," July 6, 1978, Beltsville, Maryland. Twenty-four scientists representing government agencies, industry and private laboratories participated in this workshop to review sulfa assay methods including the Bratton-Marshall-Tischler method, thin layer chromatography (TLC), and high pressure liquid chromatography (HPLC).

7) "Economic Impacts of Alternative Regulatory Procedures to Control Sulfa Residues in Swine."

8) "Detection Methods for Sulfa Residues in Feed."

9) Improved Detection and Measurement of Sulfa in Carcasses and Live Animals."

10) Final workshop reporting results of the Sulfa Campaign, January 9, 1980, Washington, DC.

Research results of these studies contributed to a fuller understanding of causes of the sulfa problem and potential practical solutions for hog producers and feed manufacturers. For example, the research into problem causes enlarged understanding of the role of cross-contamination in feed handling equipment in commercial mills and on farms. Swine producers and feed manufacturers thus gained awareness of the need for more care in all aspects of feed preparation in order to reduce the probability of sulfa contamination in non-medicated feeds. Similarly, the fact became known that a finishing swine housed with others receiving sulfa medication or in a pen with feces from medicated hogs could quickly pick up sufficient sulfa to produce violative levels at slaughter. A recommendation growing out of this finding for strict segregation of hogs on sulfa medication from non-medicated hogs then followed.

Research on improved detection methods for sulfa in feeds, carcasses and live animals is ongoing, but has the potential of permitting regulatory agencies to rapidly screen far greater numbers of animals for chemical residues than currently. Impacts of improvements in assay methodology are discussed in Section 5, below.

5.3.2 Effectiveness of the Sulfa Task Force Program

From 1973 through 1977 sulfa violation rates in swine livers sampled under the National Residue Monitoring Program averaged over 10 percent, ranging between 10 and 15 percent. In 1978, rates fell to 9.6; in 1979 to 6.4; and for 1980, the annual violation rate was 4.4 percent.

How effective was the government-industry Sulfa Task Force program in achieving this reduction in residue rates? By what means does such a program influence producer decision-making? How can program effectiveness be improved? Will residue rates remain low even after Sulfa Task Force activities have ceased?

Chapter III developed a conceptual model of producer decision-making which can be utilized here. In this model economic actors satisfice; that is, they attempt to attain satisfactory levels of profit or income along with other objectives. The producer acts in an uncertain world of costly information. Uncertainty originates in the market, from the institutional arena or as a result of the firm's own performance. In this world, the economic actor makes three classes of decisions with respect to regulation: decisions related to seeking information about regulation, decisions related to influencing the design or the enforcement of regulation and, finally, decisions related to choosing a compliance strategy. The model suggests that the producer seeks information, attempts to influence regulatory design (or enforcement), and adopts a compliance strategy on the basis of the relative expected costs and benefits of doing so and subject to various resource constraints including time and money.

Sulfa regulations, prior to FSQS increasing its sampling rates in 1977, exerted relatively unimportant influences upon producers' decision-making. In other words, the regulations provided a relatively weak incentive for producers to exercise care in following withdrawal periods and cleaning pens or feed handling equipment. Inspection rates for sulfas and many other routinely monitored drugs averaged about 300 animals per year prior to 1977 and the subsequent Sulfa Campaign. At the same time, the number of hogs slaughtered annually has averaged 82.7 million in the five years 1976-1980. The Census of Agriculture indicates 430 thousand hog producers in the U.S. in 1979.

Low perceived probabilities of being sampled contribute to low producer assessments of the expected cost of marketing a violative hog. The same factors contribute to producer assessments of only negligible benefits from seeking regulatory information or information regarding management practices to avoid sulfa contamination (the identical argument applies to feed mills).

In addition, prior to the completion of publicly supported research into sulfa use and handling characteristics, the information costs to any individual producer of discovering the various potential sources of sulfa contamination in feed mills, on farms and elsewhere in the environment and identifying management practices to correct them were so high that it was not feasible or rational for an individual producer to invest in attaining this knowledge. In summary, under these conditions, producers viewed sulfa almost entirely in its role as an input and dismissed contamination potential. (Similarly, the feed industry considered only costs and benefits associated with sulfa as inputs or products.)

The impacts of a regulatory policy which, on the one hand, increases the expected costs of marketing a violative hog and on the other, reduces the information and transactions costs involved in learning how to prevent sulfa contamination would be expected to alter a rational producer's optimal decisions relating to regulatory compliance. Given the change in enforcement and the reduction in information costs, a rational producer begins to acknowledge sulfa as a potential contaminant with some associated costs which must be balanced against sulfa's value as an input.

Empirical evidence in the sulfa case generally, and that gathered in this research, particularly, supports the conclusion that Sulfa Task Force research, educational and informational activities--combined with increased inspection rates--did in fact alter hog producer decision-making regarding sulfa use. Interviews with Michigan and Kansas producers indicated many had altered their former patterns of sulfa use: some stopped or reduced use of both major sulfa combination drugs (this is consistent with a decline in national sales of sulfonamide feed additives);[1] others switched from sulfamethazine to sulfathiazole feed additives (this corresponds with national increases in Diamond Shamrock's market share[2]); others indicated they medicated with sulfa drugs only in water or only in cases of disease or were careful to restrict only to starter feeds and to segregate medicated from unmedicated hogs. Still other producers

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[1] Interview with Holmes, Doanes Agricultural Services.

[2] IMS America, Ltd.

initiated other alterations in management practices, some large and some minor, reflective of the new information which came to their attention on costs of a violation and practical steps to reduce the probability of contamination.

One interesting fact about the decline in residue rates was noted above: the rate of sulfa violations declined overall but the relative proportion of high level violations increased. The Sulfa Task Force program appears to have successfully aided many producers who had marketed swine with low level violations in identification of problem causes and solutions.

The program was not uniformly effective, though, with respect to high level "violations" or geographical areas. Reasons for this are unclear. However, the decision-making model suggests two possible factors for consideration: either producers were out of touch with the information channels which appear to have been successful in the majority of cases, that is, Extension personnel and trade organizations (or sulfa program emphasis was not as strong in some geographical areas) or producers did not expect to have to bear any significant costs due to marketing a violative swine. Some evidence from FSQS indicates a correlation between violative levels and rates and the use of auction markets or other markets through which animal identification is difficult to preserve. For the producer, this difficulty implies a low probability of a producer incurring a regulatory sanction.

Spokesmen for the Sulfa Task Force addressed this concern in summarizing the accomplishments of the Sulfa Action Campaign and making

recommendations for further action. Stated Dr. John Spaulding, "Producers whose animals have high levels appear to have minimal concern about the sulfa problem."[1] Regarding future steps FSQS could take, he stated:

> Our thoughts have been influenced by those programs proven successful in the past. The most effective approach has been that used by USDA in its disease eradication efforts. Once the area of greatest contamination is defined, an eradication program is planned and carried out, with the aid of those people most directly involved. FSQS can make enough additional laboratory resources available so it can test enough samples from a local geographical area to clearly define the sources of contamination.[2]

The effects of the Sulfa Task Force program on market participants other than hog producers include impacts on decision-making within the animal health industry, the feed industry and the meat packing and marketing segments of the swine industry. Impacts discussed in the previous chapter include the decisions in 1980 among sulfamethazine additive producers to alter the physical form of the drug. This technological development appeared to result chiefly from decreasing sales of these animal health products.

In the feed industry, results are the least clear cut. Evidence indicates feed firms pursued a variety of strategies. Because no systematic statistical sampling program for feed products exists, however, analysts of drug handling practices within this industry lack the convenient performance indicator of residues in product samples which is available when scrutinizing the swine industry.

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[1] Dr. John Spaulding, Acting Director, Residue Evaluation and Surveillance, Food Safety and Quality Service, USDA in speech before USDA/FDA/Swine Industry Task Force, Washington, DC, January 9, 1980.

[2] Ibid.

The FDA feed mill survey presented some disturbing results, however, when statistical analysis revealed that those feed mills mixing registered feeds (as opposed to custom mixing), following a sequencing or a flushing or a clean out procedure were positively associated with the percentage of feed samples taken with sulfa levels in excess of the action level (1 ppm). This is contrary to what one would expect. In addition, the study concluded variables such as: the amount of material used to flush equipment; whether a GMP (Good Manufacturing Practice) violation was present which might be expected to result in contamination; the amount of static material present in the mixing system; the size of mixer used; and the size of the feed mill in terms of sales volume were not associated with the percentage of samples with sulfa concentrations above 1 or 2 ppm. The Food and Drug Administration could not explain these results at the time of its preliminary report to the Sulfa Task Force in January of 1980 except to offer the tentative explanation that an association between the institution of quality control procedures and higher percentages of violative feed samples demonstrates that feed mill operators knew they had a problem, were attempting to correct it, but were either not following procedures correctly, or the procedures were not sufficient. As a result of these sorts of problems, the feed industry supported efforts to have the FDA tolerance level raised. When efforts failed, a number of feed companies (including at least two state cooperative organizations supplying dozens of member co-ops) decided to stop manufacturing sulfamethazine products completely.[1]

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[1]The actions of the commercial feed industry are more fully discussed in Chapter IV. Many felt the industry didn't have technology for compliance.

Evidence gathered during the research process, as well as results of FDA and USDA feed mill surveys, indicates several important effects of the Sulfa Task Force program and increased FDA surveillance of feed mills. First, a high degree of awareness of problems of sulfa cross-contamination exists among virtually all commercial feed establishments contacted. Publicization of sulfa residue problems in swine along with the USDA finding (confirmed by FDA) that a majority of swine finishing feed samples taken from farms contained detectable levels of sulfamethazine, clearly increased the feed industry's consciousness of sulfa problems as well as their sense of vulnerability to problems of feed carry-over.

At the same time, many firms within the industry expressed frustration over their situation. On the one hand, these firms mix and handle sulfamethazine medications in response to demand within the swine industry. On the other hand, the spectre of product liability problems was magnified by USDA recommendations to swine producers to retain samples from purchased feed and components to identify the source of purchase.

When firms within the industry sought advice regarding procedures for handling sulfamethazine, no clear cut recommendations were available. USDA researchers determined that contamination occurred with high probability in at <u>least</u> the two batches of feed mixed after a sulfa-medicated feed. This finding would appear to support recommendations that a flushing or sequencing practice be adopted through all feed conveying equipment for purposes of quality control.

The Sulfa Task Force has apparently had very little impact upon meat packers or others in the marketing chain. This is consistent with a conceptual model which predicts that an economic actor seeks regulatory information, attempts to exert regulatory control or adopts a compliance strategy on the basis of expected benefits and costs. Because meat packers and other members of the marketing chain bear negligible costs from buying and selling a sulfa contaminated hog under current monitoring procedures, they are relatively unconcerned with the problem at present. (Alternative monitoring procedures which would change the probable strategies of this group of participants are examined below.)

5.3.3 Public Program Costs of the Sulfa Task Force Program

Published cost estimates of the sulfa program range from $1.4 million to $4 million depending on assumptions employed and the defined scope of the program. The $1.4 figure is an estimate by USDA officials encompassing research, education, and informational activities of FSQS, APHIS and SEA over the 18 month period of the Sulfa Task Force.[1] The latter estimate was made by C. D. Van Houweling, former director of the FDA Bureau of Veterinary Medicine.[2] Van Houweling included what he termed conservative estimates of governmental, feed industry and

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[1] Roger I. Gerrits, SEA/AR, USDA. "The Use of Sulfa Compounds in Swine Production," Speech to Pork Producers, received from Dr. Gerrits during interview September 27, 1979. Gerrits estimated costs to FSQS, APHIS and SEA at $1.4 million.

[2] C. D. Van Houweling (National Pork Producers Council, formerly Director of the Bureau of Veterinary Medicine) quoted in Food Chemical News, July 28, 1980, p. 7.

swine problems and regulatory efforts over the six-year period 1974-79. Estimates of this research place costs within a range of between $2.8 and $4.8 million. These figures are explained below.

While estimating specific costs of public programs such as the Sulfa Task Force is somewhat problematic due to difficulties in assessing opportunity costs of salaried personnel working on multiple activities[1], still figures such as those presented in Table 5.9 permit ultimate ranking of alternative regulatory programs based upon relative order of magnitude.

According to its records, the Food Safety Quality Service sampled 22,084 swine sample units for sulfa over the period January 1, 1977 through 1979.[2] Collection and analysis of these samples--at alternative

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[1]Many Extension specialists, for example, devoted substantial portions of their time over an approximately two-year period to a combination of field investigations, public meetings, and other educational or informational activities related to sulfa problems. Similarly, the acting administrator of the Food Safety Quality Service (FSQS) explained that while his agency's budget consists of approximately 90 percent salaries, in 1979 sulfa residues ranked as the principal problem facing his agency; accordingly, some portion of the agency's salaried man-years were appropriated in an informal manner to the sulfa problem. (One administrator termed his agency's budgeting procedure a "cookie jar approach" where money is found, as needed, for different problems.) Interviews with J. E. Spaulding, Acting Director, Residue Evaluation and Surveillance Division and R. E. Engel, Acting Deputy Administrator, Science, Food Safety Quality Service, USDA, Washington, DC, May 11, 1979.

[2]Food Safety Quality Service, annual statistical reports of the National Residue Monitoring Program, unpublished, 1977-79.

TABLE 5.9. ESTIMATED PUBLIC COSTS OF SULFA RESIDUE PROGRAM

	Estimated Costs	
	Low	High
ITEM		
Inspection	$1,104,200	$2,208,400
Research	650,000	1,300,000
USDA	(400,000)	(800,000)
FDA	(250,000)	(500,000)[1]
State Extension Services	300,000	450,000
Sulfa Task Force	270,000	360,000[2]
FDA Residue Follow-up	450,000	450,000
Totals	$2,774,200	$4,768,400

[1] includes costs of Sensitivity of Method research
[2] higher salary estimates of personnel involved

sampling cost estimates of $50 and $100[2] per sample--totals $1,104,200 and $2,208,400, respectively.

Research sponsored directly or jointly by USDA (and listed above) which related to one of the several aspects of the sulfa case totals approximately $400,000. A number of these research projects received financial support from land grant universities, thus upping public costs of the sulfa program. Van Houweling estimated that FDA had spent approximately $250,000 on sulfonamide research as of 1980. This figure does not include FDA research on sulfamethazine carcinogenicity under the Sensitivity of Method protocol test case, research ongoing at the National Center for Toxicological Research in Pine Bluff, Arkansas in 1981 on which cost accounting was incomplete as of spring, 1981.

Information and educational activities included a variety of media efforts as well as public appearances and meetings, and training sessions for Extension specialists and others involved in the Sulfa Campaign. Costs associated with these activities include salaries committed to personnel involved in Sulfa Task Force work as well as a percentage of agencies' budgeted line items comprising general overhead and operating expenditures.

Cooperative Extension personnel in 49 states were instrumental in transmitting information about sulfa to hog producers and, in some states, swine specialists and veterinarians also participated in on-farm

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[1]Based on estimate of Dr. Van Houweling.

[2]Based on estimate of Dr. Engel which includes inspector time.

investigations and collected feed and environmental samples. Participation levels of Extension personnel doubtless varied broadly from state to state. For purposes of illustration, if it is assumed that one swine specialist per major hog producing state (20 states) devoted one-half time during the 18 months of the Sulfa Campaign at a salary level of $20,000-$30,000 per year, Extension salary resources devoted to the Sulfa Campaign would have approached $300,000-$450,000. This figure does not account for any of the overhead normally supporting Extension specialists and to that extent underestimates a true measure of public resource costs devoted to the Sulfa Campaign.

At the Federal level, personnel within both USDA and FDA participated in planning, research and administrative activities of the Sulfa Task Force. Informal in composition, about nine persons regularly participated on the Sulfa Task Force. They included a majority of USDA personnel with one permanent FDA representative. If the assumption is made that these Task Force members devoted on average one-half time over a two-year period to the Sulfa Campaign and earned an average salary of $30,000-$40,000, then salary costs at the Federal level contributed from $270,000-$360,000 to total public program costs.

Van Houweling estimated that FDA spent approximately $450,000 conducting follow-up investigations to the 2,611 FSQS reports of sulfa violations over the two-year fiscal period of the Task Force. This estimate assumes a 50 percent follow-up rate and a cost of $350 per investigation.

5.3.4 Additional Costs Associated with the Sulfa Program

The commercial feed and swine industries, and to some extent the animal health industry, participated primarily through major trade organizations in shaping the industry-government sulfa program. Activities included planning, disseminating information, supporting some research projects and encouraging membership support for those governmental activities considered desirable.

Firms within three of the four major industries (the animal health, the swine and the feed industries) bore most of the costs associated with sulfa regulatory activities:

1) the major animal health industry firm manufacturing sulfamethazine products experienced economic losses due to declining sales;

2) the three manufacturers of sulfamethazine supported costs of public affairs staffs working on regulatory and public relations aspects of the sulfa case;

3) animal health industry firms which are competitors of American Cyanamid appeared to benefit from sulfa regulatory activities;

4) the commercial feed industry bore costs associated with FDA inspections including adjustments to plant, equipment, or operating procedures in attempts to reduce probabilities of residue violations. Many costs may be termed transactions costs, that is, costs involved in learning about cross contamination problems, deciding upon strategies of action, and handling interactions with regulators;

5) the feed industry suffered uncertainty related to potential product liability problems;

6) some firms in the feed industry lost sales due to actual or potential sulfa contamination;

7) additional industry costs include those borne by the swine industry as in 4) above. Included are any increases in hog production costs attributable to reduction or cessation of sulfa use.

An additional category of regulatory compliance cost includes costs borne due to interruption of marketing in cases where hog producers were identified as marketing a violative swine. In order to regain market access, producers are required to clear a subsequent lot of swine by sampling five animals. If the producer elects to have FSQS run the tests, there is no charge but there is a delay of two to three weeks during which time market animals must be fed, housed and managed. A delay may also result in a drop in prices. If a producer wishes more rapid results from a private lab, estimated costs are from $300-$400 per lot. Should one of these hogs prove violative, the procedure must be repeated. During the clearance testing process, sampled carcasses are held at the packing plant; if results are violative the animal cannot be sold for human consumption.[1]

5.3.5 Summary and Conclusions of the Sulfa Task Force Scenario

In summary, the Sulfa Task Force Program and associated increases in the monitoring rate appear to have been most effective in increasing

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[1]These costs are discussed above. See Chapter V, Section 2.

compliance and the level of drug-handling expertise on hog farms. Explanatory factors include a USDA research orientation toward problems of the hog producer and an Extension effort at disseminating the practical applications of this research utilizing an Extension network oriented toward agricultural producers. Because the monitoring program exists, it is possible to measure improvement in the rate of violative swine.

The Task Force program succeeded in increasing awareness of drug handling problems within the feed industry, but appeared less successful in coming up with, and extending clear recommendations for manufacturing procedures which could eliminate residues. As a result many firms within this industry have experienced high degrees of uncertainty regarding sulfa and other drugs. No measurement tool exists similar to the monitoring program for swine. The FDA appears to place a higher priority upon changing the overall rules of the game regarding which firms may qualify to mix medicated feeds[1] than in attempting to solve the sulfa problem for all firms.

The program appears to have had few, if any, impacts upon the meat packing industry. Meat packers bear no costs if a swine is contaminated with sulfa, because the carcass is sold and consumed by the time assay results are known.

The animal health industry scrutinized the design and implementation of Sulfa Task Force activities with great interest from start to finish. However, activities of members of this industry appear to have been

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[1]Through the Second Generation Policy discussed below.

oriented in large measure toward defining the problem out of existence. The Task Force was unsuccessful (as was the FDA) in providing direct incentives to this group to undertake the research into product granulation which was eventually begun in 1980, apparently in response to market pressures. Because this lack of regulatory mechanism resulted in a tremendous expenditure of government and swine and feed industry resources, means by which government agencies might identify, encourage and support research into promising technological developments to future problem situations are developed below (in Chapter VI).

Cost estimates of the Sulfa Task Force vary between $1.4 and $4 million, depending upon assumptions and defined scope of the program. Public program costs over the three-year period 1977 to the end of 1979 include increased inspection and sampling, research, education, Extension and administrative activities and total between $2 and $4 million.

Costs to specific industries vary widely. The meat packing industry appeared to bear negligible costs; the animal health industry appeared to experience primarily distributional modifications; the commercial feed industry experienced increased costs of compliance with sulfa regulations, increased regulatory uncertainty and transactions costs and reduced economic benefits from mixing and selling sulfa. Finally, the swine industry bore costs of regulatory inspections, regulatory compliance (pre-testing), costs of capital modification and some costs associated with loss of feeding benefits of sulfa.

5.4 Feed Mill Options

This section analyzes policy options directed exclusively at the commercial feed industry. As such, these policies represent partial solutions to the sulfa problem at best. However, examination of the policies permits a focus being drawn upon some of the major issues involved in Food and Drug Administration regulatory responsibility regarding one industry which has been an important identified source of the sulfa problem.[1]

The policy options presented vary with respect to extent of governmental involvement in both structural modification and day to day operations of the feed industry. That policy option representing the least dramatic modification of the status quo would increase or alter FDA inspections of feed mills producing sulfa-medicated feeds. FDA alternatives for selective sulfa inspections are included in the analysis of this policy option. The second policy option directed at the feed industry is FDA's proposed Second Generation of Medicated Feeds Policy. Proposals for various sulfa combination drugs and medicated feed articles represent a significant departure from the status quo and one which has generated substantial favorable response from much of the feed industry but the strenuous objections of most of the swine industry along with some members of the commercial feed industry (principally smaller firms).

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[1]Analysis of the Sulfa Task Force Program above suggests that the program had only limited success (at least prior to product granulation) in reaching feed manufacturers with workable solutions regarding sulfa.

5.4.1 Increasing the Inspection Rate for Mills Mixing Sulfa-Medicated Feeds

FDA's regulatory jurisdiction over commercial feed establishments emanates from the Federal Food, Drug and Cosmetic Act. The 1938 Act for the first time bestowed upon the agency the authority to enter premises and survey records of commercial establishments producing food items.[1] One ramification of this regulatory power has been policy decisions over the years at the FDA to employ process rather than product performance standards in many compliance strategies. (This has led to the dramatic difference in inspection procedures for meat and poultry, on the one hand, and most remaining foods[2], on the other.)

The law directs the Food and Drug Administration to conduct a biennial inspection of all those facilities mixing medicated feed. Medicated feed establishments must register with the agency each year. A recent tally of the number of establishments on the FDA's rolls indicated between 15,000 and 16,000 drug using or producing establishments[3]

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[1]Melvin J. Hinich and Richard Steelin, "Regulation of the U.S. Food Industry," in U.S. Senate, Committee on Governmental Affairs, Study on Federal Regulation, Appendix to Vol. VI (Washington, DC: Government Printing Office, 1978).

[2]The meat and poultry acts administered by the USDA mandate continuous product inspection. As a result all slaughterhouses must have an inspector on duty in order to operate. The FDA determined that it is more cost-effective from a program standpoint to institute process rather than performance standards.

[3]Roy Teidahl, "Directed Inspection Training Didn't Work, Says FDA Man," Feedstuffs, June 1, 1981, p. 7.

including feed manufacturers, on-farm mixers, and animal drug manufacturers or premixers requiring inspections. FDA resources in previous years have been insufficient to carry out the agency's legally mandated workload. The total number of animal drug or feed manufacturing establishments inspected by FDA in 1979, for example, was 1,939.[1]

In order to alleviate the problem, the agency has negotiated a series of cooperative agreements with several individual states whereby the states contract to conduct feed mill inspections in conformance with FDA guidelines. The number of states participating in cooperative agreements with the FDA varies from year to year but generally numbers in the high twenties. Some states not participating have relatively minor feed industries. Others, however, (for example, Illinois and Pennsylvania) are major producers of formula medicated feeds and yet have elected in recent years not to participate in cooperative inspection programs with the FDA.[2]

Summarizing then, limited regulatory resources for feed mill inspections, along with incomplete participation by individual states in cooperative inspection programs results in a current situation in which the Food and Drug Administration is unable to fulfill its mandated requirement for biennial feed mill inspections.

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[1] USDHEW, PHS, FDA. FDA Quarterly Activities Report, Fourth Quarter, Fiscal Year 1979.

[2] Interview with William Bixler, Special Assistant to the Director, Bureau of Veterinary Medicine, Food and Drug Administration, February 15, 1979. (Bixler authored the proposed Second Generation Policy.)

In light of current economic realities at the Food and Drug Administration, the regulatory program costs of increasing the number of feed mill inspections of plants specifically producing sulfa-medicated feeds would appear to be a major constraint to the implementation of this policy option on a regular basis. A selective inspection strategy appears more feasible. In 1981 the animal health industry developed a granulated formulation of sulfamethazine which it anticipated would greatly reduce sulfamethazine cross-contamination in mills. At the time of writing, the effects of this innovation in feed industry performance were not known with certainty. One purpose of selective inspections might be to assess the degree of adoption by the feed industry of granulated sulfa products and the impact of granulated sulfa use on the quality of feeds produced.

5.4.1.1 Selective Use of Inspections

A policy based on the selective use of inspections would appear to be more feasible at this point from the standpoint of agency resource constraints than broad based increases in inspection rates of all mills.

The Food and Drug Administration conducted one feed mill survey in 1979 regarding mixing practices and performance relating to use of sulfa drug feed additives. The survey involved mills and utilized regular members of FDA's inspection force. One purpose of the inspection was to document characteristics of sulfa mixing and handling procedures in a variety of mills and to attempt to analyze the performance impacts of procedures by assaying for sulfa content in intendedly medicated and nonmedicated feeds. (This survey is described in Chapter IV.)

Another selective use of FDA's inspection powers directed at the sulfa problem has been FDA follow-up of USDA notices of findings of contaminated commercial finishing feed or components drawn from swine producer feeders. FDA inspected some 42 mills in response to USDA notification in 1978 and 1979.

A third possibility with respect to sulfa inspections is that without increasing the actual number of feed mill inspections, the FDA might instruct its own and cooperating inspectors to emphasize features of feed mill operations particularly pertinent to sulfamethazine cross-contamination and to draw samples for sulfa assays. Finally, as suggested above, FDA and the feed and swine industries would benefit from information regarding the extent of adoption of granulated sulfamethazine in the feed industry and the association under actual operating conditions between granulation and cross-contamination. Such knowledge would reduce information costs and uncertainty for those wishing to mix sulfa and use it in swine production. If sulfamethazine can be used with confidence that cross-contamination possibilities are minor, then any losses in feed efficiency, disease prevention and growth promotion incurred due to halting sulfamethazine use could be restored.

5.4.1.2 Development of a "Quick" In-plant Screening Test for Feed and Feed Ingredients

One technological development which may facilitate the inspection of feeds by the FDA and the production of non-contaminated feeds by the feed industry is a quick screening test for sulfamethazine, under

development in 1981. Such a test could be performed in the plant in a matter of minutes.

The assay test would permit feed manufacturers or inspectors to quickly, reliably and inexpensively (these are performance objectives of tests currently under development) sample feeds if concern arose.

The test could also be a boon for swine producers who could sample and then refuse shipment if feeds contained sulfa contamination.

Such an assay could reduce uncertainty and information costs of all parties involved in the sale, purchase and inspection of feed and ingredients. Whether it would significantly improve feed purity would depend substantially upon whether it were used. Use would depend in turn upon the existence of incentives encouraging use.

5.4.2 "Second Generation of Medicated Feeds" Policy

This section analyzes the Food and Drug Administration's currently proposed Second Generation of Medicated Feeds policy from the perspective of its impact upon the sulfa case, and the feed and swine industries. As previously explained, the new policy is a comprehensive attempt by the FDA to rationalize the current medicated feeds program. By general consensus of regulators and industry alike, the current program has grown in a piecemeal fashion into a nearly incomprehensible and unenforceable compilation of rules, exemptions, contradictions and inconsistencies. Inconsistency of treatment applies even

within the sulfa case when on one hand both ASP-250 and CSP-250 are exempted from regulations pertaining to new animal drugs while the identical sulfamethazine in combination with tylosin is regulated as a new animal drug. The paperwork burden upon the FDA of processing annual registrations of approximately 15,000 medicated feed establishments is by itself a powerful stimulus toward a change in policy.[1] In addition, as indicated above, the law mandates biennial inspections of each one of these facilities, a task beyond agency resources.

Under the proposed version of FDA's Second Generation policy, regulation of sulfamethazine and sulfathiazole combination swine feed additives would be substantially different than currently. Essential features of the new policy relating to sulfa swine feed additives include the following:

1) at drug concentration levels exceeding 250 mg per 40 pound bag of diluent, use or further processing of both ASP-250 or CSP-250 by feed manufacturers and swine producers would necessitate registration as a medicated feed establishment with the FDA; successfully passing an FDA directed inspection to establish ability to comply with Current Good Manufacturing Practices for medicated feed establishments; and adherence to other procedures (including annual registration, completion of an FDA form FD-1900, and biennial inspections by FDA);

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[1] Interview with Bixler, FDA.

2) at drug concentration levels less than 250 mg per 40 pound bag of diluent, producers and feed manufacturers would be able to use ASP-250 and CSP-250 and remain exempt from many of the requirements applied to medicated feed establishments. The GMPs applicable to this group were under discussion in 1981 at the time of writing;

3) regulation of the third sulfa swine feed additive containing equal measures of sulfamethazine and tylosin would be amended to indicate that at use levels below drug concentrations of 200 mg per 40 pounds diluent, hog producers and feed manufacturers would be exempt from compliance with GMPs designed for medicated feed establishments.

If this version of the proposed Second Generation policy is implemented it will represent a reversal of current policies respecting ASP-250, CSP-250 and Tylan-Sulfa in the sense that conditions of use of the first two will be made more stringent and the last, relaxed. The opportunities of respective animal health industry sponsors will be affected accordingly.

The expected categorization of sulfa swine feed additives has been the target of vigorous disapproval by the swine industry, in which approximately 80 percent of all producers maintain some type of grind and mix operation.[1] Currently, ASP-250 and CSP-250 are obtainable in

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[1]Van Houweling commented that the proposal will work for the small producer with three sows, who goes to town to buy a couple of pounds of premix. "But when you're buying soybean oil mean in truckload or carload quantities, and you're conveying them into feeder mixers and

concentrations of 250 mg per five-pound bag of diluent. Hog producers mixing sulfa feeds for their own livestock use need not register with the FDA at all as a medicated feed establishment. Feed manufacturers mixing sulfa feeds commercially must now register as a medicated feed establishment, but are not required to file a Medicated Feed Application (FD-1800) or a New Animal Drug Application (NADA Form 356). Under proposed regulations, both hog producers and feed manufacturers wishing to use ASP-250 or CSP-250 in concentrations greater than 250 mg drug per forty-pound bag would have to register and thus become subject to GMPs applicable to medicated feeds establishments. Agency decision-makers hope at least half of all feed manufacturers and a large majority of swine producers will opt to use drugs at lower concentrations, thus eliminating inspection requirements.

5.4.2.1 Probable Economic Impacts Upon Swine Producers of Second Generation Policies Affecting Sulfa Drugs

The hog producer conventionally using either ASP-250 or CSP-250 and now confronted with a new set of sulfa regulations may choose: 1) to purchase ASP-250 (or CSP-250) in a proportion of 250 mg drug per 40-pound bag of feed diluent; 2) substitute another feed additive in place of ASP-250 (or CSP-250), possibly one categorized in a lower risk

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grinders, to start adding 40 lbs of diluent, it gets to be uneconomic. You're paying a lot for your carrier. We were utterly opposed to the last draft and I'm not sure this is going to be a whole lot more acceptable." C. D. Van Houweling, National Pork Producers Council cited in "FDA Revamps Feed-Drug Rules for Farm Mixing," National Hog Farmer, February 15, 1981, pp. 26-27.

category under the program and available in higher concentrations;[1] 3) elect to comply to the GMPs applicable to medicated feed establishments.

Should a producer elect to purchase the 40-pound bag of sulfa premix for each ton of feed produced, it is probable that total feed costs will increase if he attempts to maintain previous levels of ASP-250 in the diet. Included in the costs of commercially manufactured feeds are cost components attributable to:

1) ingredients (drug, 250 mg and diluent, 40 pounds);

2) manufacturing (receiving, grinding, processing, pelleting, bagging, warehousing, etc.);

3) distribution and transportation;

4) marketing (advertising and promotion).

A regulated change in maximum concentration levels from 250 mg drug per 5-pound bag of feed to 250 mg drug per 40-pound bag of feed will raise ingredients costs to the hog producer now forced to buy 35 extra pounds of diluent per bag.

Spokesmen for the feed industry argue they will have to be competitive with respect to diluent and will be forced to supply high quality ingredients. Mixing characteristics may limit protein content, however, under currently proposed confidence intervals for drug content, as drugs adhere to protein in such a way that feeds appear below tolerance in drug content, forcing feed manufacturers to overmedicate. Even if the producer normally purchases the same ingredients contained in the

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[1] A strictly economical choice examines the relative cost-effectiveness of the substitute and original drug in diluent pack.

diluent, he frequently purchases such items as soybean meal or other protein sources in bulk (supplements, for example, constitute a minimum of 300 pounds per ton of feed). Hence, by purchasing in 40-pound bags, it is probable that he will incur the manufacturer's costs of bagging smaller quantities.

A sizeable number of swine producers are self-sufficient in grain and major protein source, implying that these producers will incur the additional cost, per ton of ASP-250 medicated feed, of 35 pounds of ingredient they would not otherwise have purchased at all. In summary, it is probable that the component of cost per ton of ASP-250 medicated feed to the hog producer represented solely by ingredients will increase.

If we examine additional costs associated with the manufacture and distribution of feeds and feed ingredients, which the purchaser of ASP-250 will now have to pay, probable sources of cost increases to the hog producer become apparent. Manufacturing cost increases which the "exempt"[1] feed mill and hog producer might be expected to bear include increased receiving costs associated with the higher physical volume of bagged feed ingredients entering the plant and increased warehousing costs associated with the demands of suddenly warehousing a bag of premix weighing 800 percent of what was required previously. With respect to transportation costs, the same argument applies. Premix companies formerly shipping 250 mg/five-pound bag under the proposed policy must ship eight times the quantity of diluent for drugs such as ASP-250 or CSP-250.

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[1]Exempt from GMPs applying to medicated feeds establishments under the proposed policy.

By contrast, Tylan-Sulfa sales should be favored by changes in animal drug regulations. Current interpretations of the proposed policy categorize Tylan-Sulfa as a Category II drug. Implications are that the exempt swine producer or feed manufacturer can use the drug at a maximum level of 200 mg drug/40-pound bag feed without an FD-1900 and compliance with the other regulatory requirements for a medicated feeds establishment.

The hog producer not wishing to continue use of ASP-250 (or CSP-250) under the new regulations may consider a number of alternative options including substitution of Tylan-Sulfa, an alternate feed additive, using waterers as the route of sulfa administration or substituting a combination of growth promotants, rhinitis vaccinations, and selective therapeutic use of sulfas or other drugs in place of traditional reliance upon ASP-250.

The third type of decision a hog producer or feed manufacturer may make is to register as a feed establishment, undergo a directed FDA inspection, and become subject to biennial FDA (or state) inspections. Ironically, all feed firms and hog producers currently holding approved medicated feed applications (FD-1800) have already signed legal agreements with the Food and Drug Administration stating their ability to comply with existing GMPs (this would include, for example, all hog producers currently holding an FD-1800 permitting them to mix Tylan-Sulfa). In practice, however, the quality of feed mixing operations varies significantly in the commercial feed industry and on hog farms. Many of the latter have never been inspected.

At the time of writing (summer of 1981), despite the fact the Second Generation Policy had not yet been published as final policy, directed inspections of feed manufacturing firms were underway and spokesmen for the FDA Bureau of Veterinary Medicine reported a 60 percent failure rate of firms to comply with GMPs at that time.[1] A stated purpose of architects of the Second Generation Policy is to eliminate thousands of mills and producers currently on the rolls whom the agency does not believe capable of adequate quality control with respect to handling concentrated drugs.

What costs are involved for a hog producer or feed manufacturer attempting to register as a medicated-feed establishment under the proposed policy?

FDA Good Manufacturing Practices for the manufacture of medicated feeds include provisions regarding buildings, equipment, employees, inshipments of drugs, formula records, production and control procedures, packaging and labeling, laboratory controls, record keeping, and complaint handling procedures.[2]

FDA directed inspections emphasize the adequacy and accuracy of scales and metering equipment; the existence of formula feed master and batch records; the existence and accuracy of drug inventory control

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[1] See "BVM Says Many Feed Firms Failing 'Directed Inspections'; Lists Eight Specific Concerns," Feedstuffs, January 26, 1981, p. 4; Tiedahl, "Directed Inspection Didn't Work," Feedstuffs.

[2] "Directed Inspection Criteria," Feedstuffs, July 23, 1980, p. 122. See for complete text of GMP regulations (revised November 30, 1976).

records; provisions for routine cleaning or flushing of equipment or sequencing or other procedures to avoid cross-contamination; timely and sufficient product assay records; label controls. Also checked are equipment access points to enable inspection and cleanout.[1]

For the hog producer seeking to comply for the first time with these GMPs, a significant portion of initial costs probably consists of management time involved in setting up a drug inventory control system, sequencing procedures, formula and batch records and other aspects of record keeping systems required by FDA. Additionally, an on-farm producer of medicated feeds would be required to demonstrate that his mixer and other feed handling equipment were adequate for the task of quality control. A scale capable of measuring fewer than 100 grams represents another potential cost for the producer seeking certification as a medicated feed establishment.

5.4.2.2 Summary

To summarize impacts of the altered regulatory status of sulfa swine feed additives under the proposed Second Generation policy upon swine producers:

1) If the producer chooses to continue feeding ASP-250 or CSP-250 at subtherapeutic levels, but does not wish to comply with GMPs for medicated feed establishments, he will be required to purchase 40 pounds of diluent instead of the 5 pounds now required in order to purchase

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[1] Ibid.

250 mg of drug (sufficient for one ton of complete feed). In all probability, this requirement will increase total feed costs associated with maintaining previous levels of ASP-250 or CSP-250. Manufacturing and distribution cost increases for sulfa products due to requirements for handling increased volumes of diluents may be reflected in sulfa product pricing (if feed industry cost accounting is accurate).

2) The producer may turn to a variety of substitutes for sulfa products ASP-250 and CSP-250, including Tylan-Sulfa, which the regulations make relatively more attractive. At this point, there are few indications of relative product price changes as the regulations are not finalized.

3) The producer may decide to register as a medicated feed establishment, apply for an FD-1900, and comply with GMPs for medicated feed establishments thereby committing himself to the resource expenditures entailed in the design and operation of quality control procedures, and the selection and/or maintenance of adequate feed handling equipment.

As a final note on policy impacts upon the swine industry, spokesmen for the swine and beef industries bitterly criticize the philosophy underlying the FDA decision to evaluate hog producers and commercial feed manufacturers on an equal basis. They argue that because livestock industries do not produce feed for sale, feed products at this point should not be the focus of regulatory scrutiny; rather, product inspection should be aimed at livestock which is sold in the market. The feed industry disagrees. The AFMA has argued strongly that there should be only one set of medicated-feed regulations applicable to all parties.

Outlining additional impacts of the Second Generation Policy upon costs, prices, the structure of the commercial feed industry, and exposure of consumers to sulfa in swine is a highly tentative exercise. If the policy had the effect of greatly reducing the number of feed establishments and swine producers mixing high concentration medicated feed products, however, a significant probability for the following impacts could be argued:

1) those firms and producers not qualifying to mix "high risk" or highly concentrated medicated feeds would pay higher prices per unit of medication than formerly (see above);

2) this effect could be mitigated somewhat if animal health firms experience decreased marketing costs (due to fewer customer units) but maintain total sales and pass along reduced costs. Due to the structure of the industry, little certainty of this eventuality exists.

3) marked substitutions would occur in the use of medicated feed products by swine and feed producers with distributional impacts for animal health firms largely dependent upon the categorization of the product under the Second Generation Policy;

4) if significant numbers of farmer-mixers decide they cannot afford to use dilute drugs (e.g., 250 g ASP per 40-lb bag of diluent), they may attempt the FD-1900 route which would imply an enormous additional demand would be placed upon FDA for directed and biennial inspections. At current resource levels, any expanded inspection load could not be carried out;

5) it is probable the adoption of the Second Generation policy would cause a general realignment of medicated feed prices within the industry, likely raising those containing drugs classified high risk and reducing those classified low risk. The reason for the former was discussed above. Regarding the latter, drugs which currently require an FD-1800 but would not necessitate an FD-1900 due to policy changes might fall in price as costs of registration, etc. were eliminated;

6) the potential impact of the Second Generation Policy upon human exposure to sulfa residues in swine cannot be easily surmised. In the words of C. D. Van Houweling, NPPC director of governmental affairs and former director of the Bureau of Veterinary Medicine:

> FDA has the idea that if the drug is in feed in less concentrated amounts or mixed in less concentrated amounts, there's less chance for contamination. Part of this stems from the definition of a concentrate in the present regulations. . .(a concentrate) cannot cause a residue even if it was fed undiluted. This dilution idea is an attempt to achieve the same thing but it won't.[1]

A proposal for separate regulations applying to mixer-feeders and commercial feed mills prepared by the National Pork Producers Council and the National Cattlemen's Association argued:

> FDA and USDA data indicate that the principal causes of residues will not be avoided by restricting access to drug level. The principal causes are failure to withdraw medicated feed and improper cleaning of equipment. These failures can occur regardless of the drug level. So, residue prevention by restricted access based on drug level or concentration is not the appropriate answer and will not solve the problem of residues in food.[2]

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[1] "FDA Proposal Complicates On-farm Ration Mixing," National Hog Farmer, May 15, 1980, pp. 48-9.

[2] Ibid.

Van Houweling also argues that if implemented the proposed policy could result in many mills and producers purchasing from large mills mixing 50-60 different kinds of feed with innumerable drugs. In a busy mill handling numerous drugs, cross-contamination might increase rather than decline;[1]

7) finally, structural impacts upon the feed industry are likely to be such that firms able to qualify to handle concentrated medications will gain a competitive advantage over firms not qualifying. To the extent economies exist in complying with regulations, large firms may benefit at the expense of smaller ones. At this point no definitive research done by FDA exists demonstrating a correlation between firm size and capacity to handle sulfamethazine without contamination.

5.5 Alteration in Swine Inspection Procedures and Marketing Rules

This section analyzes major changes in swine inspection procedures and associated marketing rules, in order to assess their impacts upon the exposure of consumers to illegal residues in meat, economic impacts upon participants in different markets and influences on regulatory program costs. Options analyzed include:

1) use of an in-plant sulfa screening test;

2) USDA obtaining expanded power of quarantine over animals, carcasses, or meat products believed to be contaminated with biological residues;

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[1] "FDA Proposal Complicates On-farm Ration Mixing," National Hog Farmer.

3) development of an animal identification system for swine which would preserve identity from the farm gate to the packing plant;

4) development of a blood serum assay capable of testing live hogs.

A common rationale for these proposals is that current inspection procedures have resulted in a situation where sizeable quantities of contaminated meat products regularly enter the human food supply. This reflects limitations in analytical capabilities for the detection of chemical residues and limitations in regulatory authority to require animal identification and to quarantine animals or meat believed to be contaminated. Estimates of the percentage of USDA sampled meat and poultry by dressed weight which contained violative chemical residues but was in most cases sold to consumers ranges from a USDA estimate of 2 percent to a General Accounting Office (GAO) estimate of 14 percent.[1] These rates refer to substances for which assays are performed. Neither of these figures reflect potential contamination in livestock and poultry meat attributable to 97 of 143 drugs and pesticides which the GAO identified as likely to leave residues in meat but which are not monitored. (GAO also reported that among the 97 drugs and pesticides not included in USDA's monitoring program are

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[1] See GAO, Report to the Congress: Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues, HRD-79-10, April 17, 1979. GAO appears to have used a worst possible case estimate obtained by adding violation rates for individual substances and projecting this percentage to the total dressed weight of an entire species of animals. USDA disputes the GAO results.

24 known or suspected carcinogens and 17 substances suspected of causing birth defects.)

To summarize the general problem then, considerable concern exists regarding the adequacy of current monitoring procedures to effectively protect the public health, although particular estimates of human exposure to illegal chemicals in meat products are disputed.

Focusing on sulfa particularly, violation rates ranging from 10 to 15 percent between 1973 and 1977 imply that this percentage of swine entered the food chain with violative sulfa levels in livers. Violative percentages of total dressed weight cannot be directly inferred from rates of violative liver contamination in swine because this organ tends to concentrate sulfamethazine. (Liver rates, therefore, generally overstate residue levels in muscle or fat.) However, USDA regulations are written in such a way that a violative sample must be interpreted to indicate a violative carcass unless additional tests clear these other edible tissues.[1]

Factors contributing to a condition of public exposure to legally contaminated meat include a lack of in-plant assay methodology, low sampling rates, and regulatory inability to prevent the marketing of contaminated animals because violative animals frequently cannot be traced to the herd of origin in order to test successive market lots. Neither can meat or animals merely suspected of contamination be legally quarantined by USDA at the packing plant, on farms, or elsewhere in the marketing chain.

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[1] Ibid.

In 1980, USDA drafted a bill including provisions for agency authority to require animal identification, to condemn animals not properly identified, to quarantine any animal or animal product found to contain or suspected of containing any illegal residue, to permit an expedited hearing of any contested quarantine order by the Secretary of Agriculture, and some additional measures. The bill was introduced into Congress[1] by Representative Tom Foley and Senator Herman Talmadge in the final days of the Carter administration (December, 1980) and was not acted upon during the 1980 session.

The following analysis incorporates the measures listed above--principally regulatory authority to require animal identification and to quarantine--with use of simple, inexpensive in-plant screening tests for sulfa residues in carcasses now under development by USDA. The Sulfa Task Force initiated sponsorship of research and development of a number of "quick" assays for sulfa in food, live hogs, and in carcasses in slaughter plants. These are still in the process of development and testing, but for current analytical purposes, suitably reliable in-plant tissue testing methods are assumed to exist which are also rapid, relatively inexpensive and easy to administer.

5.5.1 Analysis of Impacts on Consumer Exposure to Sulfa in Pork Quality and Price of Pork

Implementation of the series of measures described above would result in a decreased exposure of consumers to pork containing

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[1]The bill was introduced as HR 8446 and SR S-3256. One further provision of the proposed act was for the cost of residue testing to be borne by the owner of the product or premise involved.

violative sulfa residues, but probably at the cost of higher priced pork and reduced supplies.

Under the altered system, rapid, in-plant screening tests would result in the ability for meat inspectors to screen all or a large proportion of slaughtered swine for violative sulfa residues. Assuming the existence of a test capable of furnishing results in fewer than 24 hours,[1] results would be known prior to the loss of carcass identity in further processing.

With quarantine powers in packing plants, meat inspectors could either condemn carcasses or organs as adulterated (depending on the reliability of the test[2]) or require that carcasses be retained until laboratory assays confirm or clear the carcass.

These two changes in inspection procedures, if implemented, would be sufficient to practically eliminate sulfa contamination in pork.[3]

Impacts of regulatory procedures upon the price and supply of pork products to consumers would be expected to depend upon the extent of residue testing (number of animals), the cost and financing of residue testing (by hog producers, meat packers or the government), costs associated with condemnations and disposal on the one hand, or

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[1]The animal is usually divided into wholesale cuts approximately 24 hours after slaughter. GAO, 1979.

[2]The test would have to demonstrate high levels of reliability to legally substantiate USDA condemnation. More likely, an in-plant test would be used for screening purposes.

[3]The policies would reverberate throughout the system, as well. Swine producers, for instance, might insist on feed certified as sulfa-free if they could be held personally accountable for selling a contaminated hog.

freezer or cold storage and loss of carcass bloom on the other (during the time carcasses are held pending laboratory confirmation of screening results) any costs associated with slowing down kill lines, and the rate of sulfa violations (hence, the number of animals condemned and removed from the meat supply).

Perhaps the greatest costs are those incurred by producers to assure that swine do not contain sulfa at slaughter. Many of these were discussed previously. Included are sacrifices in feed efficiency, rate of gain, and disease prevention when the drug is omitted.

Costs associated with in-plant residue testing are explored in more detail in the next section. It is relevant to note here, however, that the distributional implications of imposing user fees for residue and other forms of meat inspection differ from those stemming from government finance of the service from tax revenues. In the former case, the initial burden of paying for the residue test rests with the owner of the animal or the owner of the premises, although economic theory suggests that a user fee of this ilk would operate in the same manner as a unit tax and be treated as a cost of doing business. Assuming a relatively inelastic supply of hogs or demand for pork, the tax would initially be taken out of the price offered producers or passed on to retailers. The eventual incidence of the user charge depends upon relative elasticities of supply and demand in hog markets and supply and demand for consumer pork products, respectively.[1]

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[1]Eventually the rate of sulfa violations would vary with costs of condemnation as the system modifies to assign risks and costs of contamination.

Alternatively, if the costs of residue testing continue to be borne by taxpayers, then implicit subsidization of pork eaters by non-pork eaters continues in this case.

Another impact of greatly increased monitoring rates for sulfa in swine might be an increase in consumer demand for pork products. If consumers perceive product quality to be enhanced as a result of their increased assurance of sulfa-free pork (and conceivably the assay could be extended to screen for multiple contaminants), then increased consumer confidence might be reflected in an increased demand for pork products.

From the standpoint of reducing consumer exposure to sulfa residues in swine, an animal identification system is not necessary provided the USDA conducts in-plant screening for sulfa, and condemns carcasses found violative. In the absence of an in-plant screening procedure, an identification system and on-farm quarantine authority could benefit consumers by assisting regulators in locating potentially violative herds and clearing them prior to marketing.

Finally, from the standpoint of reducing consumer exposure to sulfa in swine, the development and use of a blood serum screening test for sulfa in live hogs is unnecessary, given in-plant carcass screening. However, such a test would permit producers to test hogs suspected of contamination prior to marketing and on a voluntary basis, thereby saving any costs associated with carcass violations; it could also be used by regulators suspicious of contamination, or by packers. Whether such a test would be used, and by whom, depends on the costs

and benefits perceived to be associated with it (and therefore, the combination of the four policy measures discussed above which is implemented). Several hog producers interviewed in 1980 in the process of this research suggested that under current monitoring conditions, a voluntary blood test for sulfa would not be used routinely by producers, particularly one which required drawing blood, as it would entail too much time, cost and trouble and would not be used by those who most need it.[1]

5.5.2 Analysis of Economic Impacts of an In-plant Screening Program

The institution of an in-plant residue screening procedure for sulfamethazine, along with USDA powers of quarantine, is not generally favored by members of the meat packing industry.[2] Such a policy would increase the expected cost of purchasing, slaughtering and handling a sulfa-contaminated hog--which might subsequently be condemned (wholly, or in part)--with consequent loss of production efficiency.

If sampling procedures entail slowing the hog kill line while inspectors take samples, then the average cost of slaughter for all hogs increases. If an in-plant assay reveals sulfa contamination,

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[1] Interview with swine producers: Curtis Bailey, Kalamazoo, Michigan, October 20, 1980; Mike Barton, Homer, Michigan, December 4, 1980; Dean Larson, Green, Kansas, November 4, 1980; Bob Harms, Vermontville, Michigan, December 5, 1980.

[2] Opinions expressed by personnel at Frederick-Harrad, Detroit; Peets Packing Plant, Chesaning, Michigan. Interview with Dr. Ralph Johnston, Microbiology, FSQS, Washington, DC, March 2, 1981.

and the inspector decides to mail in a further sample to a regional USDA laboratory for confirmation, then the carcass must be held in cold storage, or frozen, for approximately two to three weeks, the current time period required for a regional laboratory to process a sulfa sample. If a carcass hangs in cold storage for an extended period it suffers a loss of bloom and a reduction in value of approximately 60 percent.

If the animal is condemned for adulteration it must subsequently be denatured and cannot be used for food; salvage value as tankage is close to zero. At a purchase price of $45/hundredweight, the complete loss of the purchase price of a hog carcass through condemnation amounts to $99 (on a 220 pound hog); loss of bloom would amount to approximately $50. If only the liver and kidney are condemned, the meat packer stands to lose the wholesale price of a three to four pound liver and a one-half to one pound kidney.[1]

Costs of administering an in-plant sulfa-screening program include both fixed and variable costs which vary with the technology and sampling rate employed. (The bill introduced into the 1980 legislative session called for packers or owners of livestock to finance the costs of residue testing. Alternatively, the costs could be financed from taxpayer revenues.) One prototype for an in-plant sulfa-screening test is a procedure which has already been implemented to screen for antibiotic residues in dairy cows. The program, called the STOP program

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[1] "Yellow Sheet" FOB Midwest River values of these organs on December 31, 1981 were 11¢ per pound for liver and 12.5¢ per pound for kidney.

(Swab Test on Premises) utilizes a petri dish seeded with bacteria; a swab is taken from an organ of the sample animal, placed in the petri dish, and incubated overnight. The presence of an antibiotic on the swab taken from the animal sets up a zone of inhibition in bacterial growth and indicates a positive result.[1]

Under the STOP program, the positive results of an organ assay are followed up with a similar test on a sample of muscle. Positive muscle samples mean that a sample must then be sent to the regional lab while the carcass is retained in the plant. If this muscle test is negative, only the organs are condemned. According to an FSQS spokesman[2], the STOP program was in place on a national basis for dairy cows in 1981 and in the process of implementation for calves. It is considered to have contributed to a significant reduction in the number of carcasses previously retained while regional labs performed antibiotic assays. Meat inspectors may become suspicious of antibiotic presence in dairy cattle if an animal shows signs of mastitis or physical injection sites. FSQS estimated that approximately 80 percent of the 15 percent of dairy cow carcasses formerly held can now be cleared within 42 hours (assuming a positive organ sample followed by a negative muscle sample), representing a decrease in handling costs.

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[1] Interview with Dr. Jack Leighty, FSQS, USDA, Beltsville, Maryland, September 27, 1979.

[2] Interview with Johnston, FSQS.

Some of the cost elements associated with the STOP test include inspector labor time of approximately 10-15 minutes and a chemical kit which ranges from $0.85 to $1.40, and averages $1.20. The inspector time involved in the STOP procedure is less than that required in preparing a sample for a regional lab. FSQS has estimated a savings of $30 per sample over the cost of mailing in a sample to a regional laboratory.[1] If screening results are negative on one or both tests, then program savings also include mailing rates, the cost of a container and labor, and a reduction in handling and cold storage costs.

At the time of writing, a STOP test for sulfas was in the process of field testing. Criteria for an in-plant test include: appropriate degrees of specificity and sensitivity, rapidity of results, and economical cost.[2] The STOP test for sulfa currently demonstrates some problems of specificity; it does not discriminate between antibiotics and sulfonamides or among sulfonamides. However, the desirability of screening for multiple residues may imply that a lower degree of specificity for particular compounds is counterbalanced by the economic advantage of performing a single test for a number of residues. Microbiologists at FSQS believe that the current level of sensitivity of the sulfa screening test is about .2 to .3 ppm. Scientists have determined that the kidney concentrates approximately three times the level of

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[1] Ibid.

[2] Interview with Leighty, FSQS.

sulfa present in muscles. Therefore, a .2 to .3 ppm sensitivity on kidney should be sufficient to permit clearance of carcasses if the kidney is negative.[1]

Annual cost savings at $20 per in-plant test, would have ranged between $115,560 and $323,560 in 1980 (assuming 4622 sample units, a 10 percent violation rate requiring regional lab confirmation, and a regional laboratory assay cost of from $50 to $100 per sulfa sample).

If an in-plant sulfa STOP test costing from $5-$20 per sample were used to test all slaughtered swine, testing costs would range between $.4 billion to $1.6 billion for 80 million hogs and $.45 billion to $1.8 billion for 90 million hogs annually. On top of in-plant testing costs would be costs of storage, condemnation and disposal plus the additional lab charges for the percentage of swine showing positive screening results necessitating further laboratory assays. Due to the costly nature of universal in-plant screening for swine, it is probable a statistical sampling program would first be considered.

Although an in-plant screening test for sulfa would permit considerable savings in the unit cost of screening and sampling swine, the distributional implications of instituting these measures in the swine packing industry, where carcasses generally have not been held, differs from the situation for packers of dairy cattle. In these plants inspectors <u>have</u> retained approximately 15 percent of dairy cows on the basis of visual inspection.[2] In the case of swine sulfa testing, then,

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[1]Interview with Johnston, FSQS.

[2]Interview with Johnston, FSQS.

the in-plant program will impose what are in effect new costs of testing and compliance. In the dairy-packing case, the program reduced costs of holding carcasses while assay results were being completed.

An alternative method for in-plant sulfa screening utilizing a blood serum test for live slaughter hogs was costed out by USDA for 1976.[1] The envisioned system requires sampling hogs in each lot prior to slaughter and analyzing the results. If negative, the lot proceeds, if positive, more tests are required. If these tissue results are also violative, the sample is considered adulterated under the law.

USDA estimates of the total annual costs of this program in 1976 ranged from 8.1 to 8.4 billion dollars, depending on the violation rate (whether 5 or 9 percent). If the cost of condemnation is subtracted (assuming these hogs will deplete the drug from their systems), total annual costs are reduced to $7.7 billion. Table 5.10 presents the costs considered in the USDA analysis, based on 1976 prices and 1976 slaughter. (Keep in mind, at a compounded annual inflation rate of 10 percent, costs of $8.1 billion in 1976 would have risen to approximately $12.7 billion by 1981.)

What impacts would an in-plant screening program have on other industry members of the extended subsector? If packers were initially placed in a position of bearing risks and costs associated with product testing, condemnation and storage during testing, rational behavior would result in packers instituting procedures to shift some of these

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[1] USDA, "Economic Impact of Sulfa Residuals," Draft Analysis. Received from Dr. Clark Burbee, Food Economics, NED, ESS, USDA.

TABLE 5.10. ESTIMATED PROGRAM COSTS FOR PLANT-SITE BLOOD SERUM SULFA SCREENING OF LIVE HOGS[1]

Cost items	Cost per head	Cost per hundred weight	Aggregate costs
	$	$	$ million
Serum analysis	0.78	0.331	57.456
Non-technical labor	0.57	0.242	42.240
Sorting, stress shink, etc.	0.22	0.093	16.416
Added pens, working area	0.42	0.178	31.200
Technicians salaries	0.22	0.093	16.000
Sub total (1)	2.21	0.937	163.312
5 percent condemnation	(5.06)	(2.147)	(373.421)
9 percent condemnation	9.11	3.865	672.157
Added feed costs[2]	1.65	0.700	121.744
Sub total (2) at 9 percent	12.97	5.502	957.213
1976 Hog production costs	101.22	42.944	7,468.417
Total cost, 9 percent condemnation	114.19	48.446	8,425.630
Total cost, 5 percent condemnation	110.14	46.728	8,126.894

[1]Based on 1976 slaughter and 240 slaughter days.

[2]Added feed costs with preventive cross-contamination procedures.

Source: U.S. Department of Agriculture, APHIS, draft analysis.

costs. One way of forcing hog producers or buyers to share risk and cost is by instituting an animal identification system permitting packers to identify both the source of purchase (the buyer) and the producer.

5.5.3 Analysis of an Animal Identification System

The impact of an animal identification program upon hog producers and buyers would be complex. With respect to the sulfa case, producers now marketing violative swine through auction or terminal markets would be forced to identify their animals, thus closing this marketing loophole. Buyers rated upon their capacity to deliver hogs meeting packer specifications would then have incentives to take steps to ensure sulfa-free hogs.

Important impacts of an identification system relate to the assignment of the costs of violations in the short run, and the potential for the system teaching appropriate drug-handling procedures to producers in the longer run, eventually leading to a reduction in costs. At least in the short run, a mandatory identification system would result in higher consumer prices, reflecting increased costs of handling and packing hogs.

Whether or not a packer could discount the price of a hog identified as contaminated would depend upon the length of time between purchase and assay completion, and the packer's system of record keeping. (The Packers and Stockyards Act stipulates that a producer must receive payment within 48 hours of sale.)

If swine producers were forced to bear increased costs attributable to the use of sulfa, these producers could be expected to take additional steps to avoid loss, steps including modifications in management practices, stopping the use of sulfamethazine, or otherwise putting pressure on the feed industry. Interviews in the course of this research with 20 swine producers in three states, and with numerous feed manufacturers indicated that producers were aware of sulfamethazine contamination in feed mills as a source of residue problems and many had taken actions such as changing suppliers or retaining samples. Both the Indiana Farm Bureau and Illinois GrowMark ceased manufacture of sulfamethazine medicated feeds due to fears concerning potential product liability suits initiated by swine farmers. If sulfa contamination became a frequent issue for mills, evidence suggests many of them would stop handling sulfamethazine or institute other controls.

To fully appreciate the types of systemic impacts an animal identification system is likely to have it is necessary to go beyond the confines of the sulfa case alone. Potential impacts of an identification program not directly related to sulfa include the use of animal identification systems for purposes of disease control as well as control of other chemical residues. Swine brucellosis, for example, is a disease which the USDA believes could be easily eliminated if diseased animals could be traced.

An identification system could facilitate the collection of a broad range of data with many potential uses: for tracing accidental

contaminants through the marketing-transport system, for enhanced chances of success in product liability cases, for analysis of on-farm factors influencing product quality and many others. While many uses of an identification system relate to protection of public health, others are purely economic.

Many packers, for example, favor identification systems which would assist them in purchasing animals meeting their specifications in regard to lean/fat ratios and other features of concern. If they can develop dependable sources for the types of hogs they desire, they can achieve economies in production. Some hog farmers and other industry observers express concern that identification systems would work to the disadvantage of individual producers, particularly smaller ones. Without identification, for example, the packers' costs of condemnation are in effect pooled and borne by all hog producers. If animals were identifiable with a particular producer, all costs could be assigned to him. Such a possibility increases the producer's risks associated with contamination and disease. Similarly, it is sometimes argued that packers could use an identification system to establish histories for different producers. Inconsistent historical performance, then, might result in unfavorable market treatment for current market lots. Many of the impacts of an identification system transcend the scope of this study. However, both benefits and costs must be assessed in relation to the entire food system when considering the institution, design, and evaluation of an animal identification system.

Costs associated with an animal identification system depend upon the technology employed, the scope of the system, and whether a uniform system is imposed.

The range of conceivable livestock identification technology runs the gamut from mechanical means such as tatooing, branding, back and ear tags, to magnetic tags (such as used internally to trace salmon)[1], to sophisticated electronic subcutaneous implants under development at the time of writing. According to one USDA source, an identification system should be able to organize and convey as minimal information: the animal's legal ownership and the geographical place of birth of the animal, permitting traceback to the appropriate farm. In an ideal world, this person suggested, an identification system would permit traceback capability for each animal through all points where the title changed hands in the manner of an automobile registration system.[2] Additional data which are sometimes piggybacked onto owner identification as additional uses of identification devices include animal temperatures (valuable for disease control and breeding purposes) and breeding records.

Each of the identification types mentioned above--tatoos, brands, eartags, magnetic tags and electronic implants--has distinctive problems and advantages. At the risk of over simplification, the simplest devices (tags, tatooing and branding) are generally the least expensive but have problems of being easy to duplicate, hard to read, or

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[1] Y. Harache, P. Lagarde, and P. Prouzet, "An Internal Magnetic Tag for Salmon Smolts," unpublished paper presented at the 28th North Western Fishculture Conference, Olympia, Washington, December 5-7, 1977.

[2] Interview with Leighty, FSQS.

problematic in terms of conveying the requisite amount of information. A national electronic identification system for livestock, on the other hand, shows promise of managing a great deal of information of interest to public health authorities and individual herd owners,[1] but only at a cost of several dollars per animal unit.[2] With a trend toward skinning hogs in processing, the need grows for a device which is recoverable after skinning or scalding operations. One identification tag under development which is to be inserted beneath the skin behind the swine's ear shows promise as a device useful in either situations; however, initial trials showed the tags were difficult to apply correctly, raising questions about ultimate feasibility.[3]

In addition to technological design, the scope and requirements for uniformity of an identification system will influence the total costs of the system as well as who bears them. Currently, many U.S. packers use some type of identification system. In one 1976 study USDA estimated that from 50 to 70 percent of slaughter hogs carried some type of identification permitting traceback to various points in the marketing process, some intermediate to the herd of origin.[4]

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[1]Dale M. Holm, "Identification of a National Electronic Identification System for Livestock," unpublished paper submitted to the American Society of Animal Science Meetings, Tuscon, Arizona, July 30, 1979.

[2]Interviews with Leighty, FSQS; and Sherrill Nott, Agricultural Economist, Michigan State University, East Lansing, Michigan. Nott spent six months at the Los Alamos Scientific Laboratory in 1979 working on an assessment of a national electronic identification system.

[3]Identification Tag Versatile, but Imperfections Troublesome," National Hog Farmer, August 15, 1979, p. 68.

[4]USDA, "Identification of Slaughter Swine: Estimated Cost," Draft Report, APHIS, USDA.

In 1976, 71.5 percent of swine slaughtered were considered "directs," coming from buying stations, country dealers or order buyers; 17 percent were marketed through terminal markets and 11.5 percent through auction markets[1] (see Figure 5.5). From these figures, USDA estimated that at least the 30 percent of hogs moving through terminal or auction markets cannot be traced past these points. In other cases, a buyer can be located although he may have supplied a lot assembled from various sources.

USDA estimated the total cost of a mandatory animal identification system utilizing both eartags and slap-tatoos and extended to identify the estimated thirty percent of swine (48 million swine in 1976) not identifiable past an auction or terminal market, at approximately $17 million in the initial year and falling to from $8 to $9 million in following years[2] (see Table 5.11). Costs to the public sector of initiating the program, monitoring, compliance and supervisory activities were placed at approximately $4.7 million in the start-up year and $1.7 million in following years.[3]

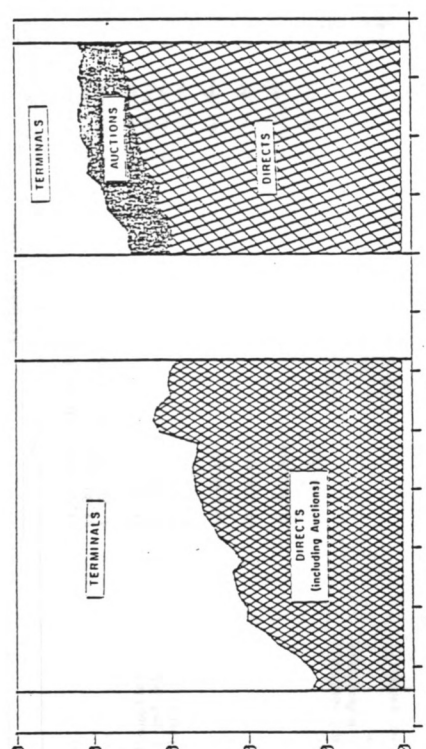
The study assumed that identification equipment would be required at nearly 18,000 points of sale or swine assembly, including stockyards, bonded dealers, packer buyers, federally inspected slaughter

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[1]USDA, Packers and Stockyards Administration Statistical Resume 1969-1978 (Washington, DC: Government Printing Office).

[2]1976 costs.

[3]1976 costs. At an annual inflation rate of 10 percent, by 1981 yearly expenditures would have grown to $2.7 million. Had the start-up year been 1981 and had costs inflated at 10 percent annually, public start-up costs would have risen to $7.54 million.



Source: P&SA Statistical Resume 1969-1978, USDA

FIGURE 5.5. HOGS, BY TYPE OF PACKER PROCUREMENT 1923-1978, U.S. PERCENTAGES

TABLE 5.11. ESTIMATED COSTS TO SWINE INDUSTRY AND GOVERNMENT OF A MANDATORY ANIMAL IDENTIFICATION PROGRAM

Item	Estimated Costs	
	Year 1	Following Years
Identification	($3,561,600 - $4,006,800)	($3,561,600 - $4,006,800)
Tatooing	$2,893,800	$2,893,800
Ear tagging	$ 667,800 - $1,113,000	$ 667,800 - $1,113,000
Equipment and supplies	($2,361,554)	($1,269,744)
Tatoo sets and ink	$2,183,619	$1,091,809
Tagging pliers	$ 44,375	$ 44,375
Ear tags	$ 133,560	$ 133,560
Facilities	$4,438,250	$ 443,825
Recordkeeping	$1,175,000	$1,175,000
Intangibles	$1,000,000	$ 500,000
Labor (federal)	$4,690,320	$1,720,670
Initiate and monitor	209.0 MY	82.2 MY
Regulation enforcement	7.8 MY	7.8 MY
Supervision	7.2 MY	2.6 MY
Total man years	224.0 MY	82.2 MY
Total costs		
Private sector	$12,536,404 - $12,981,604	$6,950,169 - $7,395,369
Public sector	$ 4,690,724	$1,720,670
	$17,226,724 - $17,671,924	$8,670,839 - $9,116,039

plants, State inspected or exempt plants and other buying points. By including an ear tag option, the study accommodated the fact that skinning is increasingly used by packers, requiring an alternative to the tatoo in order to ensure traceability. Finally, cost estimates included $1 million worth of "intangibles" in the first year, associated with increased transactions costs in the industry: for example, increased costs of handling swine consignments needing identification, and the ongoing necessity to teach personnel how to identify animals. For more details of a conservative estimate of the costs of an animal identification system (again, in 1976 costs) see Table 5.11.

More recently a USDA administrator was quoted estimating that a non-uniform identification system left to the design of packers and producers but capable of identifying every animal back to the farm (along with expanded USDA quarantine authority) would be expected to cost about $15 million for fiscal 1980, and producers approximately $8 million per year for maintenance of records.[1]

5.5.4 Summary and Conclusions: Alternative Swine Inspection Procedures and Marketing Rules

One conclusion which emerges from the previous examination of the four major changes in marketing rules or inspection procedures is that none of the proposals are close substitutes; they are more nearly complementary. Further, performance depends upon whether measures are implemented singly or in combination.

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[1]Thomas Grumbley, Associate Administrator of Food Safety and Quality Service, USDA cited in "USDA Pushes for Mandatory Identification," National Hog Farmer, November 15, 1979.

With respect to reducing consumer exposure to sulfa in pork, an in-plant screening test could come close to eliminating exposure to sulfa residues if it were widely applied. The same cannot be said for the other measures alone (that is, expanding quarantine powers, an animal identification system or a voluntary live hog blood serum test[1]). Without the capacity for extremely rapid turn-around of sulfa assay results, animals will not be held by USDA but instead will enter the marketing chain. Although quarantine powers, an identification system and the blood serum tests are not by themselves capable of eliminating sulfa residues, each policy tool could contribute to reductions in human exposure to sulfa as well as other contaminants and various animal diseases. An identification system is a critical element in enabling linkages to be made between producers and contaminated animals. Without this tool, the system's capacity for teaching proper drug handling practices is seriously diminished.

The economic impacts of the four measures depend upon specifics of implementation. Costs of an in-plant test depend upon technology, number of animals or carcasses tested, and a variety of factors discussed previously. The incidence of costs of compliance to in-plant testing depends upon the financing method chosen, whether and what proportion packers, producers and consumers pay, relative to taxpayers.

Two types of in-plant testing were discussed in this section. Both would be very costly if used for universal screening purposes. Estimated figures are shown in Table 5.12. USDA estimated on the

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[1]Unless it were administered at the packing plant.

TABLE 5.12. ECONOMIC IMPACTS OF PROPOSED CHANGES IN INSPECTION AND MARKETING RULES

PERFORMANCE VARIABLES	Policies		
	In-plant Sulfa Swab Test (all carcasses)	Plant-Site Sulfa Screening (all live hogs)	I.D. System for Slaughtering Hogs
Consumer Exposure to Sulfa Residues	Decrease to eliminate, depends on sampling rate	Decrease to eliminate	Reduce: depends on enforcement
Consumer Prices for Pork	Increase	Increase	Increase in short run. Disease control could lower prices
Meat Packing Industry Impacts	Increase costs of production	Increase costs	Increase if drug use curtailed. Decreased if disease reduced
Costs of Producing Hogs[1]	Slight increase due to sulfa avoidance	Slight increase	Indeterminate
Feed Industry Impacts	Decrease sales of sulfa feeds	Decrease sales of sulfa feeds	Increased pressure to eliminate contamination
Animal Health Industry Impacts	Decrease sales of sulfa products. Gains to rivals	Decrease sales of sulfa products. Gains to rivals	Decreased sale of troublesome drugs
Program Costs	Increase program cost $.4 billion to $1.8 billion[2]	Increase program cost $11.3 billion[3]	Increase program cost $6.26 million startup to $2.3 million ongoing annual[4]

[1]Based on 1% increase in feed costs (USDA figures, 1979). [2]Based on 80-90 million hogs sampled, cost $5-$20/sample. [3]USDA estimates for 1976 inflated to 1980. [4]Based on USDA estimates for 1976 inflated to 1979.

basis of 1976 costs that the costs of screening slaughter swine using a blood serum test for live hogs would cost approximately $8.1 billion annually. If those costs have inflated at least 10 percent annually, the same testing program in 1981 totals over $12.7 billion.[1]

If a STOP test for sulfa were administered in-plant on all swine carcasses, testing costs alone would range between $.4 billion and $1.8 billion. This estimate does not include increased carcass storage requirements, increased costs of condemnation and disposal or regional lab charges for the violative percentage sent on for further testing. Over time, were such a system to be instituted, it is probable that fewer producers and packers would choose to assume the risks of using sulfa, and adjustments in swine production and purchasing practices would be adopted. These in turn might eventually lead to fewer sulfa residue problems and decreased costs of storage, condemnation, disposal and regional lab testing.

The economic and public health impacts of an animal identification system were shown to be widespread. The capacity for animal identification is a prerequisite for establishing accountability in the marketing system. The meat packing industry has already moved part way toward implementation of identification. In many cases, however, livestock cannot be traced back to herds of origin but only to order buyers or

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[1]The CPI rose 56 percent, an average of 11 percent annually between 1976 and 1981.

other intermediate points in the marketing chain. Were an identification system required, packers could benefit by purchasing and financially rewarding for animals meeting specifications. They could also more accurately discount animals not measuring up to specifications. This includes potential price discounts for contamination.

The costs of extending a combination tag and tatoo identification system to the estimated 30 percent of all swine not otherwise identified were estimated by USDA based on 1976 figures to total $17.2 to $17.7 million in the first year ($12.5-$13 million expended by the private sector and $4.7 million by the public sector) (see Table 5.12). On successive years USDA estimated costs would approximately halve, falling to $8.7-$9.1 million annually ($1.7 borne by the public sector).

These estimates suggest that a universally administered blood serum screening test for live hogs is the most costly policy change discussed from a public expenditure standpoint, followed by a universal in-plant STOP test for sulfa. An identification system based on simple mechanical devices (ear tag or tatoo) and incorporating currently existing identification systems whenever possible appears to be the least costly policy option of the three from the standpoint of direct public program costs. If electronic technology were considered, costs per animal unit would probably skyrocket, at least initially. A blood serum screening test used by producers or packers involves no public expenditures other than initial research support and is not ranked with these other alternatives. Interview evidence cited previously raises doubts regarding producers' propensities to use blood tests except in non-routine circumstances.

To attain multiple desired food system objectives of reducing consumer exposure to sulfa and other residues while at the same time preserving reasonable prices, opportunity for gain, and reasonable participant autonomy of action, the adoption of a combination of measures and the use of statistical sampling techniques should be considered.

Chapter V has presented analysis of five policy scenarios which could be applied to problems of sulfa residue contamination in swine or to similar residue problems in meat. In Chapter VI, Section 3, policy impacts are summarized and policies compared and contrasted on the basis of their impacts upon various performance variables and their success in meeting multiple performance objectives. Chapter VI also summarizes research conclusions regarding drug- and regulation-related economic decisions throughout the food system and discusses policy issues and research needs highlighted by this research.

CHAPTER VI

CONCLUSIONS, POLICY ISSUES, RESEARCH NEEDS

6.1 Summary of Research Problem and Methodology

This research examined an important U.S. food safety problem, the case of sulfa residue contamination in swine, in order to analyze economic impacts associated with a variety of policy proposals pertinent to this and similar food safety residue problems. The research method utilized a subsectoral approach and concentrated upon identification and analysis of policy impacts upon characteristic decision-making of market participants in the principal industries involved in the sulfa case: the animal health, commercial feed, swine, and meat packing industries, as well as administrative agencies responsible for food safety.

The structural features of the various industry markets as well as organizational features of the firms within these industries were examined. By modeling the decision-making processes of these firms in relation to animal drugs and food safety regulation, the research sought to describe and analyze the influence of food safety policy measures in the sulfa case, as well as to predict probable impacts of alternative policy measures.

It was believed initially, and confirmed by the research, that many food safety problems require a systemic conceptualization for

effective solution. In the sulfa and similar cases, a clear understanding of market and institutional incentives operative at all important decision points within the value-added process is a prerequisite for identification of productive policy approaches and their probable political-economic impacts. To expand this, research conclusions in the sulfa case emphasize the need for policy makers to look beyond the jurisdictional boundaries of a particular responsible regulatory agency in order to understand the relevant determinants of contamination problems and to devise effective and creative solutions to these problems.

Procedures followed in this research involved both conceptual modeling and an interview process involving approximately 100 members of industry, government and universities. The purpose was to identify characteristic decision-making problems of members of each of these groups in relation to the sulfa problem, economic incentives influencing decisions, and a variety of potential policy solutions for analysis. Policies identified include: 1) a ban or restriction on the use of sulfa in swine feeds; 2) an increased tolerance level for sulfa residues in swine; 3) the Sulfa Task Force program; 4) regulatory measures aimed at the feed industry (including the proposed Second Generation Policy); 5) regulatory changes in swine marketing and inspection rules.

This policy study integrates theory, empirical evidence and analyses of proposed measures in order to display probable economic impacts upon consumers, industry groups, public program costs and consumer exposure to violative sulfa residues in swine. Specific

empirical results and conclusions were presented in two parts: Chapter IV examined patterns of decision-making related to sulfa and other animal drugs in the four principal industries; Chapter V built upon theoretical and empirical analysis of public program impacts upon decision-making (presented in Chapters III and IV) and applied the results to the analysis of five potential policy scenarios. In this chapter, policy options are compared and contrasted on the basis of program cost-effectiveness and other economic impacts.

The remainder of this chapter, then, summarizes major conclusions of Chapters IV and V, evaluates policies proposed to solve the sulfa problem, then expands the conclusions to explore broader policy issues raised by the sulfa case and implications of the findings of the sulfa case for design of institutional response to these policy issues. Chapter VI concludes with a list of additional research questions raised or encountered in this research. Answers to these questions will further enhance our collective capacity to anticipate and respond to future food safety problems.

6.2 Research Results and Conclusions Related to Decision-making in the Sulfa Case

Chapter IV presented case evidence and other information related to decision-making regarding sulfa and other animal drugs in the animal health, the commercial feed, the swine and the meat packing industries. The conceptual model of the firm underlying the research hypothesized that an economic entity acting in a rational, self-interested manner, but under conditions of uncertainty, costly

information, and economic power, adopts satisficing strategies to reduce uncertainty and increase control, while conserving scarce firm resources. With respect to regulatory uncertainty, it was proposed that the firm makes three different types of decisions: 1) decisions related to the acquisition and use of costly information, 2) decisions related to attempting to influence the design or enforcement of regulation; 3) decisions related to developing a compliance strategy for these regulations judged desirable or inevitable or inescapable.

In the sulfa case, theory and empirical evidence combined to suggest three major bases of participant interest in sulfa drugs: interest in sulfa drugs as products, as inputs into a production process, and as contaminants. The type of firm economic interest in sulfa drugs naturally influences the firm's interests in and reaction to animal drug/food safety regulation. Policy makers, on the other hand, are expected to view sulfa drugs as a policy problem in which various interests of third parties are balanced in the context of a job setting with its own distinctive pattern of incentives.

Given current legislation, the major policy problem involved in designing systemic incentives to attain legally mandated levels of food safety in the food product under consideration is twofold: 1) altering patterns of private costs and benefits to increase participants' appreciation of sulfa's negative value as a contaminant and increasing participant knowledge of practical methods of eliminating contamination in each of the major industries involved in the

problem; 2) altering incentive structures within the public sector in a manner which encourages policy makers to look beyond conventional technology, traditional jurisdictional boundaries and constituency groups, and established institutional mechanisms in order to fully identify problem causes and potentially cost-effective methods of solution.

6.2.1 The Animal Health Industry

A brief summary of empirical results of the examination of decision-making in the four principal industries in the sulfa case confirms the hypothesis that the animal health industry is distinguished primarily by its interest in sulfa and other animal drugs as revenue producing products, taking little account of their potential for contamination and costs to producers, consumers and others in the marketing chain. This industry did not directly experience quality control problems throughout most of the sulfa case, although animal health firms eventually experienced a high degree of market and regulatory uncertainty due to contamination problems in the swine and feed industries. Animal health industry actions in the sulfa case consisted principally of market strategies to preserve market share, in the case of those firms producing sulfamethazine, and attempts to exploit the sulfamethazine residue situation to advantage in the case of firms producing competitive products. Some efforts were expended toward increasing buyer confidence or reducing buyer transactions costs associated with animal drug regulations in order to maintain or expand market share.

With respect to animal health industry strategies aimed at reducing regulatory uncertainty and increasing control, the sulfa case demonstrated that the animal health industry utilizes an extensive information gathering system to stay abreast of regulatory developments, including potential new rules and enforcement strategies pertinent to its major products. Firms in this industry adapt organizationally to cope with regulatory problems. They employ experts in matters of food and drug law, administrative procedures and other aspects of the institutional structure pertinent to regulatory issues concerning their products.

A purpose and a result of specialized legal and regulatory affairs expertise within corporations appear to be a propensity for these organizational units to perform as buffers or deflectors which insulate and protect the firm from significant regulatory inroads into internal activities such as research and development, marketing, quality control and sales. At the same time, regulatory affairs staffs provide and interpret information on regulatory developments to firm management. They frequently initiate corporate initiatives to influence the design and enforcement of regulatory rules to advantage the company's products. Strategies of animal health firms in the sulfa case, over most of the period from 1973-80, focused upon attempting to pressure the Food and Drug Administration to raise the tolerance level for sulfamethazine residues, on the one hand, while disputing the accuracy of official chemical assay procedures, on the other. Only after an approximately

seven year history of residue problems in the swine and feed industries did the animal health industry undertake research into new formulation processes to prevent problems of drug electrostaticity. Regulatory policy tools available to FDA were not adequate to directly induce the industry to undertake research into the electrostaticity problem; FDA only succeeded in pressuring the animal health industry to undertake research after swine producers decreased demand for sulfa-medicated feed. To couch this in other terms, regulators at FDA lacked the authority to directly impose process or performance standards on the animal health industry in the sulfa case; neither did they attempt to lower industry information costs by sponsoring research into new technology. The only remaining avenue of influence open to regulators, then, was to engineer inducements through the market for medicated feeds by making swine producers wary of purchasing it. The cost-effectiveness and the equity impacts of this approach demand careful scrutiny as the brunt of the regulatory burden fell upon the swine industry.

6.2.2 The Commercial Feed Industry

A review of empirical evidence from the commercial feed industry demonstrates the complex interests of this industry with respect to sulfa, and in relation to food safety regulatory design. The commercial feed industry has economic interest in sulfa drugs as products which are resold in straight or premix form by various firms, interest in sulfa drugs as inputs into manufactured feed articles, and minor

interest in the drug as a contaminant, so long as no product liability problem occurs. Market, institutional and organizational strategies employed in the sulfa case reflect these various interests as individual firms balanced their concerns in different ways. Strategies related to firm interests in sulfa as product and as input included measures to maintain markets (through advertising and promotion, provision of advice to hog producers about contamination dangers[1]), and the decision to switch from sulfamethazine to sulfathiazole to reduce contamination problems.

Firms adopted a variety of quality control procedures and expressed a diversity of opinions regarding whether or not sulfamethazine could be handled in their plants without significant contamination. Official statements of the American Feed Manufacturers' Association indicated that the industry judged itself generally incapable of meeting existing tolerances with prevalent mixing and handling technology (prior to granulation). However, many companies, large and small, continued to mix sulfamethazine. Others stopped handling sulfamethazine for fear of product liability problems.

With regard to food safety/animal drug regulation, firms within the industry pursued objectives directed toward preserving market access to and for sulfa products, pressuring the FDA to increase the legal sulfa tolerance level and to modify official assay procedures.

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[1] This strategy appeared to be used fairly infrequently; in many cases, hog producers stated their feed salesmen had never mentioned potential sulfa problems.

Many firms expressed concern that not enough is known about various dimensions of the sulfa problem, particularly the relative efficacy of sulfamethazine versus sulfathiazole in livestock production, and the effectiveness of drug and feed handling procedures within mills to reduce cross-contamination. Several firms expressed concern, particularly some of the smaller ones, that the FDA had not provided much assistance or information about sulfa but was instead more interested in restructuring the feed industry to take many drugs away from smaller firms. The Second Generation Policy was viewed by many small firms as a means of coercing smaller firms to purchase medicated feed articles from their larger competitors.

6.2.3 The Swine Industry

Initially the swine industry was the unwilling focus of regulatory and public scrutiny in the sulfa case. This industry has two major interests in sulfa drugs: a longstanding experience with, and fondness for, the drug as a combination feed additive with penicillin and tetracycline--in other words, an input into the hog production process--and a more recent and less pleasant relationship with sulfa drug residues as contaminants of hog products.

Producers in the swine industry operate as sellers in hog markets and as buyers of inputs, particularly feed and animal health products. In each of these markets, producers confront the costs, risks and benefits of using sulfa. Some hog producers confronting regulatory sanctions endeavored to increase control over input quality assurance

to avoid the purchase of contaminated products. The exercise of exit or voice options with regard to feed ingredient suppliers appeared to be influenced by price, available information regarding substitutes and customer loyalty. Upon the advice of Extension workers, some producers retained feed samples for sulfa assays.

Interviews with hog producers in Michigan and Kansas indicated that the educational effort of the Cooperative Extension Service, along with increased USDA sulfa monitoring, succeeded in influencing these hog producers to make at least marginal adjustments in their sulfa handling practices. Whereas all but one of the interviewed hog producers continued using sulfa drugs in some form, many reported that they had reduced usage or switched to water medication or begun using the sulfas selectively for disease treatment only. All producers interviewed in Michigan and Kansas reported having received advice or hearing prepared materials regarding potential sulfa contamination problems from members of the Extension Service.

Extension efforts were not uniformly effective in reducing sulfa contamination rates, however. Particular geographic areas and types of markets continued to yield violation rates and levels far above the national norm. These results suggest a couple of explanatory factors: Extension programming may have been inconsistent or of lower priority in some regions; a hog producer wary of possible contamination in his own hogs may market them through auction markets where animal identification is more difficult, if he is unwilling to undertake the resource costs of management modifications which would reduce contamination possibilities.

With regard to preferred regulatory control strategies, hog producers favored an increased tolerance level and expressed disbelief that sulfa residues present a public health risk. The National Pork Producers Council supported animal health industry efforts aimed at increasing legal tolerances for sulfa residues, and farmers interviewed in the course of this research favored this effort. Farmers believed they can be most influential primarily through contact with legislators. Producer groups also utilized the USDA to support their interests.

6.2.4 Hog Buyers and Meat Packers

Interviews with hog buyers and meat packers revealed that the industry currently has limited concern regarding sulfa contamination in hogs. Meat packers face negligible costs associated with sulfa residues and hence perceive little risk identified with purchase of hogs. Respondents expressed the opinion that modifications in marketing rules, including in-plant sulfa screening and an animal identification system, could substantially alter the industry's concern. The meat packing industry could benefit from an animal identification system if it assisted in procurement of high or readily identifiable quality animals. Less favorable was the reaction to in-plant tests which could increase liability or reduce productivity.

6.2.5 Public Decision-makers

In seeking an explanation for swine producers' expressed lack of awareness of alleged human health risks associated with sulfa residues,

as well as the lack of public information on this subject, one is led to the conclusion that either personnel at USDA or FDA did not believe the problem actually constituted a public health problem. Alternatively, if they did perceive sulfa residues to be a health problem they did not consider it necessary to inform producers. A further explanation might be that perceptions of the problem differed between agencies and the jurisdictional division between FDA and USDA (resulting in FDA establishing tolerance levels which USDA then enforces) resulted in inconsistent policy objectives being transmitted.

Regarding the last point, USDA has traditionally provided many services to agricultural producers, considers agricultural producers to be a primary constituency group, and has developed extensive research and Extension expertise in most aspects of the agricultural production and marketing process. The orientation toward producers of the agency naturally carries with it an appreciation of producer production problems which have encouraged the inclusion of antibiotics in feed. The USDA also has a long history of inspecting meat and responding to consumers. However, the producer orientation appears to have encouraged the USDA in the sulfa case to define the sulfa problem as a marketing problem and to emphasize policy objectives of <u>controlling</u> sulfa residues in swine at some "satisfactory" violation level rather than striving to eliminate sulfamethazine from the food supply.

The FDA, on the other hand, was formed as a public health agency, has a markedly different clientele group, does not have an agricultural orientation, and is guided by a body of law, scientific and policy procedures for establishment of food safety standards which, in the

case of animal drugs, does not explicitly permit economic benefits of substances in agricultural production to be traded off against public health risk.[1] FDA regulations pertaining to any one drug are linked to regulatory treatment of similar drugs, which prevents the agency from tinkering with tolerances on a case by case basis because of the precedents for revision which would be established. These factors appear to contribute to an FDA position which explicitly emphasizes absolute reductions in the level of sulfa in swine populations with only implicit consideration of agricultural firms' economic welfare or economic benefits associated with the use of animal drugs.

6.3 Comparative Analysis and Evaluation of the Sulfa Policy Alternatives

Chapter V analyzed five policy scenarios, examining economic impacts to consumers, hog producers, meat packers, feed manufacturers and the animal health industry as well as the probable success of the policy in eliminating or reducing consumer exposure to sulfa residues in swine.

6.3.1 A Sulfa Ban or Restriction in Swine Feed

The initial policy scenario considered was a ban or restriction on the subtherapeutic use of sulfa feed additives. The analysis compared and contrasted impacts of a general ban on the use of sulfa feed

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[1] These arguments apply particularly to the Bureau of Foods within FDA which has responsibility for establishing tolerances for animal drugs.

additives in all livestock feeds, the ban of only sulfamethazine in swine feeds, and a restriction of sulfa feed additives to swine starter feeds, the last a policy adopted by Agriculture Canada.

Results of two recent government studies of the economic impacts of general bans upon subtherapeutic use of sulfa combination drugs and other feed additives were reported, to provide benchmarks for this analysis. The USDA predicted that a ban of subtherapeutic use in swine of sulfa combination drugs and the nitrofurans would cause a first year reduction of 5 percent in the supply of pork with a 5 percent increase in product prices. In a multi-commodity, five year model, pork price differentials with and without a ban drop to approximately 1 percent.

The Office of Technology Assessment, in a similar study, predicted a ban of several feed additives (including the sulfonamides) in the swine and poultry industries would result in a decrease of 2.5 percent in pork consumption and a rise of approximately 10 percent in barrow and gilt prices over an 11 year period.

The current research examined alternatives to a general ban including a ban in swine feeds of sulfamethazine only and a restriction of sulfa combination drugs to starter feeds.

Because sulfa drugs are fed only in combination with approved antibiotics, their individual effects are not currently known. Further research in this area to determine the value of sulfonamides in their own right remains a critical need. It is reasonable to assume that a ban upon the sulfa drugs alone, while preserving use of tylosin, the tetracyclines and penicillin would exert substantially less impact upon prices, pork supplies, hog producer income and feed use by the

swine industry than reported in the USDA and OTA studies cited above, particularly when other substitutes are considered as well.

The efficacy of a ban on subtherapeutic feeding of sulfa drugs in reducing consumer exposure to residues would depend upon hog producer use of other sources of sulfa in the system including water medicants, veterinary prescriptions and allegedly available straight sulfa drugs through many feed supply outlets. By removing sulfa drugs from the feed industry chances of violations resulting from cross-contamination would be reduced. To the extent other sources of sulfa cost more than feed additives to use, producer care should increase.

A sulfa ban would mean a loss to the feed industry of a popular additive to its feed products, but if all firms lose this input, intra-industry distributional impacts would be minimal. Finally, pharmaceutical producers of the sulfa feed additives would initially face substantial economic losses from a ban of major products. A ban of sulfa feed additives would eliminate three products comprising over 50 percent of the swine feed additives market.

In contrast to a ban of both sulfas, if only sulfamethazine[1] swine feed additives were banned, distributional benefits would accrue to the one U.S. producer of the approved sulfathiazole additive. In addition, there would be a less significant reduction in swine feed efficiency, disease control and growth promotion effects with a ban of only sulfamethazine due to the similarity in effects of the two

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[1]The source of over 99 percent of all swine sulfa residue violations.

sulfonamides. Because only limited research has been done on relative efficacy of the two sulfa drugs,[1] it is too soon to estimate precise impacts.

It should be noted that in all probability the policy would effectively minimize consumer exposure to sulfa contamination. Sulfathiazole depletes much more rapidly from a swine's system and demonstrates far less electrostaticity. As previously mentioned, sulfathiazole residues account for under 1 percent of all violations, while accounting for about 10 percent of the total sulfa used in drug combinations added to swine feeds.

The third variant of a ban or restriction considered was a restriction of sulfa feed additives to swine starter feeds, the so-called "Canadian option." Based on the premise violations in swine were chiefly attributable to feeding sulfa medicated feeds to finishing hogs, this option was implemented in Canada to extend the withdrawal period to 80 days. The policy measure by itself does not address contamination in hogs resulting from drug carryover in feed handling equipment or from environmental sources. Therefore, it is not judged effective for application in the U.S.

Analysis of the Canadian experience further suggests that the Canadian system of animal identification and marketing through marketing boards has probably been the major factor contributing to the apparent reduction in Canadian sulfa violation rates.

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[1]Research initiated under the Sulfa Task Force on this subject should provide some answers in the future.

6.3.2 Increased Tolerance Level

Scenario Two consisted of increasing the tolerance level for sulfa drugs in swine. Industry groups favored this policy move, arguing a slight increase in legal tolerances would reduce costs of regulatory compliance to hog producers and feed manufacturers without endangering public health.

Analysis of this policy focused on swine industry response, impacts on consumer exposure to sulfa drugs and impacts to regulatory program costs. Empirical results of the sulfa residue monitoring program suggest a bi-modal distribution for sulfa violators, the conscientious producer who inadvertently markets a violative hog with low levels of sulfa and the careless producer who markets swine with high levels of contamination. In 1979, 24 percent of all residue violations were classified as high level violations.

Alternative hypotheses about the reaction of hog producers to an increase in tolerance levels led to different conclusions regarding their regulatory compliance strategies and ultimate impacts upon consumer exposure to residues. If a reduction in the expected likelihood of a regulatory problem due to an increased tolerance leads to reduced care in sulfa use, then consumer exposure to sulfa might be increased. If producers do not believe the increase in tolerance permits relaxation in care, then exposure should remain approximately unchanged. Finally, to the extent an increase in tolerance levels reduces violation rates (due to low level, "conscientious" producers) and frees surveillance resources for "careless" producers (marketing swine with high levels of contamination), consumer exposure to sulfa

drugs might decrease. Chief among stumbling blocks here, however, is the lack of an animal identification system, unless sampling frequencies using in-plant assays, are significantly increased.

Regulatory program costs might be reduced with increased tolerance levels if regulators maintain previous monitoring rates but have fewer violations to follow up.

In the feed industry, economic impacts include reduced costs of regulatory compliance and increased incentive to promote sulfa medicated feeds.

Impacts on producers of sulfa drugs include increased sales, reduced transactions costs of regulation and, had the tolerance been raised before completion of research on granulation, diminished incentive to develop an improved technology.

6.3.3 Sulfa Task Force Approach

Scenario Three analyzed the operation and activities of the government-industry Sulfa Task Force. Task Force activities consisted primarily of research on residue problem causes and physical characteristics of sulfonamides along with their use; public information; and Cooperative Extension Service activities.

Impacts of the Task Force on hog producer decision-making consisted chiefly of reducing information costs connected with learning about sulfa and its appropriate use. Increases in swine monitoring rates with the associated publicity, on the other hand, contributed to producer expectations of increased costs of sulfa violations. On the basis of evidence in the sulfa case, this analysis concludes that

in situations where use of a drug has but small incremental benefit, or necessary management modifications required to use the drug carefully result in only a small cost, regulatory strategies reducing costs of information and increasing expected costs of violations may be fairly effective in controlling residues in the food supply. If the regulatory objective is elimination of residues from the food supply, however, this policy will not be as successful as removing the contaminant from the system. With respect to reducing violation rates, the Sulfa Task Force appears to have been effective: rates dropped in four years from between 10 to 15 percent in 1977 to 4 percent in 1980.

Evidence of sulfa program impacts on the feed and animal health industries suggests government strategies here were initially ineffective in soliciting industry action to reduce consumer exposure to sulfa. Both the feed and animal health industries fall under the regulatory jurisdiction of the Food and Drug Administration. While some useful USDA research was provided to the feed industry, it was on a much more limited scale than to the swine industry; neither were USDA Extension efforts directed at this industry with the same intensity. Finally, there was no convenient performance measure such as a violation rate for the industry to evaluate its own performance.

The animal health industry, though involved in Task Force discussions and aware of sulfa residue problems was not a focus of Task Force, or other regulatory efforts. Eventually, regulatory pressure on firms within other industries resulted in sufficient pressure on the animal health industry to cause it to undertake research and

development into sulfamethazine granulation. In retrospect, a regulatory approach directed toward inducing a change in the performance of 400,000 swine producers and over 10,000 feed manufacturers, but neglecting an industry of four sulfa feed additive producers seems less than ideal. This judgment is further discussed below.

Official estimates of the costs of the Sulfa Task Force and the sulfa program range from $1.4 to $4 million depending upon the years and activities included. As defined by this research, program costs were estimated at approximately $2.8 to $4.8 million. (During the period of the Task Force and two subsequent years, violation rates fell between 6 and 9 percent to a 1980 average of approximately 4 percent.)

6.3.4 Feed Industry Regulation: Selective Inspection, Second Generation Policy

Scenario Four examined alternative regulatory policies directed at reducing sulfa cross-contamination in feed mills (as well as cross-contamination resulting from other drugs).

The first policy considered increases in FDA inspection of feed mills for sulfa-related problems. Because FDA inspections are currently running far behind legally mandated requirements for biennial inspections of all 17,000 medicated feed and drug establishments, the economic feasibility of this alternative is low. Therefore, a selective use of inspections is a more reasonable policy under current funding constraints. Criteria might include volume of product and/or likelihood of producing contaminated feed.

The second policy examined impacts upon sulfa residue problems and major participants in the sulfa case of proposed FDA policies which will substantially restructure the commercial feed industry with respect to drug handling policies. This is the so-called Second Generation of Medicated Feeds policy. It was concluded that with respect to the sulfa problem in feed mills, the policy may have some success in limiting concentrated drug articles to firms demonstrating certain levels of expertise in drug-handling practices. However, because of the extremely low levels of sulfa concentration required in feed carryover to produce violative sulfa levels in subsequent batches, the policy will probably not be effective in eliminating sulfa residues from commercial feeds. And because the policy is directed only at feed handling practices, it will not address the portion of the problem attributable to hog producer carelessness in withdrawing sulfa.

Cost impacts of the policy are expected to result in:

1) higher costs of sulfa-medicated feeds to hog producers resulting in less use;

2) higher costs of sulfa-medicated feeds to "exempt" feed manufacturers[1], again resulting in less use;

3) lower sales and distribution costs to animal health firms;

4) ease in administering prices for animal health firms;

5) distributional benefits to animal health manufacturers of drugs recategorized as low-risk and increased costs to producers of those rated higher risk by the new policy;

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[1] "Exemptions" refer to firm decisions not to handle concentrated drug articles in order to be exempt from Food and Drug Administration Good Manufacturing Practices.

6) potentially higher costs to consumers reflecting higher total feed costs;

7) an increased inspection load in the next few years to implement the policy but reduced FDA inspection requirements eventually, leading to some cost savings in this area.

6.3.5 Regulatory Changes in Swine Marketing and Inspection Rules

Scenario Five examined impacts of five policy measures:

1) institute a simple in-plant screening test for sulfonamides for use in packing plants;

2) give USDA quarantine powers on farms, in packing plants and elsewhere in the food chain over meat or livestock believed contaminated;

3) institute or require an animal identification system for swine;

4) develop a blood serum test permitting screening of live swine for sulfa;

5) develop a screening test for sulfa in feeds.

The purpose of these modifications in swine (or feed) inspection procedures or marketing rules is to decrease public exposure to sulfa contamination by expediting and increasing sampling, retaining suspect meat, condemning adulterated meat, closing marketing loopholes and, with the assistance of new assay procedures and an identification system, permitting regulatory authorities to identify problem sources and aid producers in eliminating these. The policy measures may be implemented singly or in various combinations. The analysis predicts various impacts.

Initially, in-plant screening would increase costs of the meat packing industry due to forced identification and retention of sulfa-contaminated meat. Costs of cold storage, reduction in the value of retained meat, a slower moving kill line and losses from the condemnation of adulterated meat represent new costs swine packers would have to bear. Ultimately the proportion of the risk and cost would be shifted to swine producers, others in the marketing chain and, eventually, consumers.

The screening procedure involves labor, time and equipment. USDA estimates in 1981 that in-plant screening would permit a cost-savings per sulfa sample of approximately $30 for those animals which are not contaminated. Choice of the method used to finance residue testing carries distributional impacts; user charges, a change from traditional policy in which taxpayers have picked up the tab, would result in higher priced pork to consumers.

An in-plant sulfa-screening program if used to screen all or a large proportion of slaughter swine could virtually eliminate consumer exposure to sulfa residues in swine. In general, if sampled livestock could be screened in-plant for multiple chemicals, overall quality of meat might be significantly improved. Finally, if consumer perceptions of enhanced quality and safety lead to increased consumer confidence in pork, an increase in demand might result.

Institution of an animal identification system, given an extensive in-plant screening program, would expedite the shifting of costs of sulfa contamination back to responsible producers. If an in-plant screening

procedure were widely used, this would be sufficient to protect consumers. While an identification system would not substantially further improve pork quality at the consumer level, it would force producers to improve management practices.

Development of a blood serum test for live hogs would permit on-farm testing of suspect animals. Producers could therefore avoid or be prevented from marketing violative animals.

In all probability, an animal identification system would exert a variety of impacts not directly associated with the sulfa problem. It would enhance producer and regulatory capacity to control disease, thereby reducing aggregate costs of disease. It would also likely alter the relative balance of power between livestock producers and packers and eventually modify the structure of the swine industry. It would mean that packers could force individual producers of contaminated, diseased or otherwise low quality livestock to bear the entire costs of these problems instead of pooling them among all swine producers and packers.

Costs of an identification program depend upon its scope, its technology, information requirements and other specifications (including whether a uniform system is mandated). USDA estimates placed the initial costs to the swine industry and government of a national identification system for the 30 percent of slaughter hogs not currently identifiable at approximately $17 million in 1976 with a yearly ongoing cost of approximately $8.9 million.

If the inflation rates as summarized by increases in the CPI are incorporated in the estimate, the 1976 figure for initial costs would have risen to approximately $26.9 million in 1981.

Use of a quick screening test for sulfamethazine in feed and feed ingredients would permit feed manufacturers, hog producers and regulators to quickly sample feed items if concern about residues arises. Such a tool would permit swine producers to refuse a shipment of feed if a screening test indicated contamination. It would also enable feed manufacturers to route or categorize feed on the basis of drug content. Finally, a quick test available to regulators in feed plants could be used to facilitate the clean up of plants having sulfa problems and to identify appropriate routing or disposition of feed with excessive drug levels.

6.3.6 Summarizing Policy Impacts

Figure 6.1 summarizes analytical information regarding economic and other performance impacts of the policy measures discussed. Column headings identify policy measures while row headings indicate several performance variables of interest. It will be seen that overall evaluation and eventual choice of a particular policy measure depends in large measure on the specification and weighting of different policy objectives. If, for example, the primary performance goal is to eliminate all sulfamethazine from the food supply, that is, a zero tolerance level, a ban of this substance is indicated. Because of sulfamethazine availability in a number of forms (in water medicants, boluses, other)

PERFORMANCE VARIABLES	FOOD SAFETY POLICY OPTIONS								
	Drug Ban (both sulfas)	Ban Only Sulfamethazine	Restrict Sulfa to Starter Feed	Raise Tolerance Level	Sulfa Task Force and Increased Monitoring	Second Generation Feed Policy	In-plant Sulfa Swab Test (all carcasses)	Plant-Site Sulfa Screening (all live hogs)	I.D. System for Slaughter Hogs
Consumer Exposure to Sulfa Residues	Decrease	Decrease	Minimal impact without I.D program and other measures	Slight increase (given current inspection and enforcement)	Probable decrease	Minimal impact to slight reduction. Increase in other residues?	Decrease to eliminate depends on sampling rate	Decrease to eliminate	Reduce: depends on enforcement
Consumer Prices for Pork	Increase:[1] <5% (1 yr) <1% (5 yrs)	Increase: <5% (1 yr) <1% (5 yrs)	No impact	Slight decrease if producers use sulfa for enhanced production	No impact to slight increase	Increase in short run	Increase	Increase	Increase in short run. Disease control could lower prices
Meat Packing Industry Impacts	Slightly higher costs of buying hogs	Costs of hogs rise less with sulfamethazine ban only	No impact on costs	Minimal cost impact. Slightly lower costs for hogs	Minimal without I.D. and plant-site screening	Increase costs in short run	Increase costs of production	Increase costs	Increase if drug use curtailed. Decrease if disease reduced
Costs of Producing Hogs[2]	Increase: $52 million	Increase: < $52 million	No impact	Slight decrease	No impact to slight increase	Increase (feed costs increase in short run)	Slight increase due to sulfa avoidance	Slight increase	Indeterminate
Feed Industry Impacts	Increased demand for feed if same quantity hogs fattened to same weight	Demand for substitutes--slightly increased demand for feed	Minimal impact	Indeterminate	Decreased demand for sulfa products. Increased demand for substitutes	Structural modification of industry. Higher medicated food costs for small exempt mills	Decrease sales of sulfa feeds	Decrease sales of sulfa feeds	Increased pressure to eliminate contamination
Animal Health Industry Impacts	Loss of revenues to sulfa products manufacturers. Gains to rivals	Loss of revenues to sulfamethazine producers. Gains to rivals	Reduced sales of sulfa feed additives for growers and finishers. Gains to rivals	Distributional gains to sulfa products manufacturers	Decreased sale of ASP-250. Increase in CSP-250 and substitutes	Reduced sales and distribution costs. "Benefits to low risk" drug producers	Decrease sales of sulfa products. Gains to rivals	Decrease sales of sulfa products. Gains to rivals	Decreased sale of troublesome drugs
Program Costs	Decrease costs of sulfa testing	Decrease cost of sulfa testing	Minimal impact enforcement difficulties	Decrease	$2.7-$4.7 million over 18 months	Increase FDA feed mill inspection in short run, then reduce them	Increase program cost $.4 billion to $1.8 billion[3]	Increase program cost $11.3 billion[4]	Increase program cost $6.26 million startup to $2.3 million ongoing annual[5]

[1] Based on USDA, Economic Effects of a Prohibition on the Use of Selected Animal Drugs, 1978. [2] Based on 1% increase in feed costs (USDA figures, 1979). [3] Based on 80-90 million hogs sampled, cost $5-$20/sample. [4] USDA estimates for 1976 inflated to 1980. [5] Based on USDA estimates for 1976 inflated to 1979.

FIGURE 6.1. ECONOMIC IMPACTS OF ALTERNATIVE FOOD SAFETY POLICY OPTIONS, THE SULFA CASE

and for use in other species, potential contamination potential of these products must also be taken into account. Residue evidence produced by the monitoring program thus far does not indicate any reason for banning sulfathiazole. However, several policy makers expressed concern that such a policy move would favor the single company selling a sulfathiazole swine combination feed additive. Implicitly, an objective of distributional equity or preserving the existing measure of competition in the swine feed additive market appears to be important to some decision-makers.

An alternative approach would be more costly and more complicated than a drug ban but could accomplish public health objectives of practically eliminating consumer exposure to sulfa residues and other antibiotic residues as well. If in-plant sampling for sulfa were instituted on a broad scale and if carcasses were retained until cleared, consumer exposure to sulfa in pork would be substantially reduced. Those packing plants purchasing unidentified swine would probably quickly move to institute a system which would permit assigning liability by price discounts for contamination. The relative magnitude of costs of a ban versus costs of an in-plant screening system are indicated in Figure 6.1. (In-plant screening systems vary broadly.) If costs of an identification system are added to costs of in-plant screening for sulfa, total costs of this policy range from $.4 million to $1.8 million for start up in the initial year and from $458 million to $1.86 billion annually for operation.

It would be erroneous, however, to assign all costs of an identification or a screening test to sulfa control to the extent other purposes can piggyback on the system.

If the primary objective of a sulfa policy is to control rather than eliminate consumer exposure to sulfamethazine, at the same time reducing swine marketing problems, then a different combination of policy measures is most cost-effective. Experience with the sulfa case has indicated that if policy objectives are defined in terms of achieving a reduction in violation rates, then the Sulfa Task Force approach of reducing information costs to swine producers and others while increasing the expected cost of a sulfa violation presents a viable alternative for modifying producer drug-handling behavior and addressing an existing problem.

The Sulfa Task Force program, in conjunction with increased monitoring and surveillance assistance from the Meat Inspection Service and some increases in FDA inspections of feed mills, succeeded in reducing the percentage of violative swine sampled by the Food Safety Qualtiy Service from approximately 14 percent to approximately 4 percent over a period of four years at an estimated cost of under $4 million.

Advantages of the task force approach include flexibility of protocol, the administrative facility for integrating expertise from multiple research disciplines and from industry as well as from diverse parts of the bureaucracy. The U.S. Department of Agriculture was able to utilize the institutional mechanism provided by the Cooperative Extension Service which provides a largely effective system for disseminating information to agricultural producers.

Program "outputs" and impacts include an expanded body of scientific knowledge with useful application to many aspects of the sulfa residue

problem and an increased institutional capacity to respond to similar problems in the future. One question must be raised, however, and that concerns the extent to which consumer exposure to sulfa residues was considered an important performance variable. Violation rates dipped to approximately 4 percent and, implicitly at least, this appears to have been considered a success, presumably because 4 percent represents a significant decrease from 10 to 15 percent. Apparently, consumer exposure to frequently higher level violations[1] in just under 4 percent of swine sampled is not considered to be a public health risk when exposure in 10-15 percent of slaughtered swine had been considered unacceptable previously. (The rationality of this ad hoc policy determination deserves examination.) One further question must be raised with regard to policy impacts on consumer exposure to sulfamethazine. To the extent livestock feeds and livestock other than swine are not tested for sulfamethazine, no assurance exists that sulfamethazine cross contamination is not entering the food supply through an alternative route.

In terms of program costs the Sulfa Task Force program was fairly inexpensive. Hence, given a performance objective of controlling existing residue and marketing problems, this pragmatic policy approach has much to recommend it.

One disadvantage of policies aimed at the end rather than the beginning of the marketing chain (that is, at swine producers and meat

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[1]The proportion of higher level violations has increased as low level violators have improved management practices.

packers rather than input manufacturers) is the resource costs associated with waiting until an advanced point in the value-added process to correct a residue problem. If a carcass is condemned, for example, the resources invested in producing that animal are wasted. A related point mentioned above was that the animal health segment of the problem (consisting of four firms) was effectively ignored while a regulatory emphasis was placed instead on 400,000 plus hog producers. On grounds of both equity and regulatory efficiency this approach must be seriously questioned.

To summarize this review of regulatory impacts, the reader is again directed to Figure 6.1. Policy issues and recommendations, along with suggestions for further research, follow below.

6.4 Policy Issues and Recommendations

A number of important issues are raised by this research. The sulfa case illustrates the complexity of designing effective institutions to ensure the safety of chemical technology, particularly when that technology is superimposed upon the food system. Problems of uncertainty with regard to risks from chemical exposure have been repeatedly stressed. As the sulfa case illustrates, the food production and marketing system in this country consists of a diversity of firms producing a variety of products, employing complex and varying production practices. Firms are distinguished by various organizational forms and incentive structures; they operate in distinctive markets; they command vastly disparate resources.

Food contaminants causing food safety policy problems flow throughout this complex system.

Many cases of chemical contamination within the food system are similar to the sulfa case in the sense that the contaminant reappears at various stages within an extended subsector. Additionally, the same chemical may play the diverse roles of product, input and contaminant. Frequently the economic actor's interest in the substance is not restricted to one role.

System diversity and complexity perhaps naturally complicate the formulation and implementation of effective, even-handed regulation. The identical policy incentive aimed at distinct industries can be expected to yield quite different results. When the additional variances in philosophy, mandate, budget, jurisdictional responsibility and organizational structure of the different agencies responsible for food safety in the U.S. (principally the FDA, the USDA, EPA and various State agencies) are further considered, it is little surprise that system performance with respect to food safety has been less than perfect. There may be greater surprise that the system hasn't performed worse.

6.4.1 Statement of Policy Concerns

Before offering specific recommendations for changes in rules and operating procedures--changes which are directed toward adoption of a problem-solving approach that systematically considers the food and regulatory system as a total system--several general issues arising from

the research will be explored. These issues relate to the following concerns.

1) The cumulative body of food safety law is complex, inconsistent, and incomplete.

2) The law, as enacted by Congress, affords no consistent guidelines regarding socially acceptable risk and whether benefits should be permitted to offset risk. Currently, the law does not allow consideration of economic benefits and costs in determination of risks to the public in the case of additives in animal drugs.

3) An inadequate data base exists for making most food safety decisions.

4) Difficulties of withdrawing a chemical from the food system after approval suggest that the first line of defense against food safety problems should be prevention whenever possible.

5) Changing technology and knowledge suggest the procedural need for systematic and orderly reassessment of chemical technology in the food system.

6) Responsibility for provision of toxicological information as it becomes available and as it relates to substances used in the food system is a policy issue which has not been resolved.

7) Various conditions indicate a need for extensive rationalization of food safety jurisdictional responsibilities.

8) A need currently exists for regular, effective representation of all legitimate interests in both "routine" and "political" food safety decision-making situations.

9) Effective provision of timely information is a policy tool which should be developed and used, particularly by FDA.

10) A reassessment of the purpose, design and performance of both the national residue monitoring program and the broader meat inspection program should be made to establish priorities in the expenditure of resources for research and inspection and to improve program efficiency.

11) Assessment and rationalization of food safety priorities are also needed at FDA.

6.4.2 Discussion of Policy Concerns

With respect to the food safety institutional structure, the sulfa case is not atypical in highlighting the complexities, inconsistencies, and incompleteness of the cumulative body of food safety law. Under this law, the same substance is regulated differently merely on the basis of legal categorization although frequently representing an equivalent public health risk. As previously discussed, sulfamethazine, an "old" or "not new" drug, in combination with penicillin and tetracycline is regulated in a special category as a certifiable antibiotic. When combined with tylosin, sulfamethazine falls in the "new animal drug" category requiring users to submit a new animal drug application and undergo inspection.

6.4.2.1 Food Safety Laws Complex, Inconsistent, Incomplete

Inconsistency occurs in many examples. The nitrite situation revealed similar examples of inconsistent categorization of nitrites

between species and according to function. One result of inconsistent treatment under the law is inequity in distributional impacts, that is, the structure of costs and benefits which emerge as property rights for different participants from the system of food safety law and regulation.

One example of incompleteness in the law is the failure to recognize inevitable resource scarcities available for food safety purposes and to direct or advise administrators in the setting of priorities.

With regard to consumer interests, inconsistent and inequitable categorization of different substances implies that a certain level of risk will be assessed differently depending upon how the law categorizes the food item in which it is found. Currently for example, consumers are routinely exposed to the carcinogenic "unavoidable contaminant" aflatoxin because it is categorized as "unavoidable" and peanuts (in which aflatoxin is commonly found) are felt to be an economical source of protein. A lesser degree of risk is not acceptable if found in another category of food.[1]

6.4.2.2 No Consistent Guidelines for Determining Socially Acceptable Risk

A major emerging criticism of food safety law and regulation in this country[2], that is, that current legislation and the current

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[1]See for example, Allen R. Ferguson, Paul F. Hopper, Norman H. Jones, Jr., Eugene Smolensky, Samuel E. Stumpf, James S. Turner, Richard Zeckhauser, A New Approach: Principles and Processes for Making Food Safety Decisions. A Report of the Social and Economic Committee of the Food Safety Council (Washington, DC: Food Safety Council, 1981).

[2]Ibid.

regulatory structure do not appear to permit a consistent approach toward determining socially acceptable levels of risk, is borne out by the sulfa case. Additionally, the law is not consistent in addressing the matter of benefits deriving from a substance which may also present some risk. Whereas the Federal Food, Drug and Cosmetic Act instructs the FDA to take into account some economic and other benefits stemming from the use of pesticides, it does not explicitly call for (or even permit) a benefit accounting in the case of food additives or animal drugs. That this inconsistency should persist is not obvious.

Conceptually, benefits may be taxonomized in a number of ways: the substance may enhance health by preventing or reducing a human health risk, enhance nutrition, other. The substance may enhance supply, differentiate products, afford convenience or otherwise satisfy consumer preferences.

Clearly, benefits of various substances are frequently implicitly considered in the policy process as an outgrowth of a system of political advocacy. However, agencies are hampered in explicitly accounting for benefits or defining acceptable risk. In the sulfa case, the FDA was constrained under the law to decide whether to ban sulfamethazine because it is too risky or raise the tolerance level, saying in effect, the problem doesn't really exist. Informally, the FDA appeared to decide that on the basis of current knowledge, the drug is not risky enough to ban and yet is not "safe enough" to permit the agency to raise tolerance levels. The FDA opted for further research. However, short of sponsoring the research, the agency is left with no explicit

policy for systematically identifying, assessing and evaluating benefits of sulfa in relationship to risks.

6.4.2.3 Inadequate Data Base for Food Safety Decisions

If food safety legislation were amended to permit an explicit assessment and consideration of risks and benefits, a lack of adequate data would be quickly revealed. A second major issue which emerges in the sulfa and many cases, then, is the problem of information and the fact that inadequate evidence upon which to base assessment of either risk, benefits, or costs exists for many commonly used substances. For example, little public evidence exists of effects of sulfamethazine when administered by itself. Generally, because data requirements for making informed food safety judgments are staggering, a system of priorities must be established.

6.4.2.4 Prevention Favored Over Withdrawal

Under current law, regulators find it considerably more difficult to withdraw a substance from use than to prevent one from being approved.[1] As long as this asymmetrical situation exists, it is critical that reasonable efforts be made to ensure sufficient

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[1]Quirk points out the extreme reliance of the Food and Drug Administration on pre-market testing utilizing small animal experiments with little subsequent monitoring of the effects of actual use. He notes that the practical outcome of the bias in the FDA's statutory authority is a situation in which a pharmaceutical firm faces great initial difficulty in obtaining market approval for a drug but after approval is achieved, the FDA finds it very difficult to withdraw a questionable drug from the market. P. J. Quirk, "Food and Drug Administration," The Politics of Regulation, James Q. Wilson, ed. (New York: Basic Books, Inc., 1980).

information upon which to judge risks, costs and benefits is made available before regulatory approval is given. Such information could and should then also be used as a basis for informing consumers and others without unduly restricting choice.

An effective process for evaluating the impacts of the addition of a new drug or other chemical substance to the food system is the best protection against future food safety problems. Such a procedure must thoroughly evaluate physical characteristics and toxicological impacts of the substance. It should also thoroughly consider the probable mode and extent of use of the substance by all participants in the system, the state of technology at different points in the system and the fate (or dispersion) of the chemical through the system, defined probabilistically, if possible. A thorough pre-market study is the best defense against future problems. Yet incentives to prevent excessively risk averse behavior on the part of regulators such as time constraints and procedures for outside reviews must be instituted to avoid foot dragging and undue impediments to innovation.

6.4.2.5 Need for Periodic Reassessment of Safety

Inevitably, concerns change over time in response to new knowledge of risks and the possibilities of risk reduction. The evolutionary character of problem recognition and knowledge acquisition calls for a dynamic institutional response which can cope with change without being indefinitely forestalled by special interest groups, and yet which protects the rights of those having economic interests in a

substance from arbitrary or summary procedures. The desire to balance the interests of the public and producer groups in an orderly manner is one strong argument for periodic and routine reassessment of product approvals before situations escalate into political controversies.

One approach to the evolutionary problem of food safety is to require either the government or industry to periodically reassess what is known about an approved substance in light of new developments in toxicology and other relevant disciplines. This is a concept of cyclic review, or a type of sunset legislation upon product approval.

6.4.2.6 Responsibility for Toxicological Information

Of critical concern in the design of all policies requiring the generation of information in the impact of risk-benefit information requirements on innovation, productivity, consumer product availability and costs. One potential economic impact, particularly in the case of multinational firms, is the transfer of U.S. manufacturing to overseas locations with resultant loss to the U.S. economy. Another international trade implication of regulations requiring product information is that such requirements can impede trade as they are used as non-tariff barriers.

In the case of many chemicals, particularly drug products, a product cycle prevails whereby the price that can be charged for a product declines over the life of the product as competitors introduce close substitutes or product improvements. At some point rational firms will compare costs associated with "defensive" research and

profit opportunities and choose to allow an old product's approval to lapse. If "old" products are replaced by superior new products, then loss to consumers will not be as great as if no superior products became available. Certainly, patent laws have an impact in relation to product innovation and product support through defensive research. Possibly they should be extended in certain cases. Once a patent expires, any firm may manufacture a drug after receiving FDA approval; hence, without patent protection, no single firm wishes to bear the costs of defensive research required in a cyclic review.

Where substantial information requirements are judged necessary to protect the public health and yet supply incentives are weak, public supply or public cooperation with industry should be permitted. In the sulfa case, for example, the FDA might have worked with the Animal Health Institute (an industry trade group which sponsors cooperative research within the industry) or some other manufacturers' organization to jointly sponsor research on electrostaticity. Such information is of potential benefit to numerous producers of animal drugs or, indeed, of any chemical additives flowing through materials handling food processing systems.

6.4.2.7 Effectiveness of Agency Jurisdictional Boundaries

Yet another major issue dramatized by the sulfa case is a situation of jurisdictional gaps, redundancies and inconsistencies as agencies divide overall food safety responsibility. In the sulfa case, fragmented food safety responsibility led to a number of developments:

1) USDA and FDA operate under different mandates, demonstrate different philosophies and serve different clientele or constituency groups. Fragmentation of jurisdictional authority appeared to contribute to an overall institutional inability to apprehend the complete problem context, identify critical problem causes and potential solutions, and to design public policy measures directed toward those control points potentially most cost-effective. The sulfa case suggests that agency objectives, as translated into problem definition, search procedures and regulatory design differ between agencies with the result that agencies function inconsistently or at partial cross-purposes. The USDA was led to define the sulfa problem as a marketing problem primarily inconveniencing swine producers rather than as a public health problem. The latter definition is more characteristic of FDA, an agency devoted to public health. Exploring the importance of objectives a bit further, it is evident that if elimination of sulfa residues in all species is considered important for public health reasons, then policy makers will be concerned over which livestock feeds sulfa cross-contaminates in a sequencing procedure, realizing that if sulfamethazine is used in a powdered form, residues must go somewhere when feeds are sequenced to avoid contamination of swine finishing feed. If the policy objective is to eliminate sulfa residues in meats resulting from cross-contamination in feed mills, then an appropriate regulatory response would be to prohibit use of the drug in feeds so long as it exhibits objectionable electrostatic characteristics.

However, if the objective is merely to reduce the number of producers experiencing the results of sulfa violations in swine carcasses, and if an agency is accustomed to conducting research centered upon agricultural production, then perhaps naturally, the problem is defined in terms of hog producers. Similarly, an Extension response aimed at improving management practices of a constituency group of producers makes sense.

The sulfa case illustrates a problem solving process in which, for various jurisdictional reasons, the source of the residue problem was originally assumed to be swine production practices. The swine industry was also then assumed to be the appropriate control point. For these reasons, regulators responsible for food safety concentrated the bulk of their resources upon changing the behavior of over 400,000 hog producers responsible for, perhaps, one-half of the sulfa problem. In retrospect, a broader and more flexible view of the problem at the outset might have led to the identification of a potential control point consisting of three to four pharmaceutical manufacturers of sulfa feed additives. Pressure might have been brought to bear at an earlier point regarding problems of electrostaticity.

2) USDA and FDA each have responsibility for different industries with the result that these industries are very differently treated. USDA is better able to employ an informational regulatory strategy by providing research and extension services than FDA, due to its greater budget and organizational diversity.

As a result of current institutional design, the Food and Drug Administration has been assigned regulatory authority for food safety over a vast portion of the food system. The extent of this agency's workload far surpasses that of the USDA with respect to number of firms, number of food and feed products and types of regulatory responsibilities (that is, setting tolerances, inspecting product, establishing process standards, etc.). Yet the FDA budget devoted to food safety is only a fraction of that which the USDA can direct toward food safety problems if necessary.

3) Additionally, the FDA does not have access to the institutional research and Extension capacity of the USDA, with the result that effective problem solving research capacity capable of response to various problems associated with regulation of food safety does not exist. As a result, problems which arise frequently tend to be countered with the mainstay weapon in the agency's arsenal: more regulations; or perhaps through contracted research. In neither case does the process fully encourage institutional learning, development of an institutional memory or an institutional problem-solving capacity.

As a result of the lack of agency extension and research mechanisms to cooperate with firms, the principal linkage between the FDA and firms throughout the food system is regulatory in nature. One result may follow that the FDA perceives itself and is perceived primarily in an adversarial role. In the course of the interview process for this research, a number of firms which were contacted judged FDA regulations--including tolerance levels and some feed manufacturing

practices--to be pointless, ambiguous, ineffectual or not based upon adequate research.

4) A fourth result of jurisdictional separation is that co-ordination between agencies with different responsibilities can be problematic. The identification and traceback of violative swine to farms provides another example of jurisdictional inefficiency where swine sulfa samples must be sent to regional labs (USDA labs) for assays. The lab results are sent to FDA offices in Washington, then back down to FDA regional offices, resulting in delay and poor follow-up. This and similar situations should be scrutinized for improvements in efficiency.

6.4.2.8 Representation of Legitimate Interests in Food Safety Policy Decisions

Another issue raised by the sulfa case concerns the lack of effective, formalized consumer representation at critical points in the food safety decision-making process, both in "routine" and "political" situations. Sulfa eventually fell into the political category. Either because of the way the Sulfa Task Force was comprised or because of the way the residue problem was conceptualized, the sulfa problem was not formulated in terms of a public health issue primarily. It was viewed as a marketing problem. Because there was no serious health concern, no convenient existing performance indicator of feed product purity and because feed and livestock of various non-swine types are not tested for sulfa contamination on any regular basis,

then the possibility of sulfa contamination in alternative products may not have been seriously explored. Consequently the possibility exists that overall public exposure to sulfa was not reduced to the extent supposed, but merely redistributed in the consumption of other commodities.

In order for food safety problems to be defined and resolved in the broadest manner possible so that all legitimate interests contribute to the policy solution, effective and timely participation of representatives of all significant interests should be included in the decision-making process. The USDA Sulfa Task Force as informally established from USDA personnel did not contain any individuals clearly responsible for articulating consumer concerns or preferences. For USDA to have defined the problem more broadly in terms of public health impacts would likely have required representatives of consumer interests on the panel and with sufficient influence to counterweight producer concerns.

When attention is turned to the Food and Drug Administration, it is found that although the agency utilizes consumer advisory panels on a number of issues, the Bureau of Veterinary Medicine does not currently have in operation an advisory committee with official consumer representation. This, despite the fact that this agency has primary responsibility for animal drug regulation and animal drug residues of various types frequently present food safety problems.

6.4.2.9 Information as a Policy Tool

Public agencies responsible for issuance and enforcement of a class of regulations limiting usage of chemical or pharmaceutical substances should develop and disseminate to agricultural producers and consumers educational materials explaining the public health rationale behind regulations.

Negligible effort was expended by FDA, USDA or the Federal and State Extension Services explaining the rationale behind the sulfa regulations. One consequence of this lack of effort appears to be the general belief that neither the sulfa regulations nor, by inference, many other FDA (and EPA) regulations have any substantial reasonable basis in fact, but instead exist principally for purposes of employment of Washington bureaucrats.

The FDA could benefit from development of basic, clearly presented materials explaining the types of assumptions, techniques and evidence upon which food safety, and most public health regulations, must rely of necessity. In the course of this research, opinions such as: "Humans are not rats!" or "The FDA can find any substance carcinogenic if researchers feed large enough quantities of it," were repeatedly voiced.

In reference to these opinions, the public should be aware that the former, while true, suffers from excess simplicity and ignores the fact that toxicological research has to rely upon the use of small animal experiments; the latter, by contrast, is untrue. Only a small

percentage of thousands of known compounds has been identified as carcinogenic.

When asked about their own notions for effective regulatory design, many hog producers interviewed during this research voiced the opinion that government regulatory agencies have only limited capacities for monitoring drug use by producers. Consequently, to be effective they must rely upon the good will and informed practices of the producer. A knowledge of the rationale behind public food safety regulation might contribute to producer and firm willingness to comply with regulations if these can be justified in a credible manner and assuming producers consider the welfare of others interdependent with their own.

6.4.2.10 Reassessing Food Safety Programs at USDA, FDA

Both the purposes and the performance of the National Residue Monitoring Program, the Meat Inspection Program more generally, and food safety programs at FDA require reassessment. Are resources expended according to a priority system based on detecting and eliminating public health risks of the greatest magnitude? If not, then how?

Are appropriate tests available or under development for all contaminants or public health risks of major concern?

Are the statistical designs upon which various monitoring programs are based adequate to reliably detect an acceptable proportion of contaminants of major concern in the food system, or firms adhering to substandard manufacturing practices?

Should purposes of the residue monitoring program of the Meat Inspection Service be extended beyond monitoring to function as a deterrent to marketing violative animals? At current typical USDA sampling rates, the expected cost of marketing a violative animal is extremely low for most producers. The implementation of in-plant testing, along with an animal identification system, could greatly increase the expected costs of a market violation, particularly if violative animals were not permitted to enter the food supply as they do now in cases of residue contamination.

6.5 Policy Recommendations

1) Food safety policy makers should consciously define residue problems in as broad a manner as possible. They should employ a systematic procedure for identifying the flow of the chemical through the entire food system in both physical and institutional terms. This approach facilitates identification of potential control points, obstacles to control and policy procedures. (For an example of this approach in the sulfa case, see Section 6.6, below.)

2) It is essential for various agencies responsible for food safety to further develop and maintain institutional cooperation in order to accurately identify all major problem sources, potential control points, and potentially productive procedures.

3) Patterns of decision-making--especially recognizing participant interests in the economic impacts of a particular chemical--should be analyzed in order to assess available regulatory incentives for effectiveness.

4) A range of policy measures should be identified and analyzed for economic, public health and other relevant impacts. A systematic approach might consider a variety of process and performance standards, public provision of information (research, Extension activities, etc.) and exerting economic impacts which work through the market. Consideration of institutional feasibility is of obvious importance and depends upon legal, political and social factors.

5) Fragmentation, deficiencies, inconsistencies and inefficiencies in food safety jurisdictional authority should be rationalized.

6) The Food and Drug Administration should either be granted increased research, education, or extension resources, or some FDA food safety responsibilities should be integrated within USDA.

7) Public agencies responsible for issuance and enforcement of food safety regulations should develop and disseminate to agricultural and other producers, and to consumers, educational materials explaining the public health rationale behind the regulations.

8) The Federal Food, Drug and Cosmetic Act should be amended to clarify and specify regulatory approaches to food safety residue problems which permit the explicit accounting for and balancing of public health risk and economic benefits when feasible and desirable.

If economic benefits are not considered a desirable policy. criterion, then other criteria for prioritizing resource expenditures in the area of food safety should be specified explicitly.

6.6 Example of an Approach to Food Safety Problem Specification

The following diagram exemplifies a recommended approach to specifying a food safety problem. A contamination problem typically flows through multiple stages of a value-added food system subsector. In the sulfa case, the problem originated with manufacture of a swine feed additive by the animal health industry. Successive stages led through the manufactured feed industry, the swine industry and successive marketing stages. Figure 6.2 depicts a preliminary phase diagram of the flow of contamination through an extended value-added subsector. Any contamination problem can be approached in this manner. Successive iterations refine the problem context specification.

Such an approach should be useful in identifying a variety of potential regulatory control points. For each of the control points, a range of policy approaches can be identified and assessed.

6.7 Identified Needs for Further Research

The following research needs were identified:

1) A need for more research (or public disclosure of private research) into the physical characteristics and effects of the sulfonamides when used singly, not in combination drugs.

2) A need for better understanding of the interactions occurring between compounds present in combination drugs.

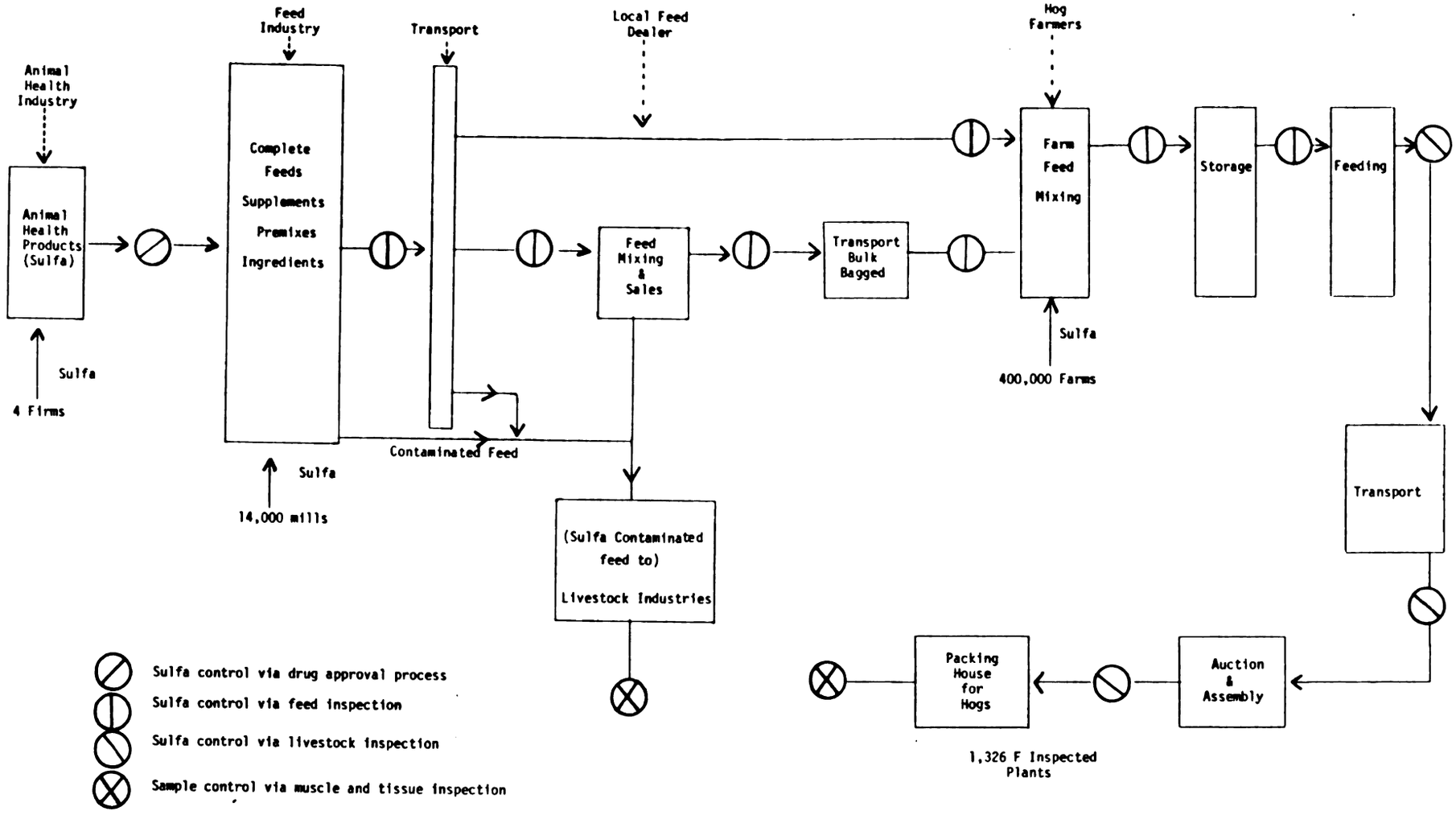


FIGURE 6.2. A SYSTEMS APPROACH TO IDENTIFYING A FOOD SAFETY PROBLEM AND SOLUTION

3) A need for more research into public health effects of low level exposure to sulfonamide residues, particularly possible carcinogenicity and possible adverse effects from resistance.

4) A thorough, systematic study of the impacts of current premarket regulatory research requirements on innovation, product availability and public health. Also, impacts of a cyclic review process should be analyzed from the perspective of all relevant participants in the food system. Such a study might examine a sample of product and company cases and address, among other variables, costs of research, pricing history, product competition over the product cycle, and additional factors influencing corporate decision-making regarding the product over time.

5) The adequacy of current national residue monitoring and surveillance programs should be reassessed in light of an objective of providing compliance incentives for producers. Both the residue monitoring and the surveillance programs should be examined so that any desired compliance objectives can be integrated into current monitoring activities.

6) Research directed at the design of economical, effective animal identification systems would assist in the passage and implementation of this critical food safety link.

7) A thorough assessment of the range and characteristics of current critical food safety residue problems confronting the food system would assist in establishing uniform priorities for expenditures on research and inspection activities by various governmental agencies.

Public health rationale should be used to allocate food safety concerns subject to available resources.

8) An assessment of the adequacy of currently available assay and screening procedures for high risk contaminants should be completed in order to establish priorities for funding further assay development efforts.

9) Research to develop prototypes of the manner in which different categories of contaminants enter the food system and disseminate through it is necessary to identify potential control points and methodologies.

10) Conceptual work related to various regulatory control mechanisms and their impact upon firms in varying market situations would assist in permitting a systematic assessment of regulatory possibilities for different categories of food safety problems and proposed control measures.

11) Identification of various mechanisms for improving inter-agency coordination and cooperation would assist in the solution of food safety problems flowing throughout the food system.

12) Specific research into the extent of industry adoption of granulated sulfa feed additives and the effect of product granulation on cross contamination under actual use conditions should be completed in order to evaluate the value of this technological solution to the sulfa and similar cases.

APPENDICES

APPENDIX A

RESEARCH INTERVIEWS, 1979-82

APPENDIX A

RESEARCH INTERVIEWS, 1979-82

David Anderson. Commercial Underwriting, Farm Bureau Services Group, Michigan Farm Bureau, Lansing, MI. August 6, 1980.

Dr. Steven Aust. Department of Biochemistry, Michigan State University, East Lansing, MI. November 15, 1978.

Al Austin. Director of Quality Control, Rodeo Meats, Arkansas City, KS. April 7, 1982.

Dr. David Bache. Department of Agricultural Economics, Purdue University, West Lafayette, IN. August 14, 1980.

Curtis Bailey. Hog farmer, Kalamazoo, MI. October 20, 1980.

Michael Barton. Hog farmer, Homer, MI. August 16, 1980, December 4, 1980.

Bonnie Bohlen. Hog farmer, Fithian, IL. July 30, 1980.

Floyd Bohlen. Hog farmer, Fithian, IL. July 30, 1980.

Dr. William Bixler. Special Assistant to the Director, Bureau of Veterinary Medicine, Food and Drug Administration (author of FDA Policy, 2nd Generation of Medicated Feeds). Rockville, MD. February 15, 1979.

Dr. Roy Black. Department of Agricultural Economics, Michigan State University. East Lansing, MI.

Matthew Bowen. Employee, Morris, Michigan Feed Mill; former employee in charge of drug measurement and handling, Hamilton Farm Bureau Coop., East Lansing, MI. February 2, 1980.

Lee Boyd. Vice President, American Feed Manufacturers Association, Washington, DC. February 19, 1980.

Robert Braden. Executive Director, Michigan Farm Bureau, Lansing, MI. August 7, 1980.

Dr. Lowell Breeden. Extension Swine Veterinarian, Kansas State University, Manhattan, KS. November, 1980.

Bill Brimberry. Food Safety Quality Service, U.S. Department of Agriculture, Washington, DC. February 26, 1981.

Dr. Robert Brown. Assistant to Deputy Administrator of Veterinary Services, Animal Plant Health Inspection Service, U.S. Department of Agriculture, Washington, DC. September 24, 1979.

Dr. Jerry Brunton. Vice President for Scientific Activities, Animal Health Institute, Washington, DC. February 19, 1980.

Dr. Clark Burbee. Economics, Statistics Services, U.S. Department of Agriculture. Washington, DC.

Dr. Catherine W. Carnavale. Bureau of Veterinary Medicine, Food and Drug Administration, Rockville, MD . September 25, 1979.

Roger Carr. Hog farmer, Colon, MI. August 15, 1980.

Dr. Grace Clark. Residue Evaluation Division, Food Safety Quality Service, U.S. Department of Agriculture, Washington, DC. February 25, 1981.

Dr. Clark. Veterinarian, Frederick-Harrads Packing Plant, Detroit, MI. December 15, 1980.

Wes Clark. Hog farmer, Mason, MI. December 17, 1980.

Dr. H. W. Connaughton. Circuit Supervisor for Michigan's Central District, Food Safety Quality Service, U.S. Department of Agriculture, Lansing, MI. May 3, 1979.

J. B. Cordaro. Office of Technology, Assessment and Food Safety Council, Washington, DC. September 18, 1979, February 19, 1982.

Bob Craig. Public Affairs, Michigan Farm Bureau, Lansing, MI. August 12, 1980.

Lauren Cunnington. State Inspector, Michigan Department of Agriculture, Climax, MI. August 12, 1980.

Jerry DeSwaan. Director of Quality Control, Hamilton Farm Bureau Coop., Hamilton, MI. August 10, 1980.

Henry DeWeerd. General Manager, Hamilton Farm Bureau Coop., Hamilton, MI. August 10, 1980.

Dr. Fay Dworkin. Office of Planning and Evaluation, Bureau of Veterinary Medicine, Food and Drug Administration, Washington, DC. February 15, 1979.

Dr. Harold Ecker. Department of Agricultural Economics, Michigan State University, East Lansing, MI. January 21, 1980.

James Ego. Manager, Feed Division, Illinois Farm Bureau Services (Growmark), Bloomington, IL. August 15, 1980.

Dr. Dave Ellis. Department of Veterinary Medicine, Michigan State University, East Lansing, MI. September 10, 1979.

Dr. R. E. Engel. Acting Deputy Administrator, Science, Food Safety Quality Service, U.S. Department of Agriculture, Washington, DC. May 14, 1979.

Dr. Charles Ettinger. Chemistry Division, Food Safety Quality Service, U.S. Department of Agriculture, Washington, DC. May 14, 1979.

John Farnham. Manager of Quality Assurance, American Cyanamid, Princeton, NJ. May 26, 1981.

Dr. Leo Figurski. Area Extension Economist, Kansas State University, Manhattan, KS.

Sondra Flick. Regulatory Affairs Specialist, Diamond Shamrock, Cleveland, OH. May 26, 1981.

C. L. Friend. Executive Secretary, Canadian Feed Industry Association, Ottawa, Canada. February 20, 1981.

Brian Gates. Director of Quality Control, Quality Assurance Lab., Michigan Farm Bureau Services, Battle Creek, MI. August 13, 1980.

Al Gehrt. Coordinator of Laboratory Services and Quality Control, retired. Moorman's Feed Company, Quincy, IL. August, 1980.

Dr. Roger Gerrits. Science and Education Administration, U.S. Department of Agriculture, Beltsville, MD. September 27, 1979.

Elmo Giffels. Hog farmer, Laingsburg, MI. December 13, 1980.

Dr. George Graver. Director, Division of Animal Feeds, Bureau of Veterinary Medicine, Food and Drug Administration. Rockville, MD. September 25, 1979.

Tom Gross. Assistant Livestock Buyer, Peets Packing Plant, Chesaning, MI. December 16, 1980.

Roger Habegger. Plant Manager, Central Soya, Portland, MI. January 22, 1981.

Dr. Larry Hamm. Department of Agricultural Economics, Michigan State University, East Lansing, MI. March 20, 1979.

Bob Harms. Hog farmer, Vermontville, MI. December 5, 1980.

Elmer Heisler, Jr. Hog farmer, Albion, MI. August 14, 1980.

Robert Hill. Senior Counsel, Diamond Shamrock, Cleveland, OH. April 21, 1981.

Dr. Maynard Hogberg. Extension Swine Specialist, Department of Animal Husbandry, Michigan State University, East Lansing, MI. May, 1979.

Bob Holmes. Product Group Manager, Marketing Sales/Production, Doanes Agricultural Services, Market Research, St. Louis, MO. April 15, 1981.

Dr. Dixon Hubbard. Science and Education Administration, U.S. Department of Agriculture, Washington, DC. September, 1979.

Dr. Jablonski. Veterinarian-Inspector, Frederick-Harrads Packing Plant, Detroit, MI. December 19, 1981.

Harry Jamison. Director of Market Research, Merck and Co., Princeton, NJ. April 14, 1981.

Jay Johnston. Technical Director, Canadian Feed Industry Association, Ottawa, Canada. February 20, 1981.

Dr. Ralph Johnston. Microbiology, Food, Safety, Quality Service, U.S. Department of Agriculture, Washington, DC. March 2, 1981.

Jerry Kennon. Field Marketing Representative, U.S. and Canada Operations, SmithKline Animal Health Products, Manhattan, KS. January 20, 1980.

Dr. Robert L. Kirkpatrick. Supervisor of Product Registration, Plant Industry Division, Michigan Department of Agriculture, Lansing, MI.

Charles W. Klinger. Director of Regulatory Compliance, Central Soya, Fort Wayne, IN. August, 1980.

Dean Larson. Hog farmer, Green, KS. November, 1980.

Wendell Law. Sales Manager, Ralston-Purina, Lansing, MI. January 23, 1981.

Dr. Jack Leighty. Pathology, Food Safety & Quality Service, U.S. Department of Agriculture, Beltsville, MD. September 27, 1979.

G. Dean Lindsey. Manager, Animal Products, International Regulatory Services, Elanco Products Company, Indianapolis, IN. July 31, 1980.

Dr. Neal Littlefield. National Center for Toxicological Research, Pine Bluff, AR. March 9, 1981.

Dick Lister. Manager, Quality Control, Safety and Training, Kent Feeds, Manhattan, KS. May 28, 1980.

Erin Lively. Manager of Quality Assurance, Ralston-Purina, Lansing, MI. January 23, 1981.

Richard Lyng. Deputy Secretary of Agriculture, and former President, American Meat Institute, Washington, DC. February 18, 1980.

Dr. Milton Manuel. Chairman, Department of Agricultural Economics, Kansas State University, Manhattan, KS May, 1980.

Mike Mayer. Plant Manager, Frederick-Harrads Packing Plant, Detroit, MI. December 19, 1981.

Robert McElhiney. Department of Grain Science and Industry, Kansas State University, Manhattan, KS. May, July, 1980.

M. McKay. Bureau of Veterinary Medicine, Department of Health and Welfare, Ottawa, Canada. February 20, 1981.

Dr. Elwin Miller. Department of Animal Husbandry, Michigan State University, East Lansing, MI. June 7, 1979.

Steve Montgomery. Toxicologist, Division of Toxicology, Bureau of Foods, Food and Drug Administration, Washington, DC. March 9, 1981.

Dr. M. G. Morissette. Meat Hygiene, Meat Inspection Service, Agriculture Canada, Ottawa, Canada. February 20, 1981.

Bob Nelson. Office of Legislative Affairs, U.S. Department of Agriculture, Washington, DC. March 2, 1981.

Gary Nelson. Hog Buyer, Frederick-Harrads Packing Plant, Detroit, MI. December 15, 1980.

Dr. Sherrill Nott. Department of Agricultural Economics, Michigan State University, East Lansing, MI. August, 1980.

Dr. Dale Olson. Nutritionist and Research Director, Indiana Farm Bureau Services, Indianapolis, IN. July 31, 1980.

Dr. Lee Penner. Swine Veterinarian, Manhattan, KS. February 8, 1982.

Dr. Harry Pfost. Development Planning and Research Associates, Manhattan, KS. July, 1980.

Dr. G. W. Probst. Director, Elanco Regulatory Services, Elanco Products Co., Indianapolis, IN. May 31, 1980.

Dr. Estes Reynolds. Department of Animal Husbandry, Michigan State University, East Lansing, MI. April 27, 1979.

Dr. Tanya Roberts. Food Economics, Economics, Statistics and Cooperatives Service, U.S. Department of Agriculture, Washington, DC.

Russell Rowe. Hog farmer, Past President Michigan Pork Producers Council, Williamston, MI. August 12, 1980.

Stephen B. Schectman. Vice President, IMS America, Ltd., Washington, DC. February 23, 1981.

De. A. Allan Schmid. Department of Agricultural Economics, Michigan State University, East Lansing, MI.

Dr. Robert Schmidt. Bureau of Veterinary Medicine, Food and Drug Administration, Rockville, MD. September 25, 1979, May 28, 1980, February 19, 1981.

Dr. Robert Schoeff. Department of Grain Science and Industry, Kansas State University, Manhattan, KS. May-October, 1980.

Dr. James D. Shaffer. Department of Agricultural Economics, Michigan State University, East Lansing, MI. Dissertation Advisor.

Lloyd Shug. Hog farmer, Galesburg, MI.

DuWain Simon. Herdsman, Feed Mill Operator, Michigan State University, East Lansing, MI.

Jack Snow. Vice President for Quality Assurance and Regulatory Affairs, Rachelle Laboratories, Long Beach, CA. May 28, 1981.

J. E. Spaulding. Acting Director, Residue Evaluation and Surveillance Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC. May 11, 1979.

Joe Stid. Hog producer, Mason, MI. December 17, 1980.

Pat Stolfa. Planning and Evaluation Services, Office of Program Planning and Budget Evaluation, U.S. Department of Agriculture, Washington, DC. 1979.

Doyle Talkington. Executive Vice President, Kansas Pork Producers Council, Manhattan, KS. July, 1980.

Dr. Howard Teague. Science and Education Administration, U.S. Department of Agriculture, Washington, DC. September 26, 1970.

Larry Toillion. Product Services Manager, Feed Division, Growmark, Bloomington, IL. August 8, 1980.

Dr. Harold Trabosh. Food, Safety and Quality Service, U.S. Department of Agriculture, Washington, DC. March 2, 1981.

Dr. Duane Ulrey. Department of Animal Husbandry, Michigan State University, East Lansing, MI.

Dr. Eileen Van Ravenswaay. Department of Agricultural Economics, Michigan State University, East Lansing, MI. Dissertation Advisory Committee.

Dr. Carl Vosloh. Economic Research Service, U.S. Department of Agricultural Economics, Washington, DC. February, 1980.

Bill White. Hog producer, Jones, MI. October 21, 1980.

Dr. Robert Wilcox. Department of Grain Science and Industry, Kansas State University, Manhattan, KS.

Jim Wilson. Production Manager, Ralston-Purina Plant, Lansing, MI. January 23, 1981.

Rudy Yost. Head, Animal Products, Michigan Farm Bureau Services, Lansing, MI. August 7, 1980.

Bob Zacharda. Hog producer, Laingsburg, MI. October, 1980.

Al E. Zimbelman. Meat Inspector, Food Safety Quality Service, U.S. Department of Agriculture, Battle Creek, MI. May 7, 1979.

APPENDIX B

CHARACTERISTICS OF SULFA DRUGS

APPENDIX B

CHARACTERISTICS OF SULFA DRUGS

Characteristics of Sulfa Drugs: Chemical Structure

Sulfa drugs are sulfur-containing aromatic compounds which have proven beneficial over the past 40-45 years in treatment of both human and animal diseases. Discovery of the parent compound sulfanilamide* in 1908 led eventually to synthesis of over 1300 additional derivatives,** including sulfamethazine (called sulfadimidine in Britain), sulfathiazole and a panoply of other sulfa drugs utilized in both human and animal disease treatment.

In total, the broad class of compounds called sulfonamides contains over 5000 different sulfur compounds.***

Sulfa Uses

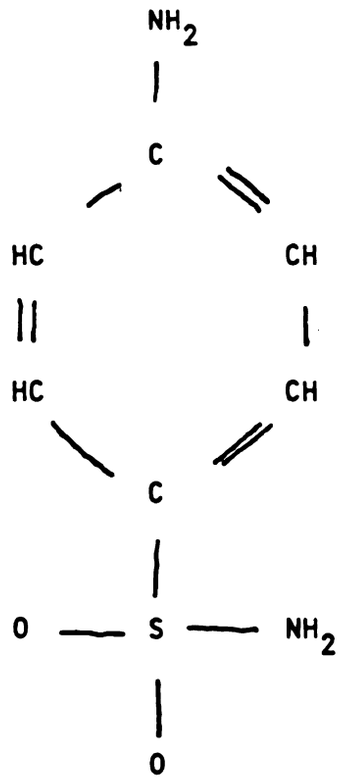
Sulfa drugs represent an extremely potent weapon in medicine's arsenal of therapeutic agents and have since the 1930s and 1940s. During World War II, sulfa compounds were broadly used among troops for disease preventive purposes. Sulfa drugs have proven valuable in the treatment of human blood poisoning, pneumonia, boils, intestinal infections, gonorrhea, meningitis and other infectious diseases.

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*See Appendix Figure 1.

**William H. Nebergall, Frederic C. Schmidt, Henry F. Holtzclaw, Jr. General Chemistry, 5th Edition, D. C. Heath and Company, Lexington, Mass., 1976.

***Gary L. Cromwell, "Effects of Dietary Sulfa Levels and Management Factors on Sulfa Residues in Swine," Proceedings of Jan. 1980 meeting of Sulfa Task Force, Washington, DC.



APPENDIX FIGURE 1. CHEMICAL STRUCTURE OF SULFANILAMIDE

Over 1300 derivatives have been synthesized through the substitution of various radicals for the hydrogens of the $-NH_2$ groups of the sulfanilamide molecule.

Source: William H. Nebergall, Frederic C. Schmidt, Henry F. Holtzclaw, Jr., General Chemistry. 5th Edition, D. C. Heath and Company, Lexington, MA, 1976.

In addition to therapeutic purposes, sulfamethazine and a few other sulfonamides find widespread use at subtherapeutic dosages in livestock production. The purposes of administering subtherapeutic doses of any antibacterial generally fall into one or more of three categories: to improve feed efficiency or conversion (unit gain/unit feed), to increase the rate of gain (unit gain/unit time) or to prevent disease. The three effects are interdependent and separation of any one from the other somewhat arbitrary.

Sulfamethazine and sulfathiazole are both cleared for administration at subtherapeutic doses in swine feeds by the Food and Drug Administration in combination with chlortetracycline and penicillin. Sulfamethazine can also be used in combination with tylosin.

Claims permitted under approved conditions of use in the Code of Federal Regulations, Title 21, Section 558.145(f) state for the sulfamethazine, penicillin, chlortetracycline combination:

> It is administered to swine in complete feed for reduction of the incidence of cervical abscesses (disease prevention*); treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis) caused by SALMONELLA CHLORAESUIS and vibrionic dysentery (disease treatment*); prevention of these diseases during times of stress (disease prevention*); maintenance of weight gains in the presence of atrophic rhinitis (growth promotion*); growth promotion and feed efficiency in swine weighing up to 75 pounds.

The sulfathiazole combination is indicated:

> For increased rate of weight gain (growth promotion*) and improved feed efficiency in animals up to 6 weeks postweaning. For increased rate of weight gain in

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*Author's labeling of effect.

> animals from 6 to 16 weeks postweaning. Maintenance of weight gains in the presence of atrophic rhinitis (growth promotion*); reduction of the incidence of cervical abscesses (disease prevention*); treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by SALMONELLA CHLORAESUIS and vibrionic dysentery) (disease treatment*). (21 CFR 558.145)

Finally, the sulfamethazine-tylosin combination carries indications for use (21 CFR 558.630):

> Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of BORDETELLA BRONCHISEPTICA rhinitis (disease prevention*); prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (P. multocida and/or C. pyogenes) (disease treatment*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci (disease prevention*). Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

As can be seen, the indications for use of the two triple combinations are very similar; the tylosin-sulfamethazine combination indication includes mention of swine pneumonia and jowl abscesses not recognized by FDA for the other combination drugs.

Mode of Action

The sulfonamides, including sulfamethazine, are believed to act as a therapeutic agent by blocking the utilization by infectious bacteria of one of their essential nutrients, paraminobenzoic acid (PABA). Sulfa drugs therefore exert a bacteriostatic effect that

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*Author's labeling of effect.

operates to inhibit natural multiplication of pathogenic organisms while permitting mobilization of the host's defensive capacities to destroy the infection.*

Hays, in an extensive review of literature regarding the efficacy of antibacterial feed additives, explains the current state of knowledge respecting the reasons for a growth promoting effect observed for subtherapeutic levels of antibacterials administered to livestock.** Three modes of action have been postulated: 1) a metabolic effect; 2) a nutrient-sparing effect; 3) a disease-control effect. Each mode of action has varying degrees of experimental support. However, researchers appear to agree that the growth promotion, disease preventive and feed efficiency effects are highly significant for the approximately 14 different antibiotics approved for either therapeutic or subtherapeutic use in livestock in the U.S. and for such chemotherapeutic agents as the sulfonamides.

Toxicological, Pharmacological Considerations

Toxicology refers to the study of poisons and their effect on living organisms. Two measures typically used to characterize toxicity of a substance (and in construction of a hypothesized dose-response curve) are the median lethal dose (LD_{50}) and the no-effect level,

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*L. H. Sophian, D. L. Piper, G. H. Schneller, The Sulfapyrimidines; Sulfadiazine, Sulfamerazine, Sulfamethazine (New York: A. Colish, 1952).

**Virgil W. Hays. "Effectiveness of Feed Additive Usage of Antibacterial Agents in Swine and Poultry Production." Paper prepared for the U.S. Congress, Office of Technology Assessment, 1978.

respectively, measures of acute and chronic toxicity. The LD_{50} indicates a dose which kills one-half of a specified group of test animals. The no-effect level is the highest continuous dosage for which no measurable effect can be demonstrated on test animals.

American Cyanamid submitted experimental evidence to the Food and Drug Administration on July 25, 1973 indicating that the Acute Oral LD_{50} for sulfamethazine measures 1.9 gm/kg and that sulfamethazine indicates no neural or renal (kidney) toxicity.

Two 90-day toxicity studies conducted by American Cyanamid to support the application for continuous FDA marketing clearance* concluded that the no-effect levels for the two small animal species utilized, rats and dogs, could be set at 7 mg/kg and 10 mg/kg, respectively. No-effect levels are incorporated into an FDA formula utilized to establish tolerance levels for drug residues remaining in foods.

Pharmacology, "the science of drugs," attends to particular "properties and reactions of drugs especially with relation to their therapeutic value."** Drug efficacy depends upon a chemical agent's ability to arrive at an infection site and to achieve and maintain an adequate concentration to exert bactericidal or bacteriostatic effect.

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*Studies submitted to FDA by American Cyanamid July 25, 1973 under Master File 3553. Original regulations permitting use of the chlortetracycline, penicillin, sulfamethazine combination were published in the Federal Register July 6, 1963.

**A. Merriam-Webster, Seventh New Collegiate Dictionary (Springfield, MA: G. & C. Merriam Co., 1967).

In general, sulfamethazine attains and maintains adequate blood levels to be effective at subtherapeutic levels in swine. Its persistence, however, contributes to some of the residue problems experienced. By contrast, sulfathiazole (the other sulfonamide permitted at subtherapeutic levels in swine feeds) is slower to attain comparable blood levels, but depletes more rapidly from the system.

Appendix Figure 2 presents evidence in support of the higher blood level achieved by sulfamethazine when administered orally at a single dose of 1/2 grain per pound of body weight. The vertical axis indicates the blood level achieved by the drug while the horizontal axis measures hours subsequent to dosage.

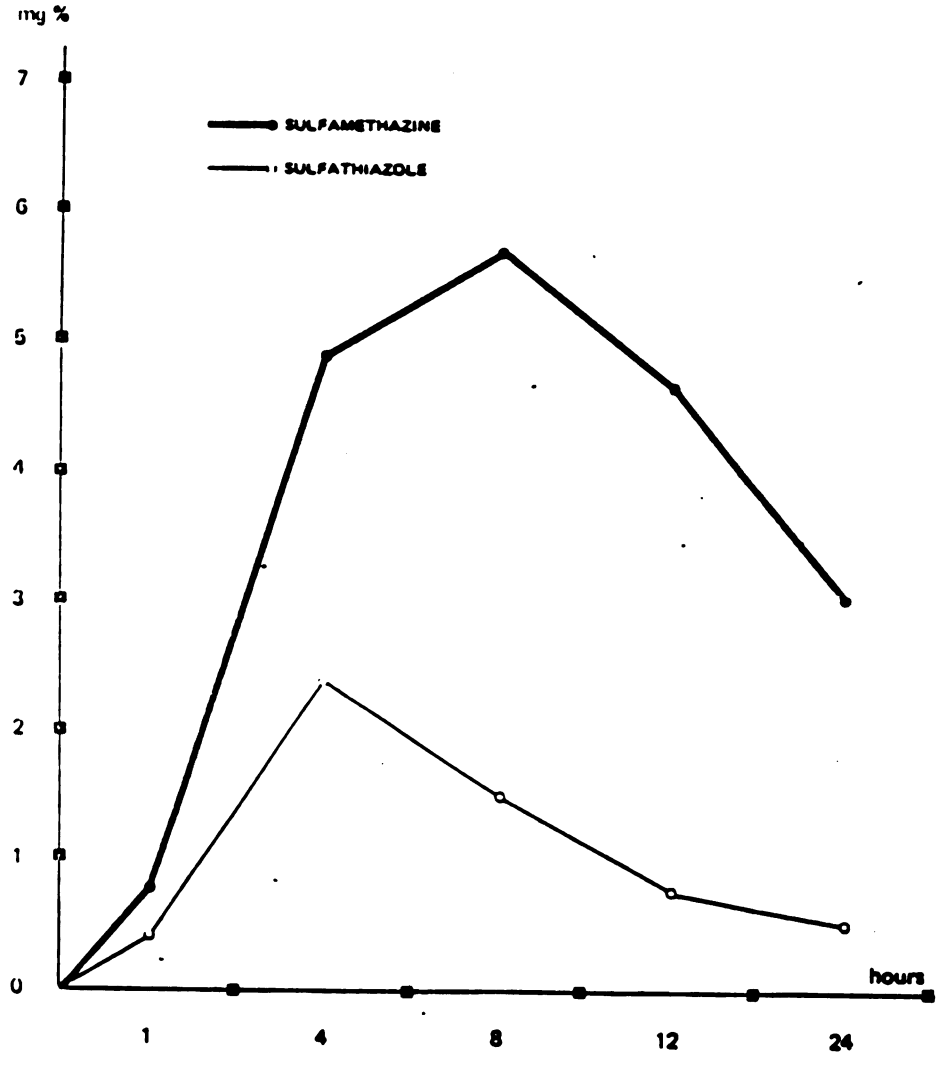
Appendix Figure 3* indicates the distribution of sulfathiazole and sulfamethazine in pigs four hours after intramuscular injection of 0.08 gm/kgm. As can be seen, sulfamethazine blood levels exceed those of sulfathiazole whereas concentrations of sulfathiazole in the kidney indicate more rapid elimination from the system.

To summarize, pharmacological characteristics of sulfamethazine suggest that it "maintains higher and more prolonged blood levels following equal doses than any of the commonly used sulfanomides."** Whereas this attribute may make sulfamethazine more attractive for use in livestock production, it also suggests that the chance of marketing an animal with violative sulfa levels is increased relative to one treated with sulfathiazole.

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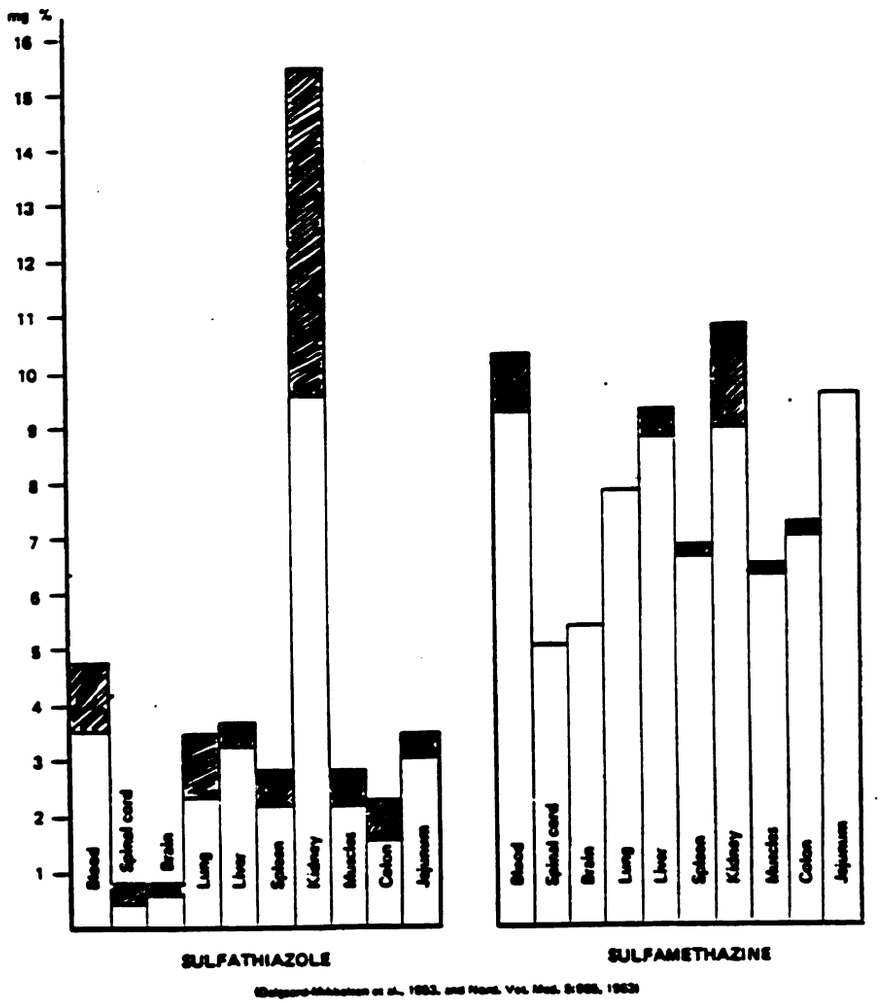
*Figures 2 and 3 have been distelbuted by Rachelle Labs which produces a sulfamethazine product.

**Clarence M. Stowe, "The Sulfanomides." Veterinary Pharmacology and Therapeutics, 3rd Edition, 1965, p. 495.



Source: U.S. Livestock Sanitary Association Proceedings, 1946.

APPENDIX FIGURE 2. BLOOD LEVELS IN SWINE (SINGLE DOSE OF 1/2 GRAIN/POUND OF BODY WEIGHT)



APPENDIX FIGURE 3. DISTRIBUTION OF SULFATHIAZOLE AND SULFAMETHAZINE IN PIGS FOUR HOURS AFTER INTRAMUSCULAR INJECTION OF 0.08 gm/kgm

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