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TESTING OF TAMPER-RESISTANT PACKAGING

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TESTING OF

TAMPER-RESISTANT PACKAGING

by

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ABSTRACT

A new regulation for tamper-resistant packaging, found in volume 41, number 215, page 50442 of the Federal Register, requires, by definition only, that certain products be in tamper-resistant containers. To determine if this definition would adequately protect the consumer, eleven sets of package forms were tested for their tamper-resistance.

Sample sets for the test consisted of tampered and non-tampered control packages shown to consumers who were asked, "Having observed this package, do you think it has been tampered with?" When the tampered (and repaired) packages were examined, 75 percent of the consumers tested could not correctly determine whether or not the package had been tampered with. Thirty percent of the consumers did not correctly determine that a control package had not been tampered with.

These results reflect a definite need for further testing and development of tamper-resistant packaging when protecting against malicious individuals.

This thesis is dedicated to my wife, Bethany Rae, Without her continual support and positive encouragement this thesis would not have been possible.

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INTRODUCTION

On September 30, 1982, three people were reported to have died from ingesting potassium cyanide laced Extra-Strength Tylenol capsules (an over-the counter drug product).[1] When the report, issued by the Coroner's Office of Cook County, Illinois, where the deaths took place, was recieved by McNeil Consumer Products, a division of Johnson and Johnson, Incorporated and manufacturer of Tylenol Products, an immediate recall was issued for the two specific lot numbers involved. This recall totalled an estimated 93,000 bottles of Extra-Strength Tylenol capsules.[2]

Within a period of three days a total of seven people in the Chicago area died as a result of ingesting potassium cyanide laced Extra-Strength Tylenol capsules. Several other lot numbers became involved and more recalls were issued totalling approximately 171,000 bottles of product.[3] The Food and Drug Administration (FDA) was called in to conduct tests on all recalled bottles in an effort to determine the extent of contamination. During the tests, two other bottles were found to contain contaminated capsules bringing a total number of potassium cyanide laced Extra-Strength Tylenol capsule bottles to eight.

On October 5, 1982, California authorities found strychnine poison in three bottles of Extra-Strength Tylenol capsules. This incident led McNeil Consumer Products to issue an immediate recall of all Tylenol capsuled products not packaged in unit dose blister packs. All recalls of Tylenol brand products involved approximately 31,000,000 bottles.[4]

Facts, details, and events surrounding the fatal Chicago poisonings were reviewed extensively by authorities in an effort to determine the source of

contamination. Based upon FDA plant inspections of Tylenol manufacturing sites and the sequence of events leading to the poisonings, it was concluded that the contamination was the result of package/product tampering by a malicious individual(s). It is believed that the tamperings took place after the product had been shipped to distributors and most likely sometime after the capsules had reached the retail shelves. This conclusion led to an immediate nationwide investigation. However, as of February 25, 1983, no conclusive evidence has been found to prove that someone tampered with the Tylenol product and the investigation is continuing.

Over the two months following the Tylenol poisonings several other package/product tampering incidents (such as the California Tylenol tampering) also took place involving food products and other over-the-counter (OTC) drug products. Many of these incidents were labelled "copy-cat" poisonings because of the similarities to the Tylenol poisonings. No one died from these tamperings but several people were injured.

State and local governments reacted quickly to the Tylenol and "copy-cat" incidents by proposing regulations requiring OTC drugs to be packaged in tamper-resistant containers. The Proprietary Association, a national trade association representing manufacturer's of OTC drugs, agreed with state and local governments that regulations were necessary and requested the FDA to assume the task of establishing specific requirements. The FDA was subsequently directed by the Secretary of Health and Human Services, Richard Schweiker, to draft a nationwide regulation for tamper-resistant packaging. In order to assist the FDA in these efforts, a Joint Committee on Product Security as well as an Expert Technical Committee were established by the

Proprietary Association. These two committee's were setup to develop and report on specific recommendations for tamper-resistant packaging.

The outcome of these efforts was a new tamper-resistant packaging regulation announced on November 5, 1982, in the Federal Register, volume 47, no. 215, page 50442. The regulation effects Title 21 of the Code of Federal Regulations (CFR) for the following Part and Section numbers: 1) 211.132, 2) 314, 3) 700.25, 4) 800.12, and 5) 200.50. The regulation will initially take effect February 7, 1983, for some cosmetic and OTC drug products. These products are considered high risk and believed to be more susceptible to tampering. Products in this category include all capsules, oral liquid cosmetics, contact lens solutions, and opthalmic preparations. Other products affected by the regulation are required to be packaged in tamper-resistant containers effective May 5, 1983. These products are tablet and vaginal products.

Tamper-resistant packaging has been available for years and there are several previous regulatory requirements involving tamper-resistant or tamper indicative packaging. None of these previous regulations dealt with malicious adulteration of a packaged product. Historically tamper-resistant packages have not been intended to deter or halt intentionally malicious individuals but were mainly used to deter common in-store opening of the package by normal consumers. Therefore, in light of the recent malicious tamperings, the following questions have become a concern: 1) Can the package adequately protect the consumer from malicious adulteration of a product through tamper-resistant packaging?; 2) Can the package protect against both "copy-cat" and "Tylenol Killer"?; 3) And if not, then why has the FDA established regulatory requirements?; 4) With the new regulation not containing an evaluation or test standard how will the package engineer objectively evaluate and determine if a package design adequately meets the regulatory

requirements?; 5) How will the new regulation affect the consumer and who will benefit the most?; 6) What legal ramifications will result if the Tylenol and/or "copy-cat" poisonings are repeated with products that are packaged in tamper-resistant containers?

These questions and subjects are looked at and addressed in this thesis. Various conclusions and recommendations are made concerning tamper-resistant packaging, the new regulation, consumer attitudes and perceptions, as well as development of a possible test for tamper-resistant packaging against malicious individuals.

The tampering incident involving Tylenol was a nationwide news event that introduced some new vocabulary and meanings for specific terms. Tylenol tamperings, Tylenol Killer, and any other such reference to Tylenol within this thesis is only meant to describe an event in a broad and general sense. It is not the author's intent to single out any brand name or manufacturer in referencing these vocabulary words and identifications.

DEFINITIONS

The events surrounding the September, October, and November 1982 Tylenol and subsequent "copy-cat" tamperings established a need for some careful definitions of vocabulary. The following are several definitions that become essential to the logical analysis and discussion of our subject.

Webster's American Heritage English Dictionary defines the word 'tamper' as "to interfere in a harmful manner." More specifically, the Glossary of Packaging Terms defines 'tamperproof' as "a term often loosely and incorrectly used for tamper-resistant or tamper-alerting." The Glossary also defines 'tamper-resistant band', 'tamper-resistant seal', and 'tamper-resistant container'. For the purpose of this thesis, we will define container, band, seal, and other such idiom as 'packaging'. Tamperproof will be used in its loose definition when quoting sources only. The term tamperproof is otherwise viewed as impossible to achieve.

"A tamper-resistant package is one having an indicator or barrier to entry which if breached or missing can reasonably be expected to provide visible evidence to the user that the package has been tampered with or opened. This definition primarily covers the immediate container and/or closure system, as well as the secondary container and/or closure system. This type of packaging will provide visual indication of package integrity when handled in a reasonable manner during manufacture, distribution, or retail display."[5]

These terms will be used throughout this thesis to explain the historical development of tamper-resistant packaging and the function it is being asked to perform in today's society.

HISTORICAL BACKGROUND

Tamper-resistant packaging has been used in many different industries for a variety of reasons. The medical products (devices) industry has used tamper-resistant packaging for years to indicate sterility and protect controlled drug products from possible theft. The military, as well as many industrial packagers, have also used tamper-resistant packaging in preventing and indicating pilferage of supplies and products. In this thesis, however, we will focus mainly upon the consumer marketplace where products are sold over-the-counter and the package becomes the point of purchase container.

Protecting product integrity has been a basic package function for many years. Protection against product/package tampering has been a part of securing this integrity for many different products in the past. This integrity, however, was only meant to be secured from non-malicious types of tampering. It was used to protect the product from inadvertent normal opening of a package/product system and is intended to insure confidence and safety for the contained product.

During the early years of Prohibition Repeal, when the sale of alcohol was again legalized, many whiskey products came in tamper-resistant packages because the "whiskey customer still wanted assurances that it was the 'real thing'."[6] Consumers thought that bartenders and store owners were watering down whiskey with an inferior and cheaper product. Distillers adapted tamper-resistant packaging to their products in order to reassure consumers. The distillers were using marketing strategy by guaranteeing the 'real thing' through tamper-resistant packaging and possibly protecting the consumer from the not-so-honest retailer. Drug and Pharmaceutical companies also used

tamper-resistant packaging "as a closure seal for the assurance it conveys that the product is genuine and pure."[7] This was also a marketing strategy as well as a protection device from inadvertent normal opening. The food industry was probably the major user of tamper-resistant packaging. This is probably a result of changes in the United States marketing structure.

As the U.S. marketing structure grew and developed, so did packaging requirements. The growth and spread of self selection retail stores meant there was no longer a store clerk around to keep merchandise out of the customer's reach. Many retailers and manufacturers were experiencing "varying degrees of annoyance from people unknown tampering and adulterating packages and products".[8] This adulteration usually comes in the form of spoilage due to rancidity, oxidation, staling, and other forms of product breakdown that occurs over time when a product is exposed to the environment. Makers of shortenings and oils found that a product's rancidity could be "traced to the habit of some women shoppers opening a bottle to smell the contents."[9] This was the reason for using tamper-resistant packaging in the mid 1960's when the problem became more apparent as to "how to keep the curious shopper from opening, tasting, testing and otherwise spoiling the package protection that has been so carefully built around the product."[10] Again, a problem of in-store tampering prior to the product's purchase and removal from the store.

Other problems surfaced with the introduction of aerosol cans and standardization of different size bottle finishes. People could not resist discharging the aerosol product while it sat on the store shelf. Tamper-resistant seals were also being used to protect "against 'cap-switchers', who have been known to switch large and small caps of the same product."[11] Manufacturers and retailers were finding it very necessary to protect

themselves and future sales. Without tamper-resistant packaging, consumers were finding spoiled products when they opened their purchases at home. Once home, the consumer had no way of knowing that someone had previously opened the package in the store. This resulted in lost future sales from consumers not repurchasing the same product. Retailers and manufacturers were seeing "thin (profit) margins evaporating due to pilferage and spoilage" from product/package tampering.[12]

Up to this point, we have discussed package tampering only in the sense of assurance and protection for the customer as well as the retailer and manufacturer from inadvertent product spoilage due to normal package opening. These are the circumstances out of which tamper-resistant packaging was developed. This concept has also been closely associated with resisting theft and pilferage. Many types of tamper-resistant packaging were developed out of a need to deter and dissuade consumers from stealing a product from its package. This thesis is not concerned with product pilferage, however, we must keep in mind that theft resistance is usually considered a part of tamper-resistant packaging.

Today, tamper-resistant packaging performs the same function that it has in the past. Our present day marketplace includes giant self-serve supermarkets and drug stores. Clerks place products on the shelves in the billions each year for customers to select themselves. These products may have as many as four or five direct competitors creating vast selection decisions for scores of consumers. Tamper-resistant packaging attempts to keep the consumer from easing this decision process through detering taste testing or in store sampling. In today's world, tamper-resistant packaging generally offers the advantages of product protection, indication of tampering at a glance and usually easy access to a product for the purchasing consumer. Disadvantages usually include

increased unit costs and machinery costs, as well as slower production speeds and higher tooling costs. As the number of tamper-resistant packages used each year grows into the billions, it is becoming obvious that the advantages are outweighing the disadvantages.

Tamper-resistant packaging assists in properly protecting the product from environmental elements prior to opening as well as indicating the opening of a package even after the closure or seal has been replaced. These functions must be accomplished, while at the same time assuring easy package opening for the purchasing consumer. In today's society, many types of products use tamper-resistant packaging. A list of many of these products by industry is shown below.

TABLE 1

FOOD AND BEVERAGES

MILK	BEER	WINE	SAUCES
PUNCH DRINKS	LIQUOR	BABY FOOD	SYRUP
PEANUTS	SODA POP	DRESSINGS	TEA BAGS
VEGTABLES			

OTC DRUGS AND MEDICINES

COUGH SYRUPS	COUGH DROPS	OINTMENTS	VITAMINS
DECONGESTANTS	LAXATIVES	ANTACIDS	EYE DROPS

A curious pattern emerges among the many different types of products listed. Many of the products, including over-the-counter drugs, are products

that utilize the sense of taste when a consumer uses them. With the many different flavors available within each of the above products the consumer is motivated to open and taste the product prior to purchasing. Foods naturally fall into this pattern but so do cough drops and syrups, liquid antacids, cold medicines, as well as laxatives. Most of the food and beverages listed (Table 1) have sensitive product stabilities when the package has been opened. Some products that are extremely sensitive to environmental factors are covered by regulations requiring tamper-resistant packaging. These products include milk and opthalmic preparations (drops, solutions, etc. for the human eye). Alcoholic beverages are also regulated with tamper-resistant packaging requirements but for reasons of tax revenue collection. These regulations are specifically discussed in a seperate section of this thesis.

So far, we have discussed foods quite heavily and with good reason. Many of the tamper-resistant packages available today were developed specifically for the food industry. However, tamper-resistant packaging has also been used in the OTC drug industry for many of the same reasons. Additionally, it has been used as a marketing strategy in this industry to assure consumers that the product is authentic and pure. But tamper-resistance has quite often been more of a secondary tool than a problem solver. The primary tool being that of appealing to the customers needs and attitudes. The secondary tool being one of protection for the consumer from normal in-store package opening.

The function of protection being a secondary concern is heavily reflected in unit dose blister products because tamper-resistance was initially an added advantage for this specific packaging system. The bulk or multiple count package can be found in non-tamper-resistant containers while the unit dose blister of the same product uses a tamper-resistant package. But the unit dose was not primarily developed for tamper-resistant reasons. It was a marketing

tool used to give the consumer the convience of carrying medicines with them without concern for contaminating the product when placed in a dirty shirt or pants pocket. So the historical pattern of using tamper-resistant packaging for marketing strategies as well as protecting the product from being removed by curious customers also holds true in the OTC drug industry. However, tamper-resistant packaging has never before been used in this industry or the food industry to protect and assure the consumer that a poison has not been added to the products they purchase.

Tamper-resistant packaging has grown extensively over the years. With the tampering events surrounding Tylenol and other products, tamper-resistant packaging will continue to grow and change in order to adapt to the increasing demand.

TAMPER-RESISTANT PACKAGING REGULATIONS

"Numerous aspects of safety and socially responsible packaging have been enacted into federal laws and regulations with administration and enforcement assigned to major branches of the government."[13] Tamper-resistant packaging is included in these many different laws and regulations. Four distinct regulations exist that specifically call out tamper-resistant packaging according to it's definition. These four regulations cover milk, alcoholic beverages, sterile opthalmics preparations, oral cosmetics and many over-the-counter drugs.

MILK PRODUCTS

The United States Department of Health, Education, and Welfare in cooperation with the Food and Drug Administration established recomendations for an ordinance in 1978 covering Grade A Pastuerized Milk. The Ordinance covers many different aspects of processing, producing, distributing and packaging of fluid milk products. The Recommendation specifically discusses capping or closing of a milk container for public retail sale. This requirement, Item 19p., titled "Capping", states that milk containers shall be capped or closed "in a sanitary manner" by approved equipment.[14] "The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection."[15] This makes these types of containers tamper-resistant by definition. However, all evidence reviewed to date has not mentioned anything about protecting against malicious tampering but rather keeping contamination by microbials, bacteria and filth to a minimum.

ALCOHOLIC PRODUCTS

The packaging of these products are mainly regulated by the Bureau of Alcohol, Tobacco and Firearms (BATF). This federal agency establishes regulations under title 27, part 19 of the Code of Federal Regulations. Tamper-resistant packaging regulations of alcoholic beverages is required under this title and part number according to the establishment of Public Law 85-859, 72 Statute 1358. The regulation deals with revenue tax stamps and states that containers of alcoholic beverages in amounts of 5 wine gallons or less are to be sealed by a stamp that "shall be broken when the container is opened, unless the container is one that cannot again be used after opening."[16] This stamp is expected to provide visible evidence that the package has been opened and guarantees that each time a bottle is filled a tax revenue will be assessed. Therefore, the stamp becomes a tamper-resistant packaging feature by definition. It was, however, established for the purpose of insuring control of tax revenues and no evidence shows any intention towards protecting the consumer from malicious tampering.

Recently some changes have been made to the BATF strip stamp requirements in 27 CFR 19. The changes are found under 27 CFR 19.663, "Strip Stamps and Alternative Devices". This section allows for the use of "alternative devices in lieu of red or green strip stamps" thereby allowing the packager of alcoholic beverages some flexibility.[17] Up until this change, strip stamps were just sealed over the package's closure so when removed, the stamp was destroyed. The packager can now use an alternative device that is securely affixed to the container so that it will leave a portion of the device on the container after opening. The devices used must first be approved by the BATF Director and meet various labelling and coding requirements. These alternative

devices can also be defined as tamper-resistant package features. Defining these devices as tamper-resistant may not be completely correct because there is room for the BATF Director to accept a design that meets the stated requirements but will not provide reasonably visible indication of opening to the average consumer.

STERILE OPTHALMICS

Opthalmics are preparations used in the human eye. These products are generally drops, washes, contact lens solutions, etc. They are sold as an OTC drug product and regulated by the FDA. Tamper-resistant packaging regulations for these products stem from the FDA's requirement for product sterility of opthalmic preparations. The FDA states that an opthalmic product must be sterile to ensure safe use by the consuming public. In order to protect the integrity of an opthalmic preparation, the FDA requires these products to be packaged in containers that "shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal."[18] This regulation, 21 CFR 200.50, continues on with requirements for multiple dose packages and proper labelling. Requirements for multiple dose containers include microorganism inhibitors so that the product will not be rendered harmful after initial use.

Integrity of a sterile product is dependent on protection from contamination. Contamination in this regulation is related to microbials, particulates, and bacteria and not malicious introduction of a harmful substance. Opthalmics are included, with reference to this regulation, in the new tamper-resistant packaging requirements.

OTC DRUGS AND ORAL COSMETICS

The Food and Drug Administration established final regulations for tamper-resistant packaging requirements of certain over-the-counter human drugs and cosmetic products including contact lens solutions on November 5, 1982. This regulation was established as a response to seven deaths due to malicious product/package tampering and was intended to improve OTC drug packaging security. The FDA also stated that this regulation would "obviate the need for State and local laws aimed at accomplishing the same objective for smaller numbers of people."[19] This statement was in response to numerous state and local reactions that were proposed across the nation within weeks of the seven deaths.

The FDA defines tamper-resistant packaging as "one having an indicator or barrier to entry which, if breached or missing can reasonably be expected to provide visible evidence to consumers that tampering has occurred."[20] They do, however, require that a tamper-resistant package be labelled in such a manner that consumers will know what the tamper-resistant feature of the package is.

The regulation is broken down into several different sections. All sections are included in Title 21 of the Code of Federal Regulations. These sections are as follows: 1) 21 CFR 211.132 - Tamper-resistant requirements for over-the-counter human drug products; 2) 21 CFR 314.8 - New Drug Applications; 3) 21 CFR 700.25 - Tamper-resistant packaging for cosmetic products; 4) 21 CFR 200.50 - Opthalmic preparations and dispensers; and 5) 21 CFR 800.12 - Tamper-resistant packaging requirements for contact lens solutions and tablets.

21 CFR 211.132

This section requires tamper-resistant packaging for all OTC drugs except dermatological, dentifrice, or insulin products. The regulation requires the tamper-resistant feature to be of distinctive design or identifying characteristic to prevent substitutions of commonly available materials. The regulation states that "a tamper-resistant package may involve an immediate container or closure system or secondary container or carton systems or any combination of systems intended to provide a visual indication of package integrity."[21] The tamper-resistant feature is required to remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

Labelling requirements state that consumers must be alerted to the tamper-resistant features of the package by a prominently placed statement on the container. This statement must be unaffected if the tamper-resistant feature is breached or missing.

The regulation goes on to discuss requests for exemptions from the packaging and labeling requirements as well as effective dates, effects to the Poison Prevention Packaging Act, and new drug applications.

The initial effective date for packaging requirements in this section is February 7, 1983. On this date, the regulation states that affected OTC drug products except oral and vaginal tablets and vaginal and rectal suppositories will be required to be packaged according to the regulation. Oral or vaginal tablet or vaginal or rectal suppositories must be packaged according to this regulation effective May 5, 1983. All affected OTC drug products on the retail shelf must be in tamper-resistant packages on February 6, 1984. However, any affected product packaged after May 5, 1983, must comply with the stated regulation.

21 CFR 314.8

Part 314 of the regulations deals with new drug applications. The tamper-resistant packaging regulations amends 21 CFR 314 by adding section 314.8. This admendment revises the packaging and labelling requirements of new drugs when filing for FDA approval. It covers specific changes or additions in vocabulary and requires new drugs to be packaged and labelled according to 21 CFR 211.132 before application is submitted.

21 CFR 700.25

This part of the regulations covers tamper-resistant requirements for cosmetic products. Cosmetic products are defined as liquid oral hygiene products and vaginal products for retail sale. The requirements for tamper-resistant packaging features are the same as 21 CFR 211.132 including material substitution prevention, immediate/secondary package definition, labelling, and exemption requests. The effective dates for packaging affected cosmetic products except vaginal tablets is February 7, 1983. Vaginal tablets must be packaged in tamper-resistant packages on May 5, 1983. Retail shelf packages of affected products must comply with this regulation February 6, 1984. Labelling and distinctive design date requirements are the same as OTC drugs; May 5, 1983.

21 CFR 200.50 and 800.12

These regulations deal with opthalmic preparations and contact lens products. Since these products are already required to be contained in

tamper-resistant packages, the new regulation adds requirements for distinctive design of tamper-resistant features and revised labelling.

This part of the new regulation now establishes a classification of opthalmic preparations and contact lens products. This section of the tamper-resistant regulations establishes 21 CFR 800.10 to cover contact lens products as medical devices. 21 CFR 800.12 goes further in requiring the tamper-resistant packaging features for contact lenses to be the same as defined for affected OTC drug and Cosmetic Products. Contact lens products were previously regulated under 21CFR200.50 as opthalmic drug products.

The effective dates for opthalmic and contact lens products is February 6, 1983, for solutions in liquid form because they are more susceptible to tampering. Tablets become affected May 5, 1983, and all products in these categories must be on the retail shelf in packages according to the regulation on February 7, 1984.

REVIEW OF NEW TAMPER-RESISTANT PACKAGING REGULATIONS

The new tamper-resistant packaging regulations have established the foreseeability of intentional tampering by malicious individuals. The packaging engineer must realize that the contained product must now be packaged so as to guarantee the protection of consumers from intentional and potentially harmful adulteration. This is not a simple task. A main problem is how to interpret the definition of tamper-resistant packaging as found in the regulation. The definition states that if tampering has occurred then the tamper-resistant feature should "reasonably" be expected to provide visible evidence. How does the word "reasonably" become interpreted? No where in the regulation does it state or tell how to objectively evaluate if the package complies with the regulation. What happens if the Tylenol incident occurs again with a package previously determined to be tamper-resistant? What might the consequences be? If the package is tested for tamper-resistance, what engineeting and/or statistical basis should be used. The regulation also does not provide guidelines for complying with the labelling requirements stated. What size should the copy or statement be and what kind of type face should be used?

The present regulation does not include the above subjects and leaves room for a variety of interpretations. The packaging engineer must determine the interpretation he or his company is going to adopt and proceed from that point to objectively evaluate the functionality of their tamper-resistant packages.

PRODUCT LIABILITY

Because there is no established standard for evaluating whether or not packages meet tamper-resistant regulations, there becomes the possibility of increased problems for the manufacturer in defending himself in court.

Most state and federal product liability cases, today, are settled either out of court or by a jury trial. In a jury trial involving tamper-resistant packaging, average consumers, who may or may not be technically trained, will be asked to determine whether or not a company packaged their product in compliance with the regulations. The problem for the manufacturer is one of defending a package that has no available test standards by which a jury can objectively judge tamper-resistance. Each member of the jury will make up his mind according to expert testimony from both sides. The manufacturer's position becomes even more difficult because the regulation has established reasonable foreseeability of the problem. The manufacturer will also have a difficult time winning a suit if they could have made their package more tamper-resistant regardless of the cost. Evidence shows that juries do not think about the economics involved and believe that a company should do whatever is necessary to make its product safe.

If standard test guidelines were set up and used as an industry standard, manufacturers will have better avenues of defense for making tamper-resistant packaging decisions. But mere compliance with the regulations will not protect the packager from liability in the event that someone is injured by malicious tampering.

CLASSIFICATION OF TAMPER-RESISTANT PACKAGING

The definition of tamper-resistant packaging lends itself to many different container and material designs. The function of tamper-resistance also varies with each combination of material and container design.

The new regulation for tamper-resistant packaging does not provide a complete classification of packages that meet the stated definition. However, the preamble to the regulation found in the Federal Register of November 5, 1982, does highlight some alternative tamper-resistant packaging systems. The eleven categories shown in the preamble are the same eleven categories recommended to the FDA by the Proprietary Association in a U.S. Senate Subcommittee Hearing regarding tamper-resistant packaging and the Tylenol incident on October 15, 1982. This list has been used in the preamble by the FDA to suggest options for tamper-resistant packaging designs. The list does not preclude any technical innovation or other package form that meets the regulation definition.

FDA CLASSIFICATION OF TAMPER-RESISTANT PACKAGING
(taken from the Federal Register)

1) Film Wrappers - transparent films that are securely wrapped around a product or product container. The film must be of distinctive design in order to comply.

2) Blister or Strip Packs - dosage units are individually sealed in clear plastic or foil.

3) Bubble Packs - the product and container are sealed in plastic and mounted in or on a display card.

4) Shrink Seals and Bands - bands or wrappers are shrunk by heat or drying to seal the union of the cap and container. The requirement for a distinctive design is stated here.

5) Foil, Paper, or Plastic Pouches - the product is enclosed in an individual pouch.

6) Bottle Seals - paper or foil sealed to the mouth of a container under the cap. The requirement for distinctive design is stated here.

7) Tape Seals - paper or foil sealed over all carton flaps or a bottle cap. The requirement for a distinctive design is stated here.

8) Breakable Caps - the container is seales by a plastic or metal cap that either breaks away completely when removed from the container or leaves part of the cap attached to the container.

9) Sealed Tubes - the mouth of a tube is sealed.

10) Sealed Carton - the flaps of a carton are securely sealed.

11) Aerosol Containers - these containers are inherently tamper-resistant.

Each of the package forms with the exception of aerosols require the tamper-resistant feature to be torn, cut, punctured, broken, or damaged when removing the package contents.

The eleven classifications by the FDA and Proprietary Association represents the major types of tamper-resistant packaging. However, the definition of tamper-resistant packaging as found in this thesis is better classified into an improved general format on th following pages.

GENERAL CLASSIFICATION OF TAMPER-RESISTANT PACKAGING

I) BANDS - these are a narrow continuous material used primarily as a secondary closure to secure without the use of adhesives.

A. Plastic

1. Heat Shrink - material shrinks when heating, thereby providing a tight, contour fit about the package's primary closure system.

2. Stretch - material provides a tight, contour fit about the package's primary closure system through tension of the film's elastic memory.

B. Cellulosics

1. Shrink - material is applied wet and shrinks upon drying to provide a tight, contour fit of the package's primary closure system.

II) WRAPS - materials used to cover, encircle, enfold, or wind around a packaging system, a package's primary closure system, or a product. Materials conform to the shape around which they are wrapped and are further defined by their end use.

A. Partial Wraps - materials that only cover, encircle, enfold, or wind around a specific part or section of a packaging system or a package's primary closure system.

B. Overwraps - materials that cover, encircle, enfold, or wind around an entire packaging system or the product itself.

III) POUCHES OR BAGS - packages made of flexible materials in which a product and/or primary package is placed and sealed resulting in a non-rigid container that covers or encircles. These package types usually do not conform to the shape of what they contain.

A. Heat Sealed

B. Adhesive Sealed

IV) TAPES - non-continuous materials that are coated with an adhesive for sealing a package's primary closure system.

V) THERMOFORMS - plastic films that are heated and forced into or over a mold or product by air, vacuum, or mechanical pressure. The thermoformed film holds, contains, or becomes an integral part of the packaging system.

A. Blister Packs - the product or primary package is sealed between a molded thermoformed plastic and a backing material.

1. Peel Off - the adhered backing material is designed to peel off from the thermoformed plastic in order to obtain the package contents.

2. Push Out - the blister pack is designed so that the product or primary package can be obtained by pushing it through the backing material.

3. Tear Out - the blister pack is designed so that the product or primary package can be obtained by tearing the backing material and/or thermoformed plastic.

B. Skin Packs - the product or primary package is sealed between a close fitting plastic film and a backing material. The product or primary package system serves as a mold for the heated plastic which is draped over and vacuum drawn to the backing material.

VI) CLOSURES - a sealing or covering device affixed to or on a container for the purpose of retaining the contents and preventing contamination. Usually an integral part of the primary closure system.

A. Caps - a cover which fits over a container neck or opening rather than into it.

1. Continuous Thread (C/T) - caps that are held by engaging internal threads to external threads of the container.

a. Breakaway

b. Strip Away

c. Vacuum Caps

2. Snap Ons - caps that are held by air pressure or friction of the internal parts against the external parts of the container opening.

   a. Breakaway

   b. Strip Away

   c. Vacuum Caps

B. Seals - materials which cover a container opening or primary closure system.

   1. Membrane seals - seals that cover the mouth of a bottle by adhering to the finish.

   2. Roll-on over-cap

C. Integrally Designed - closures that are a direct part of a package system after product filling and package closing. Destruction of the container or package form must result in order to remove the closure.

   1. Cans - metal and composite closures that incorporate closures that require a can opener or manipulation of an opening system to obtain the product. Usually results in destruction of the container lid.

D. Sealed-End Cartons - rigid or semi-rigid containers closed by securely adhered end flaps or tucks.

VII) OTHERS

A. Ampoules - a relatively small container made from glass, the end of which is drawn into a stem and closed by fusion after product filling. Opening is achieved by breaking the stem.

B. Capsules - small cylindrical container made of two parts that mate to form the closed package after filling.

   1. Snap Lock - multiple snap locks around the circumference of the capsule mating parts.

   2. Ring Lock - continuous ring or groove around the circumference of the capsule mating parts. The convex ring snaps into the concave groove.

3. Gel Band - continuous band of gelatin applied to the filled and closed capsule in such a manner that the mated capsule parts are bonded together.

4. Gelatin - one piece capsules made up of a gelatinous substance. Enclosed product must be in liquid form.

C. Aerosols - considered inherently tampered-resistant.

Each of the above classifications usually require the tamper-resistant feature or package to be damaged upon normal container entry.

This classification contains various package forms that are not usually employed by the OTC drug industry but do require listing for complete categorization. This classification can be used in the future for proper tamper-resistant packaging assignment. The classification should be modified in accordance with any future technical advances.

PROFILE OF A TAMPERER

Attempting to determine the level of tamper-resistant packaging first requires identifying the characteristics of an individual who might tamper with package/product systems. We previously discussed individuals who open shelf packages in the store to taste, sample, or generally inspect product contents. These people usually have no malicious intent and generally only spoil a product and its shelf-life. These individuals concern the manufacturer and packager but not to the same degree as the malicious tamperer. Therefore, we will concentrate exclusively on the characteristics of those individuals who poison or adulter package/product systems in a purposely harmful manner. Since the individuals responsible for the seven Tylenol deaths and assorted "copy-cat" poisonings have not yet been apprehended, we can only speculate with help from psychologists and psychiatrists as to what characteristics and personalities these people possess.

The "Tylenol Killer" who allegedly laced capsules of Extra-Strength Tylenol with potassium cyanide has been characterized as "meticulous, well organized and scientifically acute".[22] Dr. Shervert Frazier, chief psychiatrist at McLean Hospital in Belmont, Massachusetts, says the killer "knows how to carry out actions in a goal oriented, purposeful way."[23] Psychiatrists believe this individual's ability to place cyanide into small capsules and return the tainted packages to the store shelf reveals a great deal of care taken in accomplishing the desired task. Psychologists believe that this individual functions normally in society and agree with psychiatrist that the "Tylenol Killer" is probably a "loner, isolated and unnoticed, with few if any friends. He is probably low in self-esteem, paranoid and hypersensitive, taking offense at real or imagined

slights from those around him."[24] Detailed characterizations of the "Tylenol Killer" or persons having the same traits are vague. Most experts have concentrated on "copy-cat" individuals. This may indicate that those who "copy-cat" have the same traits as the "Tylenol Killer", but most evidence gathered to date does not reveal this statement to be true.

Dr. Gary Kaufmann, psychologist for the Michigan State Police, believes there are probably three different classifications of people involved. He draws his hypothesis from observing the kind and conditions of the occurences that have taken place to date. He classifies these people into three categories which we shall call lethal tamperers, "copy-cat" tamperers, and self tamperers.

Lethal tamperers are those individuals involved in poisoning or maliciously adulterating a product in a fatal manner. Dr. Kaufmann characterized this person as an individual who desires power, strength, control, and recognition. These individuals usually feel they have little or no control over their own lives. They believe they are unrecognized and have been given a "dirty deal" by society. Tampering with a product in a lethal manner serves as an attempt to strike-out at their environment and acquire the control, power, strength and recognition they feel they deserve. Society becomes a hostage. From this captivity plus the media embellishment of the event this individual can rectify his psychological frustrations. This individual may even go as far as rationalizing the deaths that occur by believing they are of a divine order. He feels that his victim's time had come and that they probably deserved what happened to them. By indiscriminantly poisoning individuals, he is able to burden all of society with the fears and frustrations he himself is feeling. Dr. Kaufmann believes these individuals may possess high levels of skill and intelligence. They even demonstrate cleverness and cunning in carring out their

desired actions. They may even be challenged by attempting to successfully poison a drug without consumer detection. The chance that this individual will repeat his actions is hard to predict. It is, however, a very strong possibility because the only predictor is past preformance. Under similar conditions this individual may repeat his previous actions.

The second classification is "copy-cat" tamperers. This classification involves many speculative theories that seem to be in accordance with one another. Dr Kaufmann believes individuals that copy this type of crime are highly suggestible and probably not as motivated as the lethal poisoner. They experience many of the same frustrations the lethal poisoner faces with desires for recognition, power, and solving their problems through example. Their potential for committing this type of crime lies in a need to be told what to do. They find a key to their problems by copying the crime of another. These characteristics are supported by those who describe the "copy-cat" poisoner as an "emotionally immature human being that is desperate for a leader and an excuse to carry out their frustrations."[25] Dr. Arnold Robbins, forensic psychiatrist at Tufts Medical School in Boston, describes the "copy-cat" as somebody who certainly has a great amount of aggression."[26] The "copy-cats" usually have difficulty running their own lives and rely heavily upon others and suggestive stimuli to pattern their lives. These "copy-cat" individuals have seen the publicity surrounding the "Tylenol Killer" and have observed the difficulty authorities have experienced in apprehending and punishing this person. All this has served to motivate the "copy-cat" to similar violence.

One major difference between the "Tylenol Killer" and the "copy-cat" poisoner must be pointed out. The "copy-cat" is not motivated to kill, he has no need to hold society hostage. He probably prefers not to kill or do great bodily harm. The "copy-cat" can satisfy his needs with a public discovery of his

tampered packages. This results in product recalls and massive society reaction, thereby, giving the "copy-cat" his desired satisfaction. The "Tylenol Killer", on the other hand, kills indiscriminantly. He is meticulous and careful in his actions making public detection difficult until someone has died and the death is a part of his success in making society pay as well as suffer in the same way he does.

The third group described by Dr. Kaufmann is the self-tamperer. This type of individual poisons or tampers with a package/product system and then calls it to the attention of authorities. They take advantage of a volatile situation in order to gain recognition. They may also feel that they might experience some sort of material gain through a law suit if their fraudulent claim is successful. These individuals are not considered as severely disturbed as the previous two groups and accomplish their desired goals without physically harming anyone.

Reviewing the various theoretical classifications of individuals who might tamper with a consumer product in a malicious manner brings about some specific conclusions. Tamper-resistant packaging has a renewed importance in protecting the public from malicious individuals. The poisoner who tampers with a product in a potentially lethal manner has been described as skilled and clever. He appears to be motivated enough to spend the necessary time required to carry out a desired goal. This motivation may lead this individual to repeat his actions and become further challenged by tamper-resistant packages. High skill, intelligence, and motivation levels drive this individual to accomplish and satisfy his desires. Tamper-resistant packaging may only serve to force this person to work harder and enjoy greater rewards if he can adequately defeat the packages safety features.

Therefore, tamper-resistant packaging may not deter this individual from accomplishing his task. The regulations, however, may lead the American public

to conclude that they are safe from the lethal poisoner. This will only serve to create a false sense of security in the consumer.

The "copy-cat", on the other hand, mainly desires recognition and will probably not go to the same lengths as the lethal tamperer. These people have no desire to kill. Tamper-resistant packaging does not concern the "copy-cat" individual as long as the media and press continue to keep tampered packages as headline news. This is because consumers will find adulterated packages through observation of broken tamper-resistant packaging features and this may cause enough news coverage to satisfy their needs. Because tamper-resistant packaging is supposed to indicate or reveal tampering, package designs and forms may better serve to satisfy the "copy-cat" than it did before. He can now tamper with a package and know that somebody will most likely find and report it.

Because the "copy-cat" tamperer may also possess high skill and motivation levels, successfully defeating tamper-resistant packaging features may not prove to be difficult. Dr. Kaufmann believes that once the media and press coverage ceases to make tampered packages a major headline, a "copy-cat" individual's need for recognition and attention may lead to the harming of others in order to satisfy his desires. Tamper-resistant packaging may protect the consumer better from "copy-cat" individuals than it does from lethal poisoners, but again the public may only be acquiring a false sense of security regarding product/package integrity.

Self-tamperers do not seem to propose a physically harmful threat to the public but do become quite damaging to a product and its manufacturer. Loss of a good name and trust in a product, as well as recalls and testing will all affect a manufacturers costs, profits, and future sales. Tamper-resistant packaging will

probably play a small role with self-tamperers due to the type of incidents involved.

It should be remembered that the experts who have discussed these three goups agree that all of these people are very much in touch with reality. They can usually function normally in society and cannot be singled out as "crazies" by their appearance or behavior. People in these categories may be very intelligent and defeating tamper-resistant packages may not prove to be very difficult for these people to accomplish.

TEST DEVELOPMENT

While studying the new tamper-resistant packaging regulations and the packages that meet its requirements, the following concerns became apparent: 1) The regulation did not specifically define the kind of packaging that would adequately deter or prevent a malicious tampering; and 2) The regulation could imply to the consumer that he is guarded against malicious tampering when in reality the protection might not exist.

The packaging, as defined in the regulation, is the type of packaging that was designed to deter and prevent casual in-store opening by normal consumers. The individual that the regulation is attempting to protect against has not been described as a normal consumer, and all evidence gathered to date indicates that the Tylenol and other tampered packages were first removed from the store, contaminated at a location outside of the store, and then returned to the store shelf at a later date. This allowed the individual an opportunity to work carefully and undetected with whatever tools or aides he could commonly obtain.

The new regulation may also instill a false sense of security in the public and they may feel protected from future malicious tamperings. Being technically uninformed, consumers may put their trust in the manufacturer, the tamper-resistant package, and the federal government when believing that they are now safe. They may become less cautious and feel that they can easily identify that a package has been tampered with because the new regulation requires the package to perform this function.

In order to effectively evaluate and determine if the current regulation will provide adequate protection for the consuming public, a test was

developed. This test should eventually lead to the development, as proposed in the regulations section of this thesis, of an evaluation test standard that will allow packaging engineers and manufacturers an opportunity to objectively evaluate their specific package design for tamper-resistance.

The developed test involved the following concepts: 1) How well does tamper-resistant packaging perform as a barrier to entry with visible evidence of breaching; 2) Can consumers identify a tampered package; and 3) The repairability of a tampered package. These three concepts are the basis on which our test was developed.

The test development is broken down into the following three different parts; 1) The initial test; 2) A consumer perception survey; and 3) A tamper identification test. The consumer perception survey and the tamper identification test make up what is discussed further on as the final test. All three of these tests are described on the following pages in terms of development, change, and procedures used.

INITIAL TEST

The initial test used representative packages from most of the tamper-resistant package classifications presented on pages 22-27 . Certain classifications such as ampoules, aerosols, capsules, and cans were not included because they are either considered inherently tamper-resistant by design or are seldom used as a package form in the over-the-counter drug industry.

Samples used in the test include:

1) Wirz tamper indicating opthalmic tube
2) Glass jar with plastic breakaway ring cap
3) Glass bottle with metal breakaway ring cap
4) Glued end paperboard box
5) Glass bottle with vertically perforated shrink band around the cap
6) Foil and plastic unit dose blister
7) Paper bag with sealed closure
8) Glass bottle with paper and corrugated overwrap
9) Stretched wrapped paperboard card of individual unit doses
10) Membrane sealed plastic bottle
11) Clear plastic overwrap with a tear tape
12) Plastic bottle with shrink banded child resistant closure
13) Foil/plastic overwrap
14) Plastic shrink wrapped paperboard carton
15) Plastic bottle with tape seal over closure
16) Glass bottle with metal/plastic center sealed breakoff lid
17) Metal sealed end tube
18) Foil pouches
19) Foil membrane seal over the mouth of a plastic bottle

A total of thirty-four samples were used with variations in materials and designs of the above nineteen categories. Product names and manufacturers are not identified in this text. None of the samples in this initial test were tampered with. Samples were purchased from local stores.

These tamper-resistant packaging samples were shown to a small group of consumers to determine whether or not they could identify tampered packages. For this initial test the consumers were all Michigan State University, School of Packaging staff and students. The consumers were asked to answer 'yes' or 'no' to the following question, "Having observed this package, do you think it has been tampered with?" Any 'yes' answers recieved were considered false positives because none of the packages had been tampered with.

Each consumer was allowed to handle and observe the sample packages as if they were in a store and about to purchase the products. They were not allowed to open any packages and they were asked to refrain from poking, picking, peeling or otherwise damaging any of the samples in making their decisions. Each sample had a 4" x 6" card assigned to it that identified the package and its tamper-resistant feature in an attempt to bring the packages into compliance with the new tamper-resistant packaging regulations. Samples were displayed on a table under flourescent lighting with consumers moving around the table from package to package in making their responses.

The consumers were given instruction and test response sheets as shown on the following two pages. Each sample had a seperate test response sheet for the consumer to mark responses. A total of one instruction sheet and thirty-four response sheets made up a consumer's test packet.

TEST FOR TAMPER-RESISTANT PACKAGES

SCHOOL OF PACKAGING

MICHIGAN STATE UNIVERSITY

Instructions

Please read all material carefully before you make an observation. Please circle only one answer and print comments legibly. You may handle the package/product system but please do not open or damage the package in any manner. If the package becomes accidentally damaged, then immediately call it to the attention of the test proctor.

Thank you for your participation. It will result in some very helpful research data.

Name:_____

Address:_____

City/State/Zip:_____

Telephone:( )_____

Age: _____ Sex:_____

Education:_____

Occupation:_____

SAMPLE TEST FORM TWO

ITEM NAME AND NUMBER: _____

THE PACKAGE/PRODUCT SYSTEM THAT YOU WILL OBSERVE MAY OR MAY NOT HAVE BEEN TAMPERED WITH. PLEASE IMAGINE THAT YOU ARE IN A STORE AND ABOUT TO PURCHASE THIS PRODUCT. THE FOLLOWING QUESTION NEEDS TO BE ANSWERED - "HAS THIS PACKAGE BEEN TAMPERED WITH?"

(Please circle and answer the appropriate answer below)

YES - INDICATES THE PACKAGE HAS BEEN TAMPERED WITH.

NO - INDICATES THE PACKAGE HAS NOT BEEN TAMPERED WITH.

If yes, please explain why you believe so - _____

_____

_____

If no, please explain why you believe so - _____

_____

_____

Additional Comments - _____

_____

_____

RESULTS of INITIAL TEST

Table 2

Total Samples Tested - 34

Total Test Participants - 43

Average time required to complete the test - 45 minutes

Total question responses recieved - 1,367

Total yes answers - 296

Total no answers - 1,071

Total skipped sample answers - 138

Average percentage of yes answers over all samples - 21.7%

Range of yes answers for individual samples - 0.0% - 74.0%

Median of yes answers for individual samples - 21.25%

Two samples were destroyed during the testing and removed from the experiment after 23 and 26 responses were recieved.

A graph of yes responses as a function of the number of participating in the test is shown below. Each consumer was numbered in ascending order according to when they completed the test.

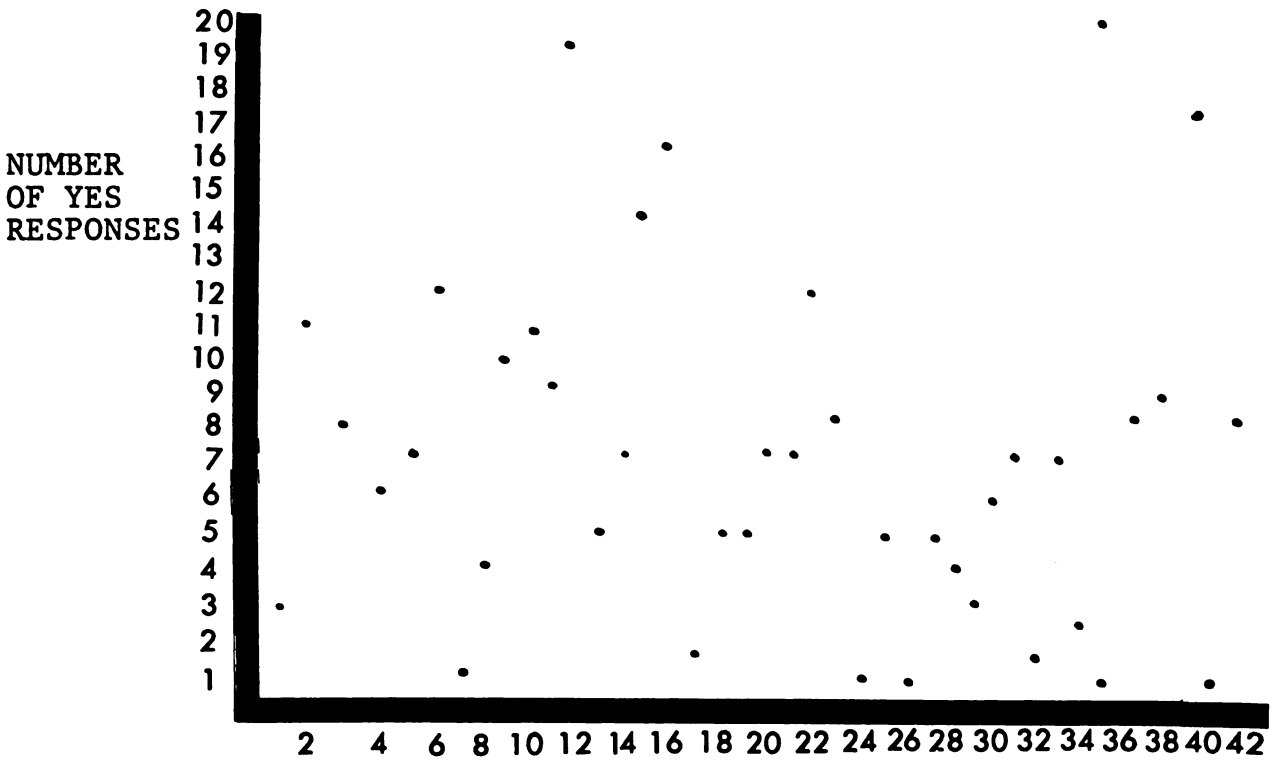

FIGURE 1

CONCLUSIONS FROM INITIAL TEST

The data from this initial test revealed some interesting observations and pointed out a need to make some changes in procedure for the final test. The packaging students and staff members of the School of Packaging appear to be highly sensitized to the issue of tamper-resistant packaging. The average amount of time taken (45 minutes) to complete the test shows their concern and sensitivity to the subject. It can be safely assumed that most consumers would not spend the same amount of time per sample that the test participants did. Furthermore it is not likely that consumers will spend this amount of time evaluating packages while shopping.

The staff and students also produced an average response of over twenty percent false positives with yes answers to the question, "Having observed this package, do you think it has been tampered with?" These twenty percent yes answers were probably due to a number of reasons such as: 1) Students were very conscientious of any package imperfection; 2) Rough handling of samples created damage that the next participant interpreted as tampering; 3) Participants answered the question with a "yes" or "no" but quite often negated their answers with comments. One example is a student who answered "yes" for a specific sample, but followed it up with the comment, "I don't think the package has been tampered with but it looks awful suspicious. I would not buy it." This percentage of false positives is probably much higher than what would be obtained in a test of a larger more representative population sample.

The data shows a range of 0.0 to 74.0 percent yes answers for the samples. The 74.0 percent reflects a very high rate of yes responses to the question asked. This high rate of yes responses reflects what the consumer perceived when told that the samples may or may not have been tampered with. After

investigating samples that received a high percentage of yes responses, we found a variety of sample imperfections from production variation and distribution handling. These imperfections were probably construed as product/package tamperings and test participant comments reflected this conclusion. This opens up a new area of problems for the manufacturer. Will it be necessary to produce a perfect package so that consumers will not think it has been tampered with; and if not will it become necessary to tighten quality control of outgoing goods?

Because of the above results and problems, the following changes were made before conducting the final test: 1) Test participants will be individuals with no technical education or training in the field of packaging; 2) Samples will be periodically checked for handling damage and replaced immediately if any problem is detected; 3) Instead of "yes" or "no" answers, test participants will be allowed to place their answer on a scale or range thus allowing a greater latitude of responses; 4) Total number or samples will be kept to less than twelve to reduce the amount of time necessary to complete the test; and 5) A general perception survey will be conducted along with the tampering study to provide greater opportunities for extended data relationships.

STATISTICAL DATA EVALUATION

No statistical computations were performed on the data collected in the initial test. However, a statistical evaluation was used for the final test. The method first chosen for analyzing the obtained data in the final test centered around a Chi-square test. This test analyzes the data according to the increase in population responses from control (non-tampered) samples to tampered samples. Based on the null hypothesis (H_0) that consumers cannot

detect tampering, the answers to control samples and tampered samples should have small increases or decreases between each other if the hypothesis is true. The test statistic analyzes and differentiates the number of "no" responses received.

This form of Chi-square test was based on the assumption that answers would be either "yes" or "no" as in the initial test. However, with the change of possible answers from "yes" or "no" to a scale, we must change the statistic used. The Chi-square test will still be used but instead of checking for a difference in responses it will test the proportionalities of the responses. If consumers cannot detect tampering, then the answers from the scale for both tampered and control samples will be proportionally the same. We will test the results using an alpha of .05 and four degrees of freedom. Specific equations and test determinations can be found in the results section of the final test.

FINAL TEST

The following pages outline the final procedures for conducting a consumer perception survey and a tamper identification test. This final test takes into account the three main concepts discussed previously. These are the following: 1) How well does a tamper-resistant package perform the barrier to entry with visible evidence of breaching; 2) Can consumers adequately identify packages that have been tampered with; and 3) The repairability of a tampered package.

The consumer perception survey was used to help determine how consumers feel about certain tamper-resistant packaging classifications. These perceptions should help inform the packaging engineer and marketing specialist of what the consumer feels the most confident about. This data might also provide a relationship between a consumer's belief that a package has been tampered with

and how he feels about a tamper-resistant packaging classification. While this thesis is not concerned with consumer perceptions, the subject must be taken into consideration when asking a consumer to determine if a package has been tampered with. Strong answers of "No, the package has not been tampered with", may relate to how confident a consumer is of the tamper-resistant packaging classification being tested. The concept of consumer perceptions and identification of tampered packages is a further area of possible research into what a consumer actually observes and perceives.

The tamper identification test of the final test will provide insights into whether or not consumers can determine if a package has been tampered with. The procedures and test forms for both parts of this final test (consumer perceptions and tamper identification) can be found on the following pages. Each part is treated as a separate entity with appropriate conclusions reported. Proctor instructions for completing the tamper identification study can be found in Appendix H.

FINAL TEST - PART I

CONSUMER PERCEPTION SURVEY

Methods

Place samples so that test participants complete this section of the test first. Enough samples for adequate representation shall be obtained for each classification allowed by the Food and Drug Administration. Participants shall be individuals having no technical training in packaging. Each person will be asked to rate each classification for tamper-resistance by circling a number on a scale that best describes their perception of feeling.

Question: "How do you rate this group of tamper-resistant packages?"

Scale:	1	2	3	4	5
	BAD				GOOD

Materials

For our perception survey the following seven groups or classifications were surveyed:

1) Shrink bands of plastic and cellulosic in white, clear, and specific logo designs.

2) Wraps of cellulose and plastic with distinctive and common designs. Partial and complete overwraps were presented in a variety of colors as well as transparent. Shrink and glued wraps were equally included.

Materials continued -

3) Breakaway caps of plastic and metal that either become completely destroyed or leave a portion of the cap behind when removed.

4) Tape seals in a variety of colors and designs including delaminates and tear aways.

5) Blister packs of only unit doses in plastic and foil.

6) Membrane seals of common and distinctive designs with pressure sensitive and induction seals.

7) Glued End Boxes.

This survey was carried out in unison with the tamper identification test.Therefore, population data for both tests (consumer perception and tamper identification) is the same. Survey sheets can be found on page with population data, results, and summary following the tamper identification test design and procedures.

FINAL TEST - PART II

TAMPER IDENTIFICATION TEST

SCOPE

The purpose of this experiment is to determine the performance of tamper-resistant packaging systems as they relate to protecting the consumer from malicious adulteration of the contained product.

TESTING PROCEDURE

1) Sample Packages

Two samples of the same package will be obtained from each major tamper-resistant classification allowed by the Food and Drug Administration. Samples will be in consumer purchased or store display form. One sample will serve as a control and remain in original store purchased form. A second sample of the same package will be subjected to various methods of tampering. Tampering in this experiment will be defined as malicious entrance into a package in such a manner that product contents can be adultered and the package resealed. Tampered and control samples (of the same package) will be evaluated separately. No participant will be allowed to compare tampered versus control samples of the same package. The concern is whether or not the consumer can adequately identify tampering without any outside assistance.

2) Tampering Techniques

a. Hand Tampering - This includes careful opening of sample packages using human hands only.

b. Tool Tampering - This includes careful opening of sample packages using any commonly available tool. A tool is defined in this test as any

common mechanical or non-mechanical device or equipment including heating or freezing apparatus.

c. Solvent Tampering - This includes careful opening of sample packages using any commonly available chemical or solvent such as water, alcohol, non-polar solvents and others.

The tampering technique chosen for each package will be determined using the easiest to perform and the hardest to detect method. A combination of methods may be used if appropriate. After successfully entering a sample package and removing some product contents, it will be repaired to its original form. Repairs will be made by any commonly available mean such as adhesives, tapes, glues, heat and others.

Tampering and repairing will be performed by a knowledgeable panel of two or three individuals. They will tamper with any part of the sample package system in attempting to successfully defeat the package protection of the contained product.

SAMPLE PRESENTATION

Test packages will be divided into two different groups. No group will consist of controlled and tampered samples of the same package. This is so participants cannot compare tampered and control samples of the same package. Each group will have at least one sample from each of the major classifications. No test participant will evaluate more than one sample group. He/she will be asked to evaluate each sample in the group by answering a specific question. The test participants will not have any technical training in the field of packaging.

Each sample will be identified by an information card. The card will describe the tamper-resistant feature of each sample. Each card and package will be identified by numbers. Numbers will be assigned in a manner that will not introduce biases.

Sample packages that require removal of a secondary container or closure in order to display the tamper-resistant packaging feature will be presented appropriately to allow participants proper observation. An example would be removal of a bottle cap to display a membrane seal or taking a blister pack out of its primary carton. Samples used in our testing as identified by tamper-resistant packaging classification are as follows: 1) A coated thin paper membrane seal with a distinctive design; 2) A white plastic vertically perforated shrink band; 3) A paper and corrugated glued overwrap; 4) A metal breakaway ring cap; 5) A distinctively designed plastic shrink band; 6) A clear plastic glued overwrap; 7) A white styrene membrane seal; 8) A glued end box; 9) A foil and plastic distinctively designed delaminating tape seal; 10) A clear plastic shrink overwrap; 11) A plastic tape seal.

None of the samples obtained totally met the new tamper-resistant packaging regulations due to the need for labelling, distinctive design or a combination of both.

TEST

Test participants will be asked to circle a number on a defined scale that best describes their response to the following question: "Having observed this package, do you think that it has been tampered with?"

Test participants will be told that the packages they observe may or may not have been tampered with. They will be instructed to answer the question as

if they were about to purchase this product in the store. They will be allowed to handle the package in a general manner but will be told not to peel, pluck, or otherwise damage the package.

QUESTION RANKINGS

The question asked will be assigned a scale which represents a range of possible answers.

Question Scale:

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

This range will allow test participants to place their response on the scale in a way that best reflects their belief or judgement.

SUMMARY

Upon completion of the experiment, results will be tabulated and reported using statistical tests. For our purposes we will test the differences in response proportionalities using Chi-square. Details concerning tampering, however, will be available to qualified individuals only. Packages chosen will only be described in generic detail.

TAMPER-RESISTANT PACKAGING STUDY

Michigan State University

This study is broken into two separate parts; one part on each table.
Your participation in completing both parts is greatly appreciated.

PART I

Please rate separately, the seven tamper-resistant package groups displayed. Each group is identified by a letter and group name. You may not pick the packages up in this part of the study. Rate the groups for their tamper-resistant ability.

▶Group K - SHRINK BANDS

"How do you rate this group of tamper-resistant packages?" Circle a number.

1	2	3	4	5
BAD				GOOD

▶Group V - WRAPS

"How do you rate this group of tamper-resistant packages?" Circle a number.

1	2	3	4	5
BAD				GOOD

▶Group I - GLUED END BOXES

"How do you rate this group of tamper-resistant packages?" Circle a number.

1	2	3	4	5
BAD				GOOD

▶Group N - BREAKAWAY CAPS

"How do you rate this group of tamper-resistant packages?" Circle a number.

1	2	3	4	5
BAD				GOOD

▶Group R - TAPE SEALS

"How do you rate this group of tamper-resistant packages?" Circle a number.

1	2	3	4	5
BAD				GOOD

▶Group F - BLISTER PACKS

"How do you rate this group of tamper-resistant packages?" Circle a number.

1	2	3	4	5
BAD				GOOD

▶Group T - MEMBRANE SEALS

"How do you rate this group of tamper-resistant packages?" Circle a number.

1	2	3	4	5
BAD				GOOD

YOU SHOULD HAVE SEVEN RESPONSES, WITH ONE NUMBER CIRCLED FOR EACH GROUP. PLEASE CONTINUE.

PART II (Continue to next table.)

Please look at each sample container separately. The samples in this part of the study may or may not have been tampered with. You may pick up the samples in this part of the study, but please do not alter the package in any manner (That is do not pick, peel, or pluck at the displayed packages.)

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"
Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"
Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"
Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"
Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"
Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"
Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"

Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"

Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"

Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"

Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

➡ Sample Container -

"Having observed this package, do you think it has been tampered with?"

Please Check One.

☐ NO ☐ NOT LIKELY ☐ DON'T KNOW ☐ MOST LIKELY ☐ YES

YOU SHOULD HAVE ELEVEN RESPONSES WITH ONE RESPONSE FOR EACH SAMPLE PACKAGE.

Some questions about yourself. ➡ SEX Male Female (Please Circle One)

▶ AGE ☐ Under 25 ☐ 26-34 ☐ 35-44 ☐ 45-54 ☐ 54-65 ☐ Over 65

▶ Do you buy over-the counter drug products such as aspirin, cough syrup, eye drops, etc.? Please Check One.

☐ Never ☐ Once every six months ☐ Once every two weeks
☐ Once a year ☐ Once a month ☐ At least once a week

COMMENTS: ____

____

POPULATIONS TESTED - FINAL TEST, PARTS I and II

A total of 200 people were tested and surveyed for the final test. These people were tested in Lapeer, Michigan during an adult education seminar and in Holt, Michigan at a Travelog Kiwanis Club meeting. At each location people chose which one of two groups of packages they were going to observe. The groups of packages were those described in the tamper identification test procedure. Choosing a group of packages put consumers into a total population for that group. Package groups were the same at each location. Therefore, two populations, according to the package group observed, were developed. These two populations are assumed to be similar for statistical procedures and are distributed by age and sex as shown on the following pages. Population one is made up of 110 people that observed one group of packages and Population two consists of 90 people that observed another group of the same packages only opposite in control or tampered status.

Table 3

Population One:

AGE

CATEGORY	NUMBER OF PEOPLE	PERCENTAGES
Under 25	9	8.2
26 - 34	18	16.4
35 - 44	32	29.1
44 - 54	12	10.9
55 - 64	24	21.8
OVER 65	13	11.8

SEX

CATEGORY	NUMBER OF PEOPLE	PERCENTAGES
Male	42	38.2
Female	60	54.5
No Response	8	

Table 4

Population Two

AGE

CATEGORY	NUMBER OF PEOPLE	PERCENTAGES
Under 25	9	36.7
26 - 34	21	18.0
35 - 44	24	26.7
45 - 54	8	8.9
55 - 64	18	20.0
Over 65	6	6.7

SEX

CATEGORY	NUMBER OF PEOPLE	PERCENTAGES
Males	33	36.7
Females	45	50.0
No Response	12	

FINAL TEST RESULTS AND CONCLUSIONS

The following pages consist of data summaries, summary tables, and results of computations for the consumer perception survey and tamper identification test.

CONSUMER PERCEPTION SURVEY

The consumer perception survey (pages 46-47) that asked test participants to rate certain tamper-resistant packaging groups resulted in a broad range of answers and distributions. The average values reported for each group in Table 5 on the following page shows generalities of responses in the numerical extremes of the "good" to "bad" scale. One example is the shrink band group which averaged about a four on the scale of five showing that the total of both consumer populations tested perceive this form of tamper-resistant packaging as being good. However, this average is further enhanced with forty percent of the answers at the "good" extreme and only twelve percent at the "bad" extreme of the scale. This shifts the responses towards the best end of the scale and reflects that consumers perceive shrink bands to be good tamper indicators. One other group that received a good rating average is blister packs. All of the blister pack examples shown to consumers were unit dose packs of plastic and foil. The consumers in the final test rated blisters as the highest group. Breakaway caps, wraps, and tape seals received middle of the scale average responses, but looking at the distributions, we can observe that wraps and breakaway caps are shifted in their distributions towards the "good" extreme. Tape and membrane seals appear to be an evenly distributed uncertainty for the consumer with neither a "good" or "bad" rating. Glued end boxes, however,

received a 2.47 rating and its distribution of answers shows them shifted towards the "bad" end of the scale. Over fifty-five percent of the respondents thought glued end boxes were "bad".

With these results in mind, the following shows a ranking of tamper-resistant packaging groups from highest to lowest average of consumer perception response:

Table 5

Group	Average Response
1. Blister Packs	4.00
2. Shrink Bands	3.905
3. Wraps	3.52
4. Breakaway Caps	3.53
5. Tape Seals	3.08
6. Membrane Seals	3.02
7. Glued End Boxes	2.47

These average responses were the number answers given by consumers to the question, "How do you rate this group of packages?"

Scale: 1 2 3 4 5

Bad Good

Raw data and complete distributions of responses can be found in Appendix C and F, respectively.

TAMPER IDENTIFICATION TEST

The percentage of responses, test statistic, and acceptance or rejection of the null hypothesis is reported for each sample set on the following pages. Complete distributions of responses and statistical computations can be found in Appendix E. Raw data is in Appendix D.

The statistical evaluation of our test is based upon the Chi-square test. This test helps determine whether or not the proportions of answers for the control and tampered samples of the same package are the same or different. Because we believe that the average consumer cannot detect careful and malicious tampering of tamper-resistant packages, we shall adopt the following null hypothesis:

H_0 : "The proportions of answers for both tampered and control samples are the same."

This states that the distribution of answers for the tampered package is the same as for the control package. If the proportions are the same, then we are able to state that consumers do not perceive a difference in tampered versus control packages. To make this statement, we must first choose a confidence level or alpha value. This level is a type I error which tells us the probability we have of being wrong when accepting or rejecting the null hypothesis. We have chosen an alpha value of .05 for this study.

The next page shows the statistical equations and mathematical set-up of our Chi-square test.

The following are the mathematical computations used to obtain statistical data. For this example we used the coated paper membrane seal packages, numbered 5021 and 2572. These are the same packages but package 5021 was tampered with. The other ten sets of sample results are on the following pages. The responses recieved were for the question, "Having observed this package, do you think it has been tampered with?" Answers were given on the following scale:

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

Table 6

Observed Results

	NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES	ROW TOTALS
Control	39	33	13	15	9	109
Tampered	35	30	6	14	5	90
Totals	74	63	19	29	14	199

Expected Numbers = (Row Total)(Column Total)/(Grand Total)

	NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES
Control	40.53	34.51	10.41	15.88	7.67
Tampered	33.47	28.49	8.59	13.11	6.33

Chi-square Test Statistic $= \sum_{i=1}^{2}\sum_{j=1}^{5}(O_{ij} - E_{ij})^2/E_{ij} = 2.318$

Degrees of Freedom = (Number of Rows-1)(Number of Columns-1)
$= \underline{4}$

Critical Value $X^2_{.05,4} = 9.488$

For each set of samples in our test the Critical Value is equal to 9.488. For this specific example the Chi-square test statistic is less than the Critical Value so we Accept H_o.

$$2.318 < 9.488 \quad \text{therefore accept } H_o$$

The following pages report response percentages and general statistics for each sample set tested. Actual computations and disribution histograms can be found in Appendix E and D ,respectively.

RESPONSE PERCENTAGES AND STATISTICAL RESULT

Table 7

COATED PAPER MEMBRANE SEAL

Responses:	1	2	3	4	5	Test Statistic	H_o
Control	27.3	28.2	24.5	12.7	6.7	1.87	ACCEPT
Tampered	25.0	29.5	19.3	18.2	8.0		

VERTICALLY PERFORATED SHRINK BAND

Responses:	1	2	3	4	5	Test Statistic	H_o
Control	25.5	24.5	18.2	20.0	11.8	1.30	ACCEPT
Tampered	25.0	29.5	15.5	18.2	7.95		

PAPER and CORRUGATED OVERWRAP

Responses:	1	2	3	4	5	Test Statistic	H_o
Control	40.7	38.4	13.95	4.7	2.3	7.34	ACCEPT
Tampered	42.6	24.1	16.7	13.0	3.7		

METAL BREAKAWAY RING CAP

Responses:	1	2	3	4	5	Test Statistic	H_o
Control	43.8	25.8	13.5	10.11	6.7	40.61	REJECT
Tampered	13.76	17.4	13.8	14.7	40.4		

DISTINCTIVE DESIGN SHRINK BAND

Responses:	1	2	3	4	5	Test Statistic	H_o
Control	46.7	35.6	7.8	6.7	3.3	8.57	ACCEPT
Tampered	58.3	25.0	12.0	.93	3.7		

CLEAR PLASTIC OVERWRAP

Responses:	1	2	3	4	5	Test Statistic	H_o
Control	49.1	35.5	9.1	2.7	3.6	21.31	REJECT
Tampered	28.1	34.8	9.0	20.2	7.9		

Table 7 continued

STYRENE MEMBRANE SEAL

Responses:	1	2	3	4	5
Control	29.2	30.3	27.0	10.10	6.7
Tampered	23.6	23.6	31.0	16.4	5.5

Test Statistic	H_o
3.58	ACCEPT

GLUED END BOX

Responses:	1	2	3	4	5
Control	10.9	21.8	23.6	30.9	12.7
Tampered	27.0	28.1	22.5	16.9	6.7

Test Statistic	H_o
10.37	REJECT

DELAMINATING TAPE SEAL

Responses:	1	2	3	4	5
Control	39.3	33.7	12.4	12.4	2.2
Tampered	30.0	28.2	22.7	16.4	2.7

Test Statistic	H_o
5.95	ACCEPT

CLEAR PLASTIC SHRINK OVERWRAP

Responses:	1	2	3	4	5
Control	60.7	29.2	7.9	1.1	1.1
Tampered	49.0	25.5	10.0	10.0	5.5

Test Statistic	H_o
10.78	REJECT

TAPE SEAL

Responses:	1	2	3	4	5
Control	35.8	30.3	12.0	13.8	8.3
Tampered	38.9	33.3	6.7	15.6	5.6

Test Statistic	H_o
2.32	ACCEPT

Reviewing the results of this study, we observe varying distributions of answers received over all pairs of tampered and control samples of the same package (See Appendix). Seven out of the eleven sets of control versus tampered packages show that consumers answer the question, "Has this package been tampered with?", in the same proportions. When testing to an alpha equal to .05, these seven sets show that the consumer tested would have answered the same way whether the package had been tampered with or not. They did not see any difference between control and tampered samples of the same package. Four sets of samples showed statistically different response proportions between tampered and control sample. Three of the four still contained over fifty percent wrong responses for the tampered samples by answering "No" or "Not Likely" that the package had been tampered. Two of the three were Clear Plastic Overwrap and Clear Plastic Shrink Wrap. For both of these, the consumers showed some ability to detect tampering, but both showed over sixty percent failure to detect tampering. One of the three, Glued End Boxes, received over forty percent "Yes" answers when in reality it had not been tampered with at all. The tampered sample received five percent responses towards the "No" end of the scale or just opposite of the control sample. This demonstrates the consumers inability to detect or identify tampering with respect to this tamper-resistant package form.

The one set of samples that did show any significant results favoring the ability of the consumer to detect tampering was the metal breakaway ring cap. This was the fourth set of samples that showed statistically different response proportions. The results showed over fifty percent of the respondents correctly identified the package as being tampered. The control sample demonstrated the same results with over fifty percent also giving right answers. We still observe

a twenty percent response rate that is wrong for the tampered sample but this is the lowest percentage of all the tampered packages.

Overall, there were 1099 and 1081 responses to the tampered and control samples, respectively. The tampered samples, overall, show a thirty-three percent wrong response rate at the far extreme of "No". When we include "Not Likely", the percentage becomes sixty percent. These two wrong answers that the package has not been tampered with, when in reality it has been, show a definite inability, in the consumers tested, to detect tampering for the samples and tampering methods used. If we include the answer of "Don't Know", we find that over seventy-five percent of the consumers did not know or could not correctly identify a tampered package.

The control samples, overall, show only a six percent wrong response rate at the far extreme of "Yes". When we include "Most Likely", the percentage rate becomes eighteen percent. This percentage is not a large increase in wrong responses when compared to the responses for the tampered samples. If we add the "Don't Know" results, the percentage becomes thirty-three percent. Again, not as great an increase in the tampered sample responses. However, the wrong answer percentages for the sample sets support some interesting conclusions.

The consumer's inability to detect and correctly identify a tampered package has already been mentioned and brings to light the question of just how safe will the consumer be with new tamper-resistant packages. With over seventy-five percent of our consumer population not able to detect and identify a tampered package, we become concerned that little or no protection will be afforded in the event of future malicious tamperings.

With the control group receiving over thirty percent wrong answers, we only generate the thought of what it will mean to sales and production. If the consumer thinks a package has definitely been tampered with or even if they

question whether it has been, then will they buy it? We do not think so, but this area needs to be further investigated. Are consumers observing production variations or imperfections normally present in the package as tampering? If that is the reason for such high percentages, then does this mean manufacturers will have to tighten tolerances and make a perfect package? Again, this area needs to be further investigated.

Overall, we have shown that consumers cannot detect the way we tampered with many of our chosen samples. There is room for error in our analysis and results as listed below, however, the data is fairly strong and initially presents some future problems for the tamper-resistant function of many packages. The next step seems clear in attempting to identify exactly what the consumer can and cannot detect. Further studies in this area could give us a level from which to work from in developing truly tamper-resistant packages.

EXPERIMENTAL ERROR

The following is a list of possible errors that may have occurred and thereby bias or change the results we received:

1. The assumption that our two populations are similar is not true.

2. Consumers were not given the chance to compare tampered packages with control packages as they might be able to in the store.

3. Consumers were not allowed to open any of the packages and thereby inspect the integrity of the package components for repairs.

4. Sample display lighting may not have been the same as what is available in a store.

5. Test proctors may have inadvertently biased test participants in regards to sample identification.

6. None of the packages tested totally met the new tamper-resistant packaging regulation requirements.

7. Test participants were initially sensitized to the fact that the samples they would look at "May or may not have been tampered with." This statement may have increased their awareness more than what it would be in a normal product purchasing situation.

GOOD TAMPER-RESISTANT PACKAGING

During the development and completion of the test certain tamper-resistant packaging features proved to be better than others. This is not surprising as there exists four major packaging materials all consisting of different properties. Within each of these four materials (glass, paper, plastic, and metal) there are hundreds of different material make-ups each with different properties. These material properties combined with numerous package design properties can produce any number of package forms. Tamper-resistant packaging is no exception. With a multitude of possible designs and material combinations, there exists a range of performance and functionality levels.

Some of the major tamper-resistant packaging classifications are listed below. For each classification there are observations that discuss certain features and designs which perform the function of tamper-resistance better than others.

L Bands

- Vertical perforations in the shrink band made it difficult to remove without breaking. The greater the number of perforations, the harder it became to remove the band without damage. Vertical perforations also made it more difficult to repair because of material breakage.

- Clear or transparent bands are hard to repair after tampering because the consumer can detect the repair by seeing behind (or under) the band. However, the presence of clear bands that contained no distinctive markings was difficult for the consumer to see.

- Heat shrink bands are more tamper-resistant than cellulosic shrink bands.

- Bottles or jars that had the shrink band sealed over the cap and a large transfer bead or other non-uniformity were more difficult to remove and replace than packages with smooth and uninterrupted finishes. The band was shrunk over the transfer bead in such a way that damage usually had to occur in order to get the material past the bead.

- The longer or further down the package the shrink band extended, the harder it became to remove the band and repair.

- All of these observations for bands assume that the material has been applied in a tight and contour fitting manner.

- Shrink bands and child-resistant closures do not usually make good tamper-resistant packages.

II. Wraps

- The clearer the wrap the easier it was for a consumer to detect repairs.

- Perforations or tear strips made it difficult to remove and replace the wrap in one piece.

- Tight one piece shrink overwraps from a heat sealed pouch are more difficult to tamper with than adhesive sealed overwraps.

III. Tape Seals

- The thinner the tape material the harder it became to peel off in one piece.

- Adhesives that were stronger than the tape materials resulted in torn paper fibers or destruction of the tape upon removal.

- Delaminating tapes of plastic and foil were difficult to defeat without detection.

- Tape sealed cartons should also have a tape seal applied to the glued carton joint or side seam.

- Glossy highly calendered materials used to manufacture cartons were easier to remove tape seals from because of little or no fiber pull.

IV.Thermoforms

- Unit dose blisters of most kinds proved difficult to defeat.

- Unit dose blistrs with push or punch through foil backings performed much better than peel offs.

- Unit dose blisters with thin foil backings were difficult to remove in one piece.

- Embossed unit dose blisters made entry to the package without damage hard to accomplish.

V.Closures

- Metal break away ring caps performed much better with horizontal scores only. Vertical scores allowed the ring to come off the bottle in virtually one piece.

- Membrane seals of thin foil sealed by induction proved to be difficult to tamper with without visible damage.

- Thin membrane seals that matched the diameter of the bottle mouth without any over hang were difficult to remove without at least some initial

damage. Membrane seals with overhang allowed for some hiding of repairs to tampered packages.

- Membrane seals with distinctive logos sometimes hid the damage or tampering that took place. A single or double print logo in the center of the seal would allow the consumer to look at the edges without any added interference.

- Glued or sealed end cartons were harder to defeat when the adhesive was spread over a large surface area. The author, however, does not believe that this type of packaging should be considered tamper-resistant by defintion.

These are observations that were noted during the course of the testing study. Some tamper-resistant types of packaging are not discussed because they usually are not used in the OTC drug industry or because samples in those categories were not reviewed and tested.

ATTITUDE SURVEY: TAMPER-RESISTANT PACKAGING

During the initial stages of this thesis, we began to focus on consumer awareness and attitudes. Since September 30, 1982, consumers have been forced into an awareness of tamper-resistant packaging because the Tylenol and "copy-cat" incidents were thrust upon them through national news, headline stories, magazine articles, and advertisements. With the introduction of a relatively new packaging concept to most consumers, many marketing and research people developed attitude surveys to gain data and information on how the consumer was feeling towards tampering, product safety and security, and future purchasing habits.

Our survey focused on how consumers feel about the new regulation and whether or not it will protect them. We build upon each question asked by leading the consumer through the survey in an orderly manner. Many of the questions use a scale for answers, thereby, allowing greater latitude in responding to the question. The survey also addresses specific subjects pertaining to tamper-resistant packaging of cosmetics, hygiene products, and food products as well as OTC drugs and medicines.

Population data, survey forms and questions, as well as results can be found on the following pages. Raw data can be found in Appendix G.

NUMBER_____

Tamper-Resistant Packaging Survey

School of Packaging
Michigan State University

The purpose of this survey is to obtain an overall view of the consumer's attitude toward tamper-resistant packaging. Please read each question carefully and answer it by circling or marking the response that best describes your personal thoughts or actions. Please complete this survey without any outside assistance or further information than presented here.

For the purpose of this study the words tamper-evident and tamper-resistant mean the samething. Both words may be used interchangeably.

THANK YOU FOR YOUR ANSWERS AND PARTICIPATION.

PLEASE READ CAREFULLY AND MARK YOUR ANSWERS CLEARLY

1. Do you buy over-the counter drug products such as aspirin, cough syrup, eye drops, etc.? PLEASE CHECK ONE.

☐ NEVER ☐ ONCE EVERY SIX MONTHS ☐ ONCE EVERY TWO WEEKS
☐ ONCE A YEAR ☐ ONCE A MONTH ☐ AT LEAST ONCE A WEEK

2. How often do you buy food products? PLEASE CHECK ONE.

☐ NEVER ☐ ONCE EVERY SIX MONTHS ☐ ONCE EVERY TWO WEEKS
☐ ONCE A YEAR ☐ ONCE A MONTH ☐ AT LEAST ONCE A WEEK

3. Think about how you select and buy a food product from the store. Do you look at the condition of the package? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
VERY SELDOM ALWAYS

4. Think about how you select and buy an over-the-counter drug product. Do you look at the condition of the package? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
VERY SELDOM ALWAYS

5. Do you know what tamper-resistant packaging is? CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
NOT AT ALL DEFINITELY

6. Are you aware of the product/package tamperings involving Extra-Strength Tylenol? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
NOT AT ALL DEFINITELY

7. Did you know that similar incidents termed "copy-cat" tamperings also occurred? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
NOT AT ALL DEFINITELY

8. Do you believe that what happened with Tylenol could also happen to food products? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
NOT AT ALL DEFINITELY

9. Do you believe that what happened with Extra-Strength Tylenol could also happen with cosmetics such as makeup, perfume, colonge, etc.? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
NOT AT ALL DEFINITELY

10. Do you believe that what happened with Extra-Strength Tylenol could also happen with hygiene products such as toothpaste and mouthwash? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 2 3 4 5 6 7
NOT AT ALL DEFINITELY

PLEASE READ CAREFULLY AND MARK YOUR ANSWERS CLEAR

11. Did you become more cautious in buying over-the-counter drug products after the Tylenol incident? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

12. Did the Tylenol and "copy-cat" tamperings stop you from buying over-the-counter drug products such as aspirin, cough syrup, etc.? PLEASE CHECK ONE.

☐ YES ☐ NO

12a If yes, have you or will you go back to buying over-the-counter drug products in the future? PLEASE CHECK ONE.

☐ YES ☐ NO

13. Did you think it was necessary to become more cautious in buying food and beverage products? CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

14. Did you know that a new U.S. Food and Drug regulation requiring tamper-resistant packaging on all over-the-counter drugs has been established? PLEASE CHECK ONE.

☐ NO ☐ HEARD SOMETHING ☐ HAVE READ ABOUT ☐ KNOW REQUIREMENTS

15. If all over-the-counter drug products were in tamper-resistant packages, would people have to look closely at each package to see tampering? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

16. Do you believe that the new tamper-resistant packaging regulations will prevent future deaths from tampering? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

17. Do you believe that the new tamper-resistant packaging regulations will prevent future "copy-cat" tamperings? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

18. The new tamper-resistant packaging regulation only applies to over-the-counter drug products and oral cosmetics such as mouthwash. Do you believe it should also apply to food and beverage products? PLEASE CHECK ONE. YES NO

19. If a package (product) had been tampered with, do you believe that you could detect the tampering upon looking at the package closely? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

PLEASE TURN THE PAGE.

PLEASE READ CAREFULLY AND MARK YOUR ANSWERS CLEARLY

20. Would you be willing to pay extra for tamper-resistant packages? PLEASE CHECK ONE.

☐ YES ☐ NO

IF YES, then how much extra would you pay? PLEASE CHECK ONE.

☐ 1-5 cents ☐ 6-10 cents ☐ 11-15 cents ☐ 16-20 cents ☐ 21-25 cents ☐ over 25 cents

A FEW QUESTIONS ABOUT YOURSELF.

Sex - Please circle one. Male Female

Age - Please check one.

☐ UNDER 25 YEARS ☐ 25-34 YEARS ☐ 35-44 YEARS ☐ 45-54 YEARS ☐ 55-65 YEARS ☐ 66-OVER

Education - (Last Year Attended) Please Check One.

☐ SOME HIGH SCHOOL ☐ COMPLETED HIGH SCHOOL ☐ SOME COLLEGE OR TECHNICAL SCHOOL ☐ COMPLETED COLLEGE OR MORE

City and State in which you live_____

COMMENTS:_____

_____

_____

_____

_____

_____

THANK YOU VERY MUCH FOR YOUR PARTICIPATION!

ATTITUDE SURVEY RESULTS

The following results are reported by averages for each question. Population results are as follows:

POPULATION

SEX:	130	MALES
	135	FEMALES
	5	NO RESPONSE
	270	TOTAL RESPONDENTS

AGE RANGE MOST FREQUENTLY CHECKED: 25 - 34 years

EDUCATIONAL LEVEL MOST FREQUENTLY CHECKED: Some College

QUESTIONS

1. Do you buy over-the counter drug products such as aspirin, cough syrup, eye drops, etc.? PLEASE CHECK ONE.

☐ NEVER ☐ ONCE EVERY SIX MONTHS ☐ ONCE EVERY TWO WEEKS
☐ ONCE A YEAR ☐ ONCE A MONTH ☐ AT LEAST ONCE A WEEK

Average Response: Once every six months

2. How often do you buy food products? PLEASE CHECK ONE.

☐ NEVER ☐ ONCE EVERY SIX MONTHS ☐ ONCE EVERY TWO WEEKS
☐ ONCE A YEAR ☐ ONCE A MONTH ☐ AT LEAST ONCE A WEEK

Average Response: Once every two weeks

3. Think about how you select and buy a food product from the store. Do you look at the condition of the package? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
VERY SELDOM						ALWAYS

Average Response for Question 3: 6.095

4. Think about how you select and buy an over-the-counter drug product. Do you look at the condition of the package? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
VERY SELDOM						ALWAYS

Average Response for Question 4: 5.67

5. Do you know what tamper-resistant packaging is? CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

Average Response for Question 5: 6.34

6. Are you aware of the product/package tamperings involving Extra-Strength Tylenol? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

Average Response for Question 6: 6.6

7. Did you know that similar incidents termed "copy-cat" tamperings also occurred? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

Average Response for Question 7: 6.21

8. Do you believe that what happened with Tylenol could also happen to food products? PLEASE CIRCLE A NUMBER ON THE SCALE.

1	2	3	4	5	6	7
NOT AT ALL						DEFINITELY

Average Response for Question 8: 6.7

9. Do you believe that what happened with Extra-Strength Tylenol could also happen with cosmetics such as makeup, perfume, colonge, etc.? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 9: 6.04

10. Do you believe that what happened with Extra-Strength Tylenol could also happen with hygiene products such as toothpaste and mouthwash? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 10: 6.44

11. Did you become more cautious in buying over-the-counter drug products after the Tylenol incident? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 11: 5.33

12. Did the Tylenol and "copy-cat" tamperings stop you from buying over-the-counter drug products such as aspirin, cough syrup, etc.? PLEASE CHECK ONE.

☐ YES ☐ NO

Average Response for Question 12: NO

12a If yes, have you or will you go back to buying over-the-counter drug products in the future? PLEASE CHECK ONE.

☐ YES ☐ NO

Average Response for Question 12A: YES

13. Did you think it was necessary to become more cautious in buying food and beverage products? CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 13: 5.33

14. Did you know that a new U.S. Food and Drug regulation requiring tamper-resistant packaging on all over-the-counter drugs has been established? PLEASE CHECK ONE.

☐ NO ☐ HEARD SOMETHING ☐ HAVE READ ABOUT ☐ KNOW REQUIREMENTS

Average Response for Question 14: Heard Something

15. If all over-the-counter drug products were in tamper-resistant packages, would people have to look closely at each package to see tampering? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 15: 4.81

16. Do you believe that the new tamper-resistant packaging regulations will prevent future deaths from tampering? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 16: 4.79

17. Do you believe that the new tamper-resistant packaging regulations will prevent future "copy-cat" tamperings? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 17: 4.65

18. The new tamper-resistant packaging regulation only applies to over-the-counter drug products and oral cosmetics such as mouthwash. Do you believe it should also apply to food and beverage products? PLEASE CHECK ONE. YES NO

Average Response for Question 18: YES

19. If a package (product) had been tampered with, do you believe that you could detect the tampering upon looking at the package closely? PLEASE CIRCLE A NUMBER ON THE SCALE.

1 NOT AT ALL 2 3 4 5 6 7 DEFINITELY

Average Response for Question 19: 4.45

20. Would you be willing to pay extra for tamper-resistant packages? PLEASE CHECK ONE.

☐ YES ☐ NO

IF YES, then how much extra would you pay? PLEASE CHECK ONE.

☐ 1-5 cents ☐ 6-10 cents ☐ 11-15 cents ☐ 16-20 cents ☐ 21-25 cents ☐ over 25 cents

Average Response for Question 20, part 1: YES
Average Response for Question 20, part 2: 6-10 cents

ATTTITUDE SURVEY CONCLUSIONS

While reviewing the results of the attitude survey, certain observations become obvious. Consumers appear to be very aware of both the Tylenol and "copy-cat" incidents. They also believe that they know what tamper-resistant packaging is.

Some less obvious relationships also appear. Consumers feel strongly that what has happened to OTC drugs can also happen to food, cosmetic and hygiene products. They even feel that foods should be required to have tamper-resistant packages. They state that they usually look at the condition of the package before making a purchase and that they became relatively more cautious in their purchasing habits after the Tylenol incident. With all this stated cautiousness and belief that tamper-resistant packages should be used for foods and a willingness to pay extra for it, consumers still do not demonstrate much confidence in their ability to detect tampering. They are not really sure that the new regulations will prevent future tampering problems but from the average mean values one can conclude that the consumer probably places the Tylenol deaths in the same category as "copy-cat" poisonings.

Another observation comes from the question on how closely and cautious a person looks at a packaged product before purchasing. Consumers say they look closely at packages but also show a reduction in cautiousness with the new regulation. They are not sure if they will have to look closely at packages with new tamper-resistant features in order to detect tampering. However, their indecision about any ability to detect tampering may continue to lead the consumer to closely inspect packaged products.

This survey mainly reflects the attitudes and awarenesses of consumers living in the state of Michigan. It may also reflect a higher sensitivity to the

SUMMARY

On September 30, 1982, three people died from ingesting a product that was maliciously tampered with. What followed in terms of four more deaths and numerous "copy-cat" tamperings, sent the American public into a scare and rocked the very principles upon which the OTC drug companies had built their industry. We observed a number of political reactions through proposed regulations at the state and local levels with all of them different and all requiring tamper-resistant packaging. The OTC companies saw their cutomers very lives threatened by malicious individuals that they could not control and agreed with state and local governments that regulations were necessary. However, with different regulations calling for different packaging, they saw a threat to their economies of scale, loss of profitability, and product distribution nightmares. They, therefore, asked for and received a federal tamper-resistant packaging regulation established by the FDA; a regulation which only requires that a package meet a definition that has no standard by which to measure compliance. This regulation and the function which tamper-resistant packaging is being asked to provide has been the main subject of this thesis.

Historically, we have seen the development of tamper-resistant packaging for the deterence of normal in-store package opening by consumers who sample or test products. This type of deterence has better secured the product's shelf-life from inadvertent environmental deterioration. Some other regulations requiring tamper-resistant packaging also exist for various reasons. No evidence in researching these established regulations shows a need or desire to deter malicious and intentional tamperings. The new tamper-resistant packaging regulation for some OTC drugs and liquid oral cosmetics specifically pertains to deterence of malicious tampering and package/product adulteration. It even

states one of the reasons for the regulation is to restore consumer confidence in the products they buy and use.

In order to better understand the total impact of the tampering incidents, we identified the characteristics of malicious tamperers and developed tests and attitude surveys to determine how the consumer will react to new tamper-resistant packaging. We found that the "Tylenol Killer" is quite different from the "copy-cat" tamperer because he is characterized as being quite determined, cunning, and uncaring for human life. The "copy-cat", on the other hand, may not want to injure or harm someone because they can gain power and recognition without it.

Test developments and surveys show that consumers are aware of product/package tamperings, overall, but demonstrate an inability to detect a tampered package. Their perceptions and attitudes reflect a concern for requiring tamper-resistant on many products including food, yet they show indecisiveness in its ability to protect them and other consumers. Our tests have reinforced what most people have been saying, that no package is tamperproof.

As this subject becomes more important and research is completed, then certain conclusions and concepts will come to be better understood. The manufacturers today are working and performing in this area to the best of their abilities. They have put forth a conscientious effort to protect their customers and themselves. However, the packaging we have in our society, today, whether it be tamper-resistant or not, will probably not afford the necessary protection needed to stop a malicious individual. The type of packaging that is defined in the new regulation was not developed to stop this malicious tamperer but rather to deter normal in-store opening by average consumers. The present regulation is open-ended and needs to be developed further if it is expected to be totally effective. Ironically, the tampering

incidents took place during an election month and many policitians jumped on the bandwagon all across this country. They over-reacted to the situation by immediately looking toward legislative actions and a simple solution in a product's packaging. This over-reaction forced the OTC drug industry and FDA to enact regulatory requirements in the best possible manner. Evidence of possible over-reaction is reflected by other free capitalistic countries. Our closest neighbor, Canada, has not enacted or proposed any such legislation to date, but they have drawn it to manufacturer's attention.

RECOMMENDATIONS

Based upon the research and studies completed for this thesis, I have some recommendations for those concerned. First of all, a re-evaluation of the message being conveyed to consumers needs to be examined. The FDA, in its regulation, and many others are stating that tamper-resistant packaging will re-establish consumer confidence in the product's integrity and that the tamperings should not deter the public from safely using OTC drugs and other products. These statements may be erroneous and misleading to the consumer, who feels a false sense of security by believing that tamper-resistant packaging will deter a malicious individual and identify to them whether or not a package has been tampered with. We need to insure that the consumer has an understanding of who might be doing the tamperings and that the characteristic profiles of "Tylenol Killers" and "copy-cat" tamperers are quite different.

• If we are to expect tamper-resistant packaging to perform its new functions and duties, we must first establish an identification level at which the consumer is capable of detecting a tampered package. The regulation should reflect this

detection level by establishing a test standard that will enable the packager to adequately perform his duties.

Most tamper-resistant packages on the market today, which meet the general FDA regulation definition present very little deterence to malicious individuals. As long as our society continues to be terrorized by intentionally malicious people the problems experienced by OTC drug manufacturers and other product companies will continue to be prevalent.

APPENDIX A:

SEQUENCE OF EVENTS

SEQUENCE OF EVENTS LEADING UP TO TAMPER-RESISTANT REGULATIONS BY THE FDA ON OTC DRUGS AND MEDICINES

September 30, 1982

An early morning report of three deaths due to cyanide laced Extra-Strength Tylenol in capsules was received by McNeil Consumer Products, Division of Johnson and Johnson. The report came from the Cook County, Illinois, Coroner's Office Chief Toxicologist, Michael Schafer.

McNeil Consumer Products immediately issued a recall of the lot number involved -- some 93,000 bottles of Extra-Strength Tylenol in capsules.

October 1, 1982

A fourth person who had been in serious condition since having been poisoned September 30, 1982, also dies from cyanide laced Tylenol. Two additional deaths from cyanide laced Tylenol (Extra-Strength capsules) are also reported in the Chicago area. Two additional bottles of Extra-Strength Tylenol capsules are found on the shelves containing cyanide laced capsules. A second lot number is identified as being involved and a second recall is issued -- some 171,000 bottles. A precautionary withdrawal is ordered of all Extra-Strength Tylenol capsule bottles in an eight county Chicago area. McNeil Consumer Products, in cooperation with the Illinois State Attorney General's Office, issues a 100,000 dollar reward for information leading to the arrest and conviction of any person or persons responsible for the deaths.

Production of all Regular and Extra-Strength Tylenol capsules is halted by McNeil Consumer Products until further notice.

October 2, 1982

A seventh death is reported in the Chicago area as a result of cyanide laced Extra-Strength Tylenol capsules. McNeil Consumer Products issues a withdrawal of all Regular-Strength Tylenol capsules. Chicago authorities issue an order for suspension of sales of all Tylenol products.

October 3, 1982

The OTC Proprietary Association establishes a committee to seek ways of dealing with malicious tampering and adultering of OTC drug and medicine products. The committee will deal with product security.

October 4, 1982

United States Department of Health and Human Services Secretary, Richard Schweiker, directs the FDA to draft a national regulation for tamper-resistant packaging.

Cook County, Illinois, passes an ordinance without public hearings making it unlawful to sell OTC medicines that are ingested, inhaled, or inserted into the human body in containers that do not possess a separate seal which secures the lid or cap to the container. The ordinance takes effect January 2, 1983, ninety days after passing.

October 5, 1982

Reports from California are confirmed that strichnine has been found in three bottles of Extra-Strength Tylenol capsules. One person becomes ill but not seriously. McNeil Consumer Products issues a nationwide recall of all Extra-Strength and Regular-Strength Tylenol capsules.

The Proprietary Association's committee meets with top leaders of OTC drug and medicine companies, pharmacy experts, and the FDA to explore ways of reducing the risk of future problems due to malicious adulteration of OTC medicines.

FDA Commissioner, Dr. Arthur Hayes, announces that the FDA is working on regulations for tamper-resistant packaging as well as identifying additional tamper-resistant packaging that may not have been thought of in regards to the Tylenol problem.

Joint Committee for Product Security is established to develop and recommend a workable framework for a national regulation on tamper-resistant packaging and to identify various kinds of packaging that are tamper-resistant.

October 7, 1982

McNeil Consumer Products recalls all Tylenol and CoTylenol products in capsules and not in individual blister packs. This was done so the Tylenol name would not become an abused target for tampering. All recalls totalled an estimated 31,000,000 bottles of product removed from the consumer shelves by McNeil Consumer Products.

Between October 4 and October 15, 1982

Bills calling for regulations on tamper-resistant packaging have been introduced in the city of Chicago, the state of Massachusetts, the state of Ohio, Cook County, Illinois, and Los Angeles County, California. Hearings for possible action have been scheduled in the states of California, Connecticut, Pennsylvania, Maryland, and New Jersey. The Pennsylvania Department of Health and the New York City Health Department are considering issuing regulations on tamper-resistant packaging.

October 12, 1982

A man in Grand Junction, Colorado, is reported in good condition after his eye was burned by hydrochloric acid in a Visine A.C. eye drop bottle. Authorities found several bottles of the Visine A.C. on the store shelf with the acid inside the bottles. It is believed a "copy-cat" individual tampered with the product. Visine A.C. is packaged with a shrink band around its closure. All tampered with bottles had the bands removed.

October 15, 1982

A series of Health and Environment Senate Subcommittee hearings are held on tamper-resistant packaging. Present at the meeting are Dr. Hayes and other representatives from the FDA, representatives from the Proprietary Association, and representatives from McNeil Consumer Products and its parent company, Johnson and Johnson, Inc.

October 17, 1982

Authorities in Florida report that four bottles of Lavoris mouthwash were found on a store shelf to contain acid laced product. A man received minor burns from using the product, found to be laced with muriatic acid.

A teenager is arrested in Kentucky after reportedly trying to extort money from a grocery store. He allegedly wrote a letter stating that some food products in the store had been tainted with neurotoxic poison and demanded 5,000 dollars in return for identifying the contaminated foods.

A rural couple in Cedar Rapids, Iowa, were arrested for allegedly threatening to inject insecticide into grocery items.

October 24, 1982

A tranquilizer pill is found in a frozen pie in Grand Junction, Colorado.

October 25 to 27, 1982

Anacin capsules are found to be tainted with rat poison in Grand Junction, Colorado. A man becomes poisoned with mercuric chloride after consuming Extra-Strength Anacin capsules.

As many as sixty containers of laxative are found to be tampered with on Florida's west coast.

A woman suffers minor mouth burns from drinking an acetone laced Tropicana fruit punch.

October 29 to 31, 1982

Pins, nails, razorblades, and poisons are reported found in Halloween candies across the nation. Only minor injuries are reported.

A petroleum compound was found to have been injected into a carton of Tropicana Orange juice consumed by a Florida police officer. Minor stomach and throat burns are reported.

Nails and razorblades are reported found in Hygrade Ball Park hot dogs. Five separate reports are made resulting in a Michigan, Ohio, and Indiana recall of the frankfurters from the store shelves. All five incidents are later found to be hoaxes.

November 5, 1982

The FDA anounces new tamper-resistant regulations for OTC drugs and medicines. Some oral cosmetics, such as mouthwash, are also regulated. The regulation requires all high risk items such as capsules and liquids to be contained in tamper-resistant packages within ninety days. All other products are given a six to fifteen month effective date. The regulation also imposes new labelling requirements informing the consumer of the tamper-resistant features of the package.

*Numerous other accounts of tamperings and poisonings are reported in the following months. Some of the incidents resulted in minor injuries to the consumers involved. Within this time span, authorities have checked out some 270 reported cases of possible product contaminations and an estimated 8,000 phone calls were answered from individuals that thought they had ingested or taken a tampered medicine.

APPENDIX B:

SENATE SUBCOMMITTEE HEARING

COMMENTS AND RECOMMENDATIONS FROM THE OTC PROPRIETARY ASSOCIATION TO A HEALTH AND ENVIRONMENT SENATE SUBCOMMITTEE HEARING ON TAMPER-RESISTANT CLOSURES: OCTOBER 15, 1982

Definition of tamper-resistant packaging according to the Proprietary Association as stated in a Health and Environment Senate Subcommittee hearing on tamper-resistant closures -- October 15, 1982.

> "A tamper-resistant package is one having an indicator or barrier to entry which if breached or missing can reasonably be expected to provide visible evidence to consumers that the package has been tampered with or opened."

An explanation followed with this definition:

> "Tamper-resistant packaging involves the immediate container or closure systems or secondary container carton systems or any combination thereof intended to provide a visual indication of package integrity when handled in a reasonable manner during manufacture, distribution, or retail display. The visual indication will be enhanced by appropriate illustrations or statements on the product calling to the buyer's attention the safeguarding mechanism. An illustrative list of tamper-resistant packaging which we believe meets the definition should be attached to this statement."

Further recommendations by the Proprietary Association:

> Products to be covered should be all OTC drugs for human use including the following:
>
> 1. All drugs that are ingested such as capsules, tablets, liquids and others inclusive.
>
> 2. All products (OTC) that are inhaled such as throat and nasal sprays, nose drops, and inhalants.
>
> 3. OTC drugs intended for insertion into the human body including suppositories, vaginal foams, creams, and gels, douches, and ear drops.
>
> 4. Interocular products such as and including eye drops, eye washes, and contact lens solutions.

The Association suggested the following list of allowable tamper-resistant packaging:

1. Film wrappers which cover or wrap completely around the entire product or secondary/primary package.
2. Blister or strip packs - unit doses in punch through or peel backings.
3. Bubble packs - blister trays permanently or securely affixed to a display card.
4. Shrink seals or shrink bands around closure and bottle.
5. Foil, paper, plastic pouches - more unit doses.
6. Bottle seals - induction seals and others under the closure over the mouth of the container.
7. Tape seals - including tax stamps, tapes over or around closure and container, flaps taped on shelf-carton.
8. Sealed tubes - such as blow molded contact wetting solution bottle. Container and closure are one, the closure must be snapped off, single usage containers.
9. Sealed cartons - glue ends or taped.
10. Aerosol containers
11. Breakable caps - plastic and metal; roll ons and strip caps (milk bottles, etc.).

These were the eleven categories with only a few examples from each for explanation.

The Association stressed to the subcommittee and to the FDA that pre-emptive federal government regulation is essential in order to achieve regulatory uniformity throughout this nation.

The Association also emphasized "that tamperproof packaging is impossible to achieve, hence the term tamper-resistant." They went further to say that this case was "probably one of criminal tampering" and that it is "impossible to completely protect society from malicious criminal acts."

In the Senate Subcommittee meeting the Chairman of the meeting, Mr. Henry Waxman, Senator from California, stated that "tamper-resistance will give the public the assurance that the product has, as best they can tell, not been tampered with and they should feel comfortable to purchase the product again. That's clearly what we must now do to re-establish the confidence that we've had in the past. It's a goal I think all of us should be working toward."

This statement was somewhat of an echoing of the two important points Dr. Arthur Hayes, FDA Commissioner, made in his statements:

1. We must now do something to prevent or deter willfull tampering and at the same time make this tampering evident to the consumer.

2. Our goal is to reassure the consumer of the protection so that they can once again trust the product.

APPENDIX C:

RAW DATA - TAMPER IDENTIFICATION TEST AND CONSUMER PERCEPTION SURVEY

RAW DATA: TAMPER-RESISTANT PACKAGING PILOT TEST

I.D.NO.	GK	GV	GI	GN	GR	GP	GT	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	SEX	AGE	C
1000	5	5	4	4	5	1	5	1	1	1	2	2	2	1	5	1	4	1	1	3	3
1001	2	3	1	2	2	3	1	1	1	3	2	2	2	2	2	2	2	2	2	2	4
1002	5	5	1	3	1	5	3	1	1	2	4	1	1	1	5	1	1	1	2	3	5
1003	5	5	1	3	5	1	1	1	1	3	1	1	1	1	5	1	5	1	2	4	4
1004	5	4	2	2	3	5	2	4	4	2	2	2	2	2	2	1	2	1	1	3	5
1005	4	5	3	2	5	1	5	3	2	2	4	3	1	1	3	1	4	2	0	5	4
1006	5	5	4	4	4	3	3	1	1	1	2	2	1	1	1	1	1	1	1	3	3
1007	1	5	4	1	3	2	4	2	4	4	2	3	2	2	5	4	5	4	2	3	4
1008	2	4	4	3	4	4	4	2	2	2	3	1	1	2	2	1	2	1	1	2	3
1009	3	3	2	4	3	4	4	2	1	2	2	3	1	0	1	1	1	3	2	2	3
1010	4	3	2	3	3	5	5	3	2	3	3	2	2	2	3	1	3	1	1	2	4
1011	4	3	4	3	3	3	4	2	2	3	2	2	2	2	3	2	1	2	2	1	5
1012	4	4	2	2	2	4	3	4	1	2	1	1	1	1	4	1	1	1	1	1	3
1013	5	2	1	5	4	5	5	5	1	2	4	3	2	1	2	1	2	2	1	1	2
1014	4	4	3	3	2	5	3	2	2	4	2	3	2	2	4	2	4	2	1	2	4
1015	3	3	1	2	2	3	1	4	2	5	4	3	1	1	5	1	1	2	1	2	2
1016	3	2	1	3	2	3	4	3	2	4	4	3	3	2	5	3	2	3	2	1	3
1017	4	3	1	3	1	4	2	1	1	3	3	3	2	1	4	3	2	3	2	3	4
1018	4	4	3	3	5	5	4	2	1	1	2	2	1	1	3	4	2	2	2	2	3
1019	2	3	2	4	4	4	3	2	1	2	3	4	2	2	2	4	1	2	1	2	3
1020	4	3	1	3	3	5	5	2	1	3	3	2	1	1	5	1	1	2	2	2	3
1021	5	5	1	5	1	5	1	1	5	2	4	5	1	3	5	5	4	3	2	2	2
1022	1	1	1	3	1	1	1	3	3	3	3	3	3	3	4	2	3	3	2	3	2
1023	4	3	2	4	3	5	3	2	1	3	4	3	1	2	5	4	5	2	2	3	3
1024	4	1	1	3	1	2	1	4	4	4	4	4	2	5	1	4	4	4	1	5	4
1025	3	5	2	5	3	5	2	4	3	4	4	4	1	1	5	1	1	3	0	0	4
1026	5	4	2	3	2	3	3	1	1	1	1	1	1	3	1	1	3	1	2	2	3
1027	5	5	3	3	3	5	5	4	1	2	2	2	2	1	5	1	2	2	2	2	2
1028	5	5	5	4	2	5	5	2	4	2	2	2	2	2	4	2	3	2	1	2	2
1029	4	4	1	2	5	4	1	4	1	2	3	3	2	3	5	1	4	3	2	3	3
1030	3	4	1	2	3	5	3	1	1	1	1	1	1	1	2	0	4	1	1	3	2
1031	5	4	3	5	2	4	3	2	1	3	3	3	2	0	2	2	2	3	1	6	4
1032	3	3	1	3	4	4	4	5	1	1	1	1	1	1	5	1	3	1	2	4	3
1033	4	1	2	4	3	5	5	2	1	1	2	1	1	1	3	2	2	1	1	2	6
1034	5	3	2	4	3	4	2	1	1	1	2	3	1	1	4	1	2	2	0	3	4
1035	4	4	2	4	1	4	4	5	1	2	4	1	1	2	4	1	2	2	2	3	3
1036	5	4	4	5	3	5	3	4	2	4	4	5	1	1	5	2	1	4	2	5	4
1037	5	4	1	2	3	5	4	3	4	2	3	2	1	1	2	2	3	3	2	3	2
1038	5	4	4	5	3	5	4	1	3	3	3	3	3	5	5	4	3	3	1	3	2
1039	5	5	3	5	3	5	3	2	2	3	4	2	1	4	5	3	2	4	2	3	3
1040	5	4	3	4	4	4	3	1	4	4	4	4	3	1	5	1	2	4	2	3	3
1041	3	4	2	4	2	4	3	4	1	4	4	4	2	5	5	2	1	2	1	3	3
1042	4	4	5	4	5	4	5	1	1	1	3	4	1	1	5	1	5	2	2	2	2
1043	1	5	3	2	5	5	5	1	1	1	4	3	2	1	5	1	3	1	2	2	3
1044	4	4	2	5	3	5	5	4	4	4	1	2	4	1	3	3	4	2	0	0	0
1045	4	5	3	1	3	4	5	3	2	2	4	1	2	1	2	1	3	3	1	3	4
1046	4	2	2	5	4	5	2	2	5	2	3	3	1	1	1	2	1	3	1	3	2
1047	3	1	3	1	5	1	1	1	1	1	3	3	1	1	3	1	1	3	2	3	2
1048	3	4	4	4	4	5	5	2	5	4	2	1	2	1	4	2	1	2	2	3	4

RAW DATA: TAMPER-RESISTANT PACKAGING PILOT TEST

I.D.NO.	GK	GV	GI	GN	GR	GF	GT	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	SEX	AGE	C
1049	3	5	5	1	1	5	5	2	5	4	5	2	5	1	4	1	4	4	2	5	3
1050	4	2	2	2	2	2	2	2	2	2	3	3	2	3	4	2	2	3	2	4	2
1051	2	4	1	3	2	1	1	2	2	3	4	5	2	2	5	3	4	5	2	1	2
1052	3	1	3	2	3	5	4	2	4	3	3	4	1	2	2	2	2	0	2	1	3
1053	3	2	4	4	4	3	3	2	1	2	2	1	2	3	1	3	4	2	2	1	5
1054	2	4	2	4	2	1	1	1	2	2	4	1	5	1	5	1	2	1	2	1	2
1055	5	3	2	1	3	5	3	5	1	3	4	4	2	1	5	2	3	2	2	4	3
1056	5	5	4	4	5	5	5	5	1	1	1	1	1	1	5	1	1	1	1	4	4
1057	4	4	2	4	2	4	3	3	2	4	4	4	2	1	5	4	2	2	2	1	3
1058	4	3	4	4	1	3	4	1	1	2	2	3	1	1	3	1	2	2	1	2	2
1059	5	4	1	1	2	3	3	1	3	1	3	2	2	1	5	2	2	2	1	4	3
1060	5	3	1	2	3	5	3	1	1	1	4	2	1	1	5	3	2	2	2	4	5
1061	5	2	2	5	4	5	5	1	1	1	5	1	1	1	5	1	1	1	1	3	4
1062	5	4	1	5	3	4	2	3	1	2	5	2	2	1	5	1	5	1	2	3	3
1063	1	1	1	2	2	3	1	4	1	4	5	5	1	1	5	1	5	5	2	3	3
1064	5	4	3	5	3	5	3	2	2	3	3	3	2	1	5	2	2	3	2	3	3
1065	3	3	3	3	2	2	4	4	1	1	2	2	1	1	0	4	1	1	1	3	3
1066	3	5	5	5	5	5	3	1	1	1	4	4	2	1	5	1	4	4	2	3	3
1067	5	5	2	2	1	2	1	2	1	3	3	3	1	1	3	1	1	3	2	3	3
1068	5	5	2	1	1	5	1	4	1	2	5	2	1	1	4	0	1	1	2	3	2
1069	4	3	2	4	4	5	5	2	3	2	3	2	4	2	1	3	3	3	1	4	3
1070	4	5	2	4	4	4	4	1	3	1	5	4	1	2	2	4	1	1	1	5	4
1071	5	5	1	5	2	5	1	1	1	3	4	4	1	2	1	2	3	4	2	5	4
1072	5	5	1	2	1	5	3	3	2	2	3	3	2	1	2	4	1	2	1	6	4
1073	1	3	3	2	3	1	1	6	3	3	3	3	2	3	3	3	2	3	2	5	3
1074	5	5	1	4	3	5	3	3	3	4	2	3	3	2	1	3	3	3	2	5	3
1075	2	1	2	5	4	5	1	2	2	2	2	3	2	2	3	2	4	4	0	6	3
1076	4	4	3	4	4	3	3	2	3	3	4	3	2	2	1	1	3	4	1	4	4
1077	1	2	4	1	5	5	4	1	1	1	1	3	2	1	5	1	1	2	2	3	3
1078	3	5	3	5	4	5	1	1	1	2	5	4	1	1	1	1	1	4	1	6	4
1079	3	5	4	5	4	5	1	1	1	1	4	1	1	1	5	4	5	1	2	5	4
1080	5	3	2	3	2	4	2	3	3	3	3	3	3	3	3	2	3	3	1	5	2
1081	5	5	4	3	1	2	1	5	1	5	5	1	1	1	5	1	5	5	1	4	3
1082	4	3	2	4	4	5	2	4	1	3	4	4	3	1	2	4	4	4	2	5	3
1083	1	3	1	2	4	4	1	1	2	2	2	2	3	1	1	2	5	3	2	3	3
1084	5	5	5	5	5	5	5	2	1	1	2	2	1	1	5	1	1	1	2	5	3
1085	5	5	5	5	4	5	3	1	1	1	4	3	1	3	5	5	4	5	2	5	5
1086	5	4	3	2	3	4	1	1	1	4	4	1	1	1	4	5	1	1	2	5	3
1087	5	4	1	2	4	5	1	4	2	4	5	4	5	5	2	3	5	5	1	6	3
1088	5	5	1	4	4	5	3	2	2	3	3	3	3	2	2	3	3	3	2	5	4
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1090	4	4	2	3	3	5	3	2	1	1	4	4	1	1	1	3	3	2	1	4	5
1091	3	4	2	2	4	4	4	5	5	3	4	1	3	3	2	3	4	1	1	6	4
1092	4	4	3	5	5	5	1	1	1	1	5	1	5	1	5	1	1	1	1	6	3
1093	3	5	3	2	2	5	4	5	2	1	4	4	1	2	5	3	2	1	2	4	3
1095	3	4	2	5	4	4	2	2	2	2	3	2	1	2	2	3	2	3	2	5	2
1096	5	5	3	4	5	5	5	3	2	1	5	5	1	1	5	1	3	2	2	6	3
1097	5	5	2	4	1	4	1	1	2	4	5	5	2	2	5	3	4	5	2	6	3
1098	4	3	3	4	4	4	3	2	2	1	2	3	2	3	2	4	2	2	1	5	3
1100	3	3	2	4	2	3	3	2	2	3	1	1	1	1	3	4	4	3	1	5	2
1125	3	4	2	3	2	1	2	5	4	2	2	2	2	1	2	2	4	2	1	5	4

RAW DATA: TAMPER-RESISTANT PACKAGING PILOT TEST

I.D.NO.	GK	GV	GI	GN	GR	GP	GT	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	SEX	AGE	C
1127	2	4	4	5	3	2	3	1	5	2	3	2	1	1	4	2	2	1	1	3	4
1130	1	1	3	3	4	3	1	3	4	3	3	3	4	3	4	2	3	4	2	5	3
1131	4	5	3	2	3	4	1	1	1	1	1	1	1	1	1	1	5	1	0	6	4
1132	5	4	4	5	4	5	3	1	1	1	4	3	1	3	5	1	5	3	0	5	3
1133	5	4	4	5	4	4	3	1	1	1	4	2	2	2	5	1	3	2	1	5	4
1134	2	2	3	3	2	1	2	1	4	1	5	1	1	1	3	5	5	5	0	6	3
1135	3	2	3	4	2	4	2	1	3	2	4	4	2	2	5	2	4	3	2	6	2
1136	5	3	5	3	1	5	5	2	1	5	1	1	1	1	3	1	1	1	2	2	3
1137	5	4	3	5	4	4	4	1	2	1	1	1	1	1	4	1	1	1	1	6	2
1138	5	3	2	4	2	5	2	2	2	4	5	1	2	2	4	3	4	4	2	5	4

RAW DATA: TAMPER-RESISTANT PACKAGING PILOT TEST

I.D.NO.	GK	GV	GI	GN	GR	GP	GT	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	SEX	AGE	C
1200	5	1	1	2	4	4	5	2	1	4	1	1	1	1	2	2	1	2	2	2	3
1201	5	4	4	4	3	5	5	2	2	1	1	1	1	1	2	2	2	2	0	3	3
1202	5	5	1	3	3	5	5	5	1	1	1	1	3	1	1	1	1	0	0	0	0
1203	5	5	1	5	4	5	5	1	1	3	3	1	1	1	1	0	2	0	0	2	4
1204	3	4	4	5	4	5	2	4	2	3	3	3	2	2	2	2	2	3	0	0	0
1205	5	3	2	5	2	5	2	2	2	2	2	2	2	3	1	2	2	2	1	4	3
1206	4	5	3	3	5	5	5	4	1	3	3	3	1	2	1	1	4	3	2	4	2
1207	4	2	1	2	2	5	5	4	1	5	2	2	4	2	1	1	1	4	2	1	3
1209	5	4	1	5	3	5	3	1	1	2	3	3	2	1	1	1	1	3	2	2	4
1210	4	4	2	2	2	4	2	1	1	2	2	3	4	2	1	3	2	4	2	3	2
1211	3	2	3	2	3	4	1	1	1	1	4	4	2	1	2	1	1	4	2	3	3
1212	5	2	5	3	1	3	3	5	1	1	1	3	4	5	1	1	5	4	1	2	3
1213	4	4	5	3	3	4	3	1	1	1	1	1	1	1	1	1	1	1	1	3	4
1214	5	4	1	5	5	5	1	2	1	2	3	3	2	1	1	3	1	3	2	3	5
1215	4	2	3	3	3	5	5	2	1	4	2	1	2	1	2	2	4	2	2	3	5
1216	5	4	2	4	3	5	4	2	2	2	3	3	2	2	2	2	2	3	0	0	0
1217	4	5	4	4	3	5	2	5	1	1	1	4	5	2	2	2	4	5	2	2	4
1218	3	3	1	2	3	2	4	2	2	2	2	2	2	4	4	2	4	2	1	3	4
1219	5	3	4	2	3	1	1	1	1	3	2	4	5	1	5	1	4	5	2	2	3
1220	5	3	5	5	5	2	3	1	1	1	5	2	2	1	1	2	1	1	1	2	4
1221	4	2	2	5	3	5	4	2	1	2	2	2	2	1	1	2	2	5	1	3	2
1222	4	1	2	4	3	4	4	1	1	1	1	4	2	5	4	2	4	5	2	3	2
1223	4	5	1	3	4	4	3	1	2	2	3	3	4	3	1	2	4	3	1	3	5
1224	3	1	2	5	3	4	2	2	2	2	2	2	4	2	2	2	4	3	1	2	3
1225	5	2	1	5	3	1	1	4	1	1	4	2	4	4	1	2	3	2	1	5	3
1226	5	5	1	3	3	5	5	4	1	1	3	2	2	2	2	3	2	2	2	2	3
1227	5	3	1	5	4	5	3	2	1	2	3	2	2	2	2	2	2	3	1	2	3
1228	5	3	3	5	4	5	3	5	1	2	2	1	5	1	4	2	2	4	1	1	3
1229	3	5	3	5	0	3	1	4	3	4	4	4	3	2	3	2	3	4	2	2	2
1230	5	4	4	5	3	4	3	2	1	3	4	1	3	1	1	1	2	1	1	1	1
1231	4	2	2	1	5	5	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1232	5	3	2	2	2	5	3	1	1	1	2	3	4	4	1	2	4	4	1	2	2
1233	4	5	3	5	3	3	2	1	2	2	4	2	3	2	3	4	0	2	2	5	2
1234	1	2	3	4	3	4	4	4	2	4	3	3	4	1	5	1	2	2	1	5	4
1235	4	3	1	4	3	3	4	3	3	2	1	2	0	1	4	2	5	0	0	5	3
1236	3	3	2	4	2	5	4	1	1	0	5	2	1	1	2	0	2	2	0	3	4
1237	4	3	1	3	2	3	2	1	2	2	2	0	2	1	2	5	2	2	1	4	3
1238	3	4	3	0	0	4	2	1	1	1	1	3	2	2	3	2	3	3	0	0	0
1239	4	4	2	3	2	2	2	4	2	2	4	3	3	2	3	0	0	0	0	3	3
1240	4	3	2	3	1	1	4	2	2	4	2	2	4	4	2	2	2	4	2	2	4
1241	4	4	3	3	3	4	4	2	1	2	2	2	2	2	2	2	2	2	2	3	4
1243	5	4	1	2	4	5	3	1	1	2	1	2	1	1	2	3	1	5	2	1	4
1244	2	3	3	4	4	4	5	2	2	2	2	2	2	2	1	1	1	2	2	1	4
1245	5	4	4	3	5	5	4	1	1	1	1	1	2	1	2	1	1	1	1	4	4
1246	5	5	3	5	3	5	5	2	1	2	3	3	4	1	3	3	3	3	2	3	4
1247	4	2	2	1	4	4	2	1	1	1	1	1	1	1	5	1	3	3	2	3	3
1248	3	5	1	5	5	5	3	3	1	3	3	4	1	1	1	1	5	3	2	2	4
1249	2	1	3	5	2	1	1	4	1	4	1	4	1	2	4	1	5	5	1	1	3
1250	3	1	2	4	5	5	4	1	1	2	3	1	4	3	1	2	5	2	0	3	4

RAW DATA: TAMPER-RESISTANT PACKAGING PILOT TEST

I.D.NO.	GK	GV	GI	GN	GR	GP	GT	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	SEX	AGE	C
1251	5	3	5	5	2	4	4	4	1	3	1	1	1	1	1	1	1	1	2	2	3
1252	4	3	1	4	4	5	5	1	1	1	1	1	1	1	1	1	1	3	1	2	4
1253	3	3	2	4	3	4	3	2	1	1	1	1	4	2	2	1	1	4	2	1	3
1254	5	3	3	4	4	5	3	1	1	1	5	5	1	1	1	5	1	5	0	2	2
1255	2	3	4	4	5	4	1	1	1	1	4	3	5	1	1	2	1	3	2	4	2
1256	3	3	1	5	5	5	4	1	1	1	5	1	1	1	3	0	1	1	1	5	3
1257	4	3	5	4	3	4	3	3	2	3	1	3	3	2	3	1	3	3	2	5	2
1258	3	4	1	3	2	4	3	4	1	4	3	2	2	2	2	2	3	2	2	3	3
1259	4	2	1	5	1	3	3	4	3	3	3	2	1	1	1	3	3	5	2	3	5
1260	3	4	1	1	2	4	2	1	1	1	2	4	5	5	5	1	5	1	2	3	3
1261	5	3	1	3	4	2	1	1	3	1	2	1	4	4	5	4	4	4	1	5	4
1262	2	1	1	2	1	3	3	2	1	1	3	3	3	1	1	1	2	3	2	5	3
1263	5	4	2	4	5	5	4	1	2	1	2	1	2	1	1	2	1	2	2	1	2
1264	5	3	4	5	3	2	4	1	1	2	1	2	3	2	2	1	3	2	1	3	3
1265	3	5	2	2	3	5	2	4	2	4	3	3	2	2	4	1	4	4	2	2	3
1266	3	5	5	4	2	1	5	2	1	1	1	1	1	1	1	1	1	1	2	3	3
1267	4	4	3	3	3	4	3	1	1	1	2	1	1	3	1	1	4	1	2	2	3
1268	5	3	2	5	2	4	3	2	1	2	2	2	1	1	1	1	2	2	2	3	5
1269	3	3	2	4	4	4	4	2	2	2	2	2	1	2	2	2	3	3	1	2	3
1271	5	5	1	2	1	5	3	3	2	4	4	5	5	4	1	3	2	4	2	5	4
1272	5	3	1	5	3	5	1	2	2	2	3	2	2	2	1	2	3	1	2	3	3
1273	3	0	4	0	4	4	3	1	0	1	2	4	4	2	0	4	3	4	1	6	4
1274	5	3	3	5	2	3	2	1	4	1	4	3	4	2	5	2	3	2	2	6	3
1275	1	3	0	2	3	4	1	1	2	5	4	3	2	3	3	3	3	3	1	6	3
1276	5	5	5	5	5	5	1	1	1	2	2	2	2	3	2	2	3	4	1	4	2
1277	2	3	2	2	2	4	3	2	2	4	2	3	2	2	2	3	5	0	1	5	3
1278	3	1	1	3	3	4	4	2	3	3	3	3	4	3	3	3	4	3	2	5	3
1279	4	3	1	2	3	4	3	3	1	2	2	3	2	1	3	1	3	4	2	5	3
1280	4	2	3	2	4	5	5	3	2	2	3	2	4	2	1	3	3	4	1	5	2
1281	2	5	4	4	4	5	5	2	1	1	2	2	1	2	2	1	2	2	0	3	3
1282	4	4	2	4	2	4	2	4	3	2	4	3	4	2	3	2	4	4	1	2	3
1283	5	3	5	5	3	3	3	1	1	1	1	1	2	1	1	2	2	4	1	4	4
1284	3	2	2	4	2	4	1	2	2	2	4	3	2	2	3	4	4	4	1	4	2
1286	5	5	3	2	4	5	5	1	1	1	1	1	1	1	1	1	1	1	2	5	3
1287	5	5	3	5	5	5	1	2	3	3	1	1	1	1	1	1	2	3	2	6	2
1288	5	5	3	5	5	5	5	5	1	1	4	2	5	2	1	1	2	2	2	5	2
1289	3	3	2	3	2	3	3	2	2	1	4	2	1	1	1	1	2	1	2	5	2
1290	5	2	1	5	1	5	3	2	5	2	5	5	2	1	1	1	2	2	1	6	2
1291	5	3	4	5	2	5	5	2	1	1	4	1	2	1	4	2	2	1	2	5	3
1293	5	4	4	5	4	5	5	1	2	1	5	1	2	2	3	1	5	1	2	5	2
1295	4	5	4	5	5	5	5	1	1	1	5	1	5	1	5	1	1	1	1	6	3

RAW DATA: TAMPER-RESISTANT PACKAGING PILOT TEST

I.D.NO.	GK	GV	GI	GN	GR	GF	GT	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	SEX	AGE	C
1251	5	3	5	5	2	4	4	4	1	3	1	1	1	1	1	1	1	1	2	2	3
1252	4	3	1	4	4	5	5	1	1	1	1	1	1	1	1	1	1	3	1	2	4
1253	3	3	2	4	3	4	3	2	1	1	1	1	4	2	2	1	1	4	2	1	3
1254	5	3	3	4	4	5	3	1	1	1	5	5	1	1	1	5	1	5	0	2	2
1255	2	3	4	4	5	4	1	1	1	1	4	3	5	1	1	2	1	3	2	4	2
1256	3	3	1	5	5	5	4	1	1	1	5	1	1	1	3	0	1	1	1	5	3
1257	4	3	5	4	3	4	3	3	2	3	1	3	3	2	3	1	3	3	2	5	2
1258	3	4	1	3	2	4	3	4	1	4	3	2	2	2	2	2	3	2	2	3	3
1259	4	2	1	5	1	3	3	4	3	3	3	2	1	1	1	3	3	5	2	3	5
1260	3	4	1	1	2	4	2	1	1	1	2	4	5	5	5	1	5	1	2	3	3
1261	5	3	1	3	4	2	1	1	3	1	2	1	4	4	5	4	4	4	1	5	4
1262	2	1	1	2	1	3	3	2	1	1	3	3	3	1	1	1	2	3	2	5	3
1263	5	4	2	4	5	5	4	1	2	1	2	1	2	1	1	2	1	2	2	1	2
1264	5	3	4	5	3	2	4	1	1	2	1	2	3	2	2	1	3	2	1	3	3
1265	3	5	2	2	3	5	2	4	2	4	3	3	2	2	4	1	4	4	2	2	3
1266	3	5	5	4	2	1	5	2	1	1	1	1	1	1	1	1	1	1	2	3	3
1267	4	4	3	3	3	4	3	1	1	1	2	1	1	3	1	1	4	1	2	2	3
1268	5	3	2	5	2	4	3	2	1	2	2	2	1	1	1	1	2	2	2	3	5
1269	3	3	2	4	4	4	4	2	2	2	2	2	1	2	2	2	3	3	1	2	3
1271	5	5	1	2	1	5	3	3	2	4	4	5	5	4	1	3	2	4	2	5	4
1272	5	3	1	5	3	5	1	2	2	2	3	2	2	2	1	2	3	1	2	3	3
1273	3	0	4	0	4	4	3	1	0	1	2	4	4	2	0	4	3	4	1	6	4
1274	5	3	3	5	2	3	2	1	4	1	4	3	4	2	5	2	3	2	2	6	3
1275	1	3	0	2	3	4	1	1	2	5	4	3	2	3	3	3	3	3	1	6	3
1276	5	5	5	5	5	5	1	1	1	2	2	2	2	3	2	2	3	4	1	4	2
1277	2	3	2	2	2	4	3	2	2	4	2	3	2	2	2	3	5	0	1	5	3
1278	3	1	1	3	3	4	4	2	3	3	3	3	4	3	3	3	4	3	2	5	3
1279	4	3	1	2	3	4	3	3	1	2	2	3	2	1	3	1	3	4	2	5	3
1280	4	2	3	2	4	5	5	3	2	2	3	2	4	2	1	3	3	4	1	5	2
1281	2	5	4	4	4	5	5	2	1	1	2	2	1	2	2	1	2	2	0	3	3
1282	4	4	2	4	2	4	2	4	3	2	4	3	4	2	3	2	4	4	1	2	3
1283	5	3	5	5	3	3	3	1	1	1	1	1	2	1	1	2	2	4	1	4	4
1284	3	2	2	4	2	4	1	2	2	2	4	3	2	2	3	4	4	4	1	4	2
1286	5	5	3	2	4	5	5	1	1	1	1	1	1	1	1	1	1	1	2	5	3
1287	5	5	3	5	5	5	1	2	3	3	1	1	1	1	1	1	2	3	2	6	2
1288	5	5	3	5	5	5	5	5	1	1	4	2	5	2	1	1	2	2	2	5	2
1289	3	3	2	3	2	3	3	2	2	1	4	2	1	1	1	1	2	1	2	5	2
1290	5	2	1	5	1	5	3	2	5	2	5	5	2	1	1	1	2	2	1	6	2
1291	5	3	4	5	2	5	5	2	1	1	4	1	2	1	4	2	2	1	2	5	3
1293	5	4	4	5	4	5	5	1	2	1	5	1	2	2	3	1	5	1	2	5	2
1295	4	5	4	5	5	5	5	1	1	1	5	1	5	1	5	1	1	1	1	6	3

RAW DATA: TAMPER RESISTANT PACKAGING SURVEY

I.D.	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q12A	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q20A	SX	AG	ED	CITY/STATE
1349	2	6	7	7	6	7	7	7	6	7	7	2	0	7	1	6	7	7	2	6	1	3	2	1	3	E/LNS MICH
1351	2	5	7	7	7	7	7	7	7	7	7	2	0	7	2	7	3	3	1	7	1	2	1	1	4	E/LNS MICH
1352	4	7	7	7	7	7	1	6	2	3	1	2	0	4	2	4	4	4	1	4	2	0	2	2	4	E/LNS MICH
1353	4	4	7	5	7	7	7	7	7	7	7	2	0	7	3	5	5	1	1	5	2	0	1	2	3	STLOUIS MO
1354	4	6	4	4	1	7	6	7	7	7	5	2	0	5	3	4	4	4	1	7	1	3	1	2	3	E/LNS MICH
1355	3	6	7	7	7	7	7	7	6	7	7	2	0	7	1	7	5	5	1	6	1	6	2	1	3	SYOSSET,NY
1356	2	5	7	7	7	7	7	7	7	7	1	2	0	7	3	5	3	5	2	6	2	0	1	1	4	E/LNS MICH
1357	2	5	5	5	7	6	6	6	6	6	7	2	0	7	2	2	3	3	1	2	2	0	2	1	3	DETROIT,MI
1358	3	6	7	7	6	7	7	7	7	7	7	2	0	7	3	5	5	6	1	7	2	0	2	1	4	DETROIT,MIC
1359	2	2	5	5	4	6	3	5	4	7	3	1	1	4	3	4	2	3	1	5	1	3	2	1	3	E/LNS MICH
1360	3	5	4	2	7	7	7	7	5	6	6	2	0	4	2	5	7	7	1	6	1	2	2	1	4	SAGINAW,MIC
1361	3	4	7	7	7	7	7	7	7	7	7	2	0	3	1	2	2	2	1	6	1	2	2	2	4	E/LNS MICH
1362	2	4	6	7	7	7	7	7	7	7	7	2	0	5	2	7	6	6	1	7	1	2	1	2	4	E/LNS MICH
1363	3	5	6	6	7	7	7	7	5	7	4	2	0	5	2	3	7	5	1	5	1	1	1	1	4	E/LNS MICH
1364	3	5	5	6	7	6	7	7	6	7	6	2	0	5	2	5	5	4	2	5	2	0	1	1	4	E/LNS MICH
1365	3	6	7	5	7	7	7	7	7	7	7	2	0	7	3	7	1	1	1	5	2	0	1	3	3	
1366	2	6	7	6	7	7	7	7	7	7	7	2	0	7	3	5	4	0	2	4	0	0	2	1	4	E/LNS MICH

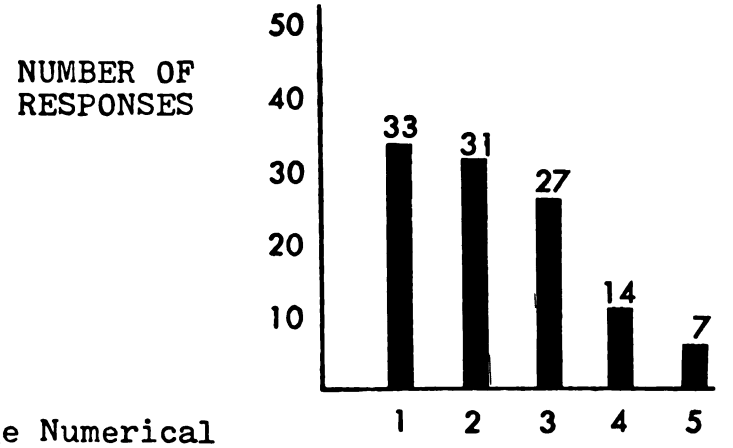
APPENDIX D :

HISTOGRAMS - TAMPER IDENTIFICATION TEST

Item Identification: Control Sample 2572-Membrane Seal

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

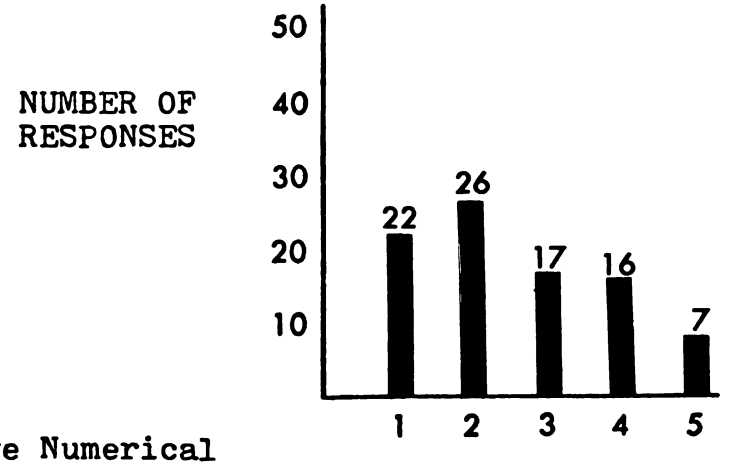


Average Numerical Response: 2.43

Item Identification: Tampered Sample 5021-Membrane Seal

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

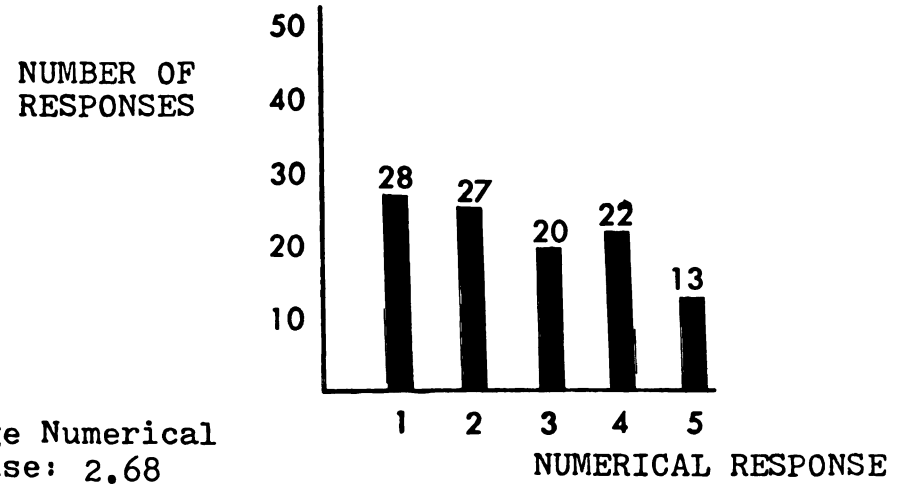


Average Numerical Response: 2.52

Item Identification: Control Sample 3190-Perf.Shrink Band

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

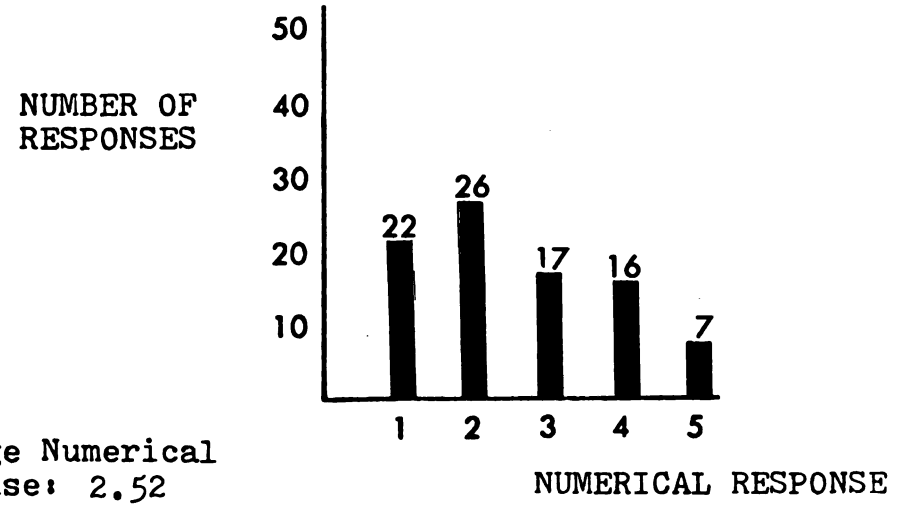


Average Numerical Response: 2.68

Item Identification: Tampered Sample 2494 - Perf.Shrink Band

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

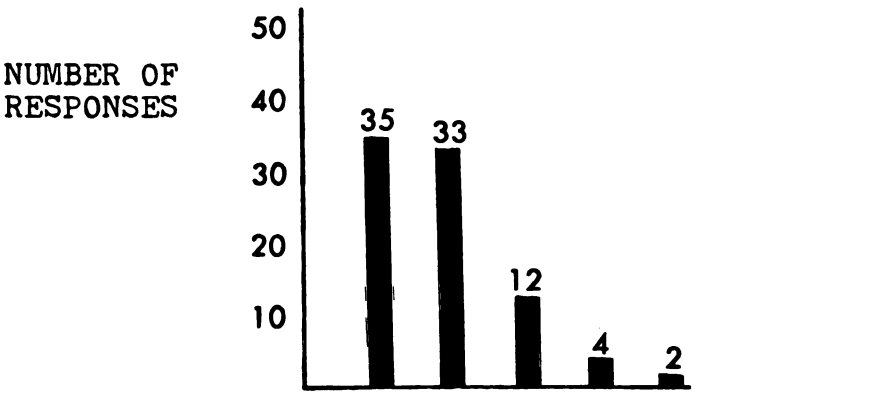


Average Numerical Response: 2.52

Item Identification: Control Sample 9034-Paper Overwrap

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

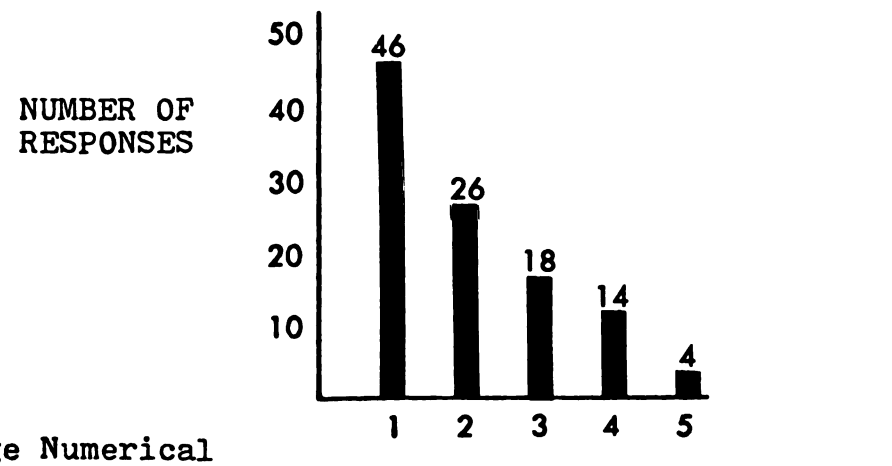


Average Numerical Response: 1.83

Item Identification: Tampered Sample 9069-Paper Overwrap

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

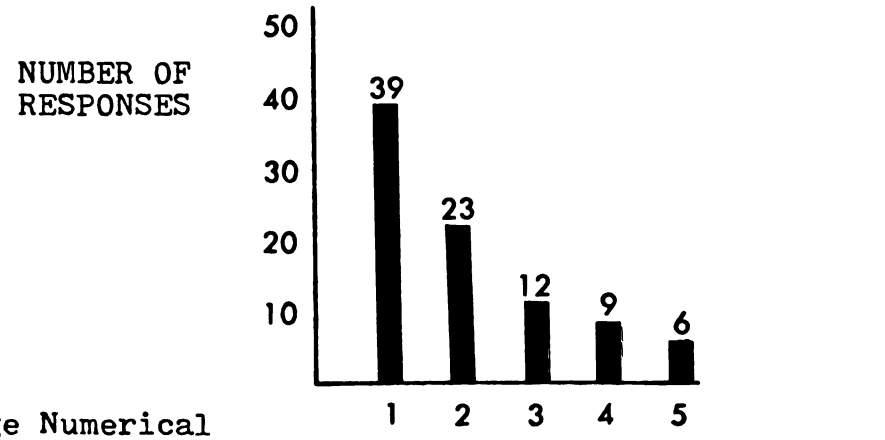


Average Numerical Response: 2.07

Item Identification: Control Sample 6715-Breakaway Ring

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

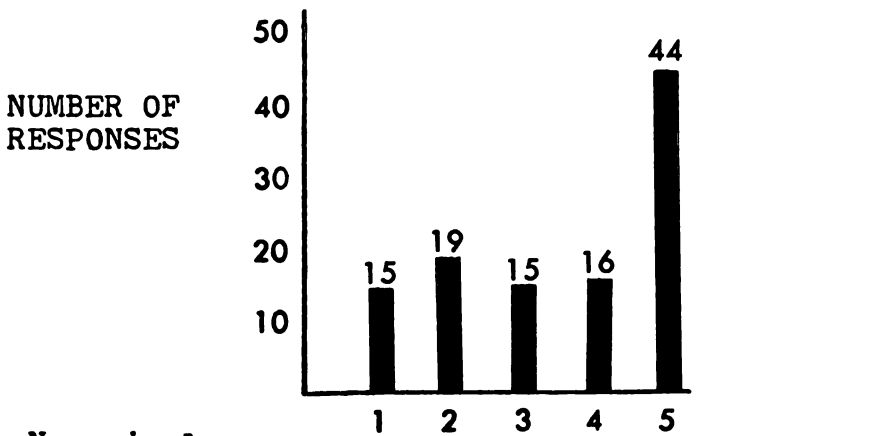


Average Numerical Response: 2.10

Item Identification: Tampered Sample 2826 - Breakaway Ring

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

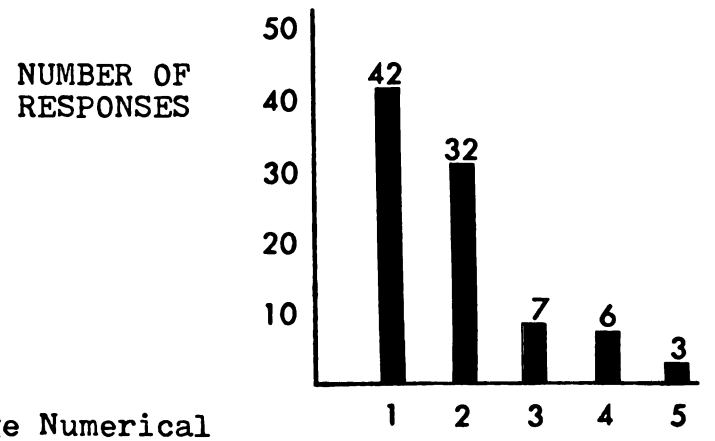


Average Numerical Response: 3.47

Item Identification: Control Sample 2861- Shrink Band

Question: "Having observed this package, do you think it has been tampered

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

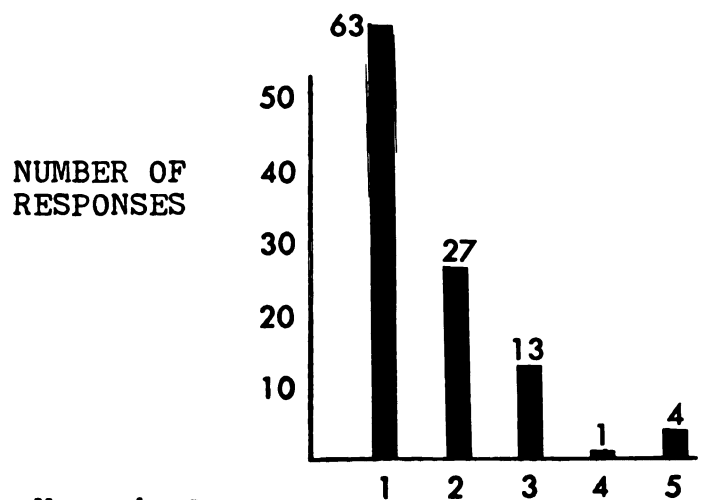


Average Numerical Response: 1.87

Item Identification: Tampered Sample 1980 - Shrink Band

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

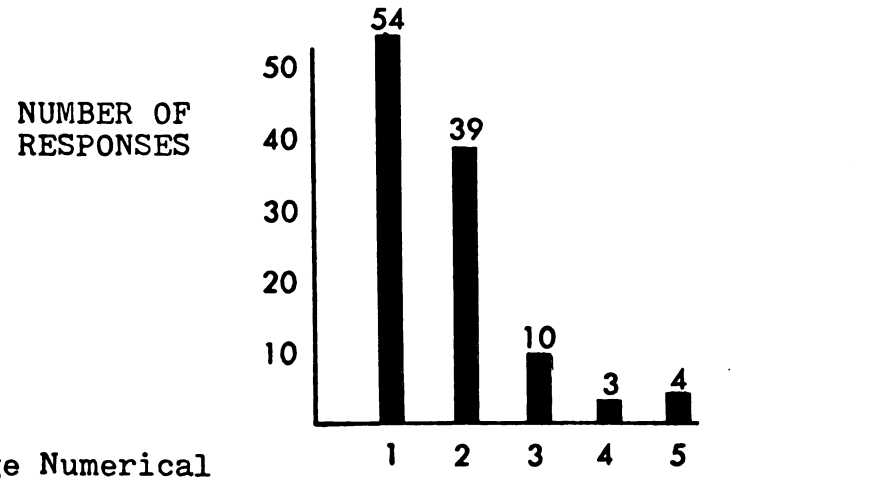


Average Numerical Response: 1.67

Item Identification: Control Sample 3492-Plastic Overwrap

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

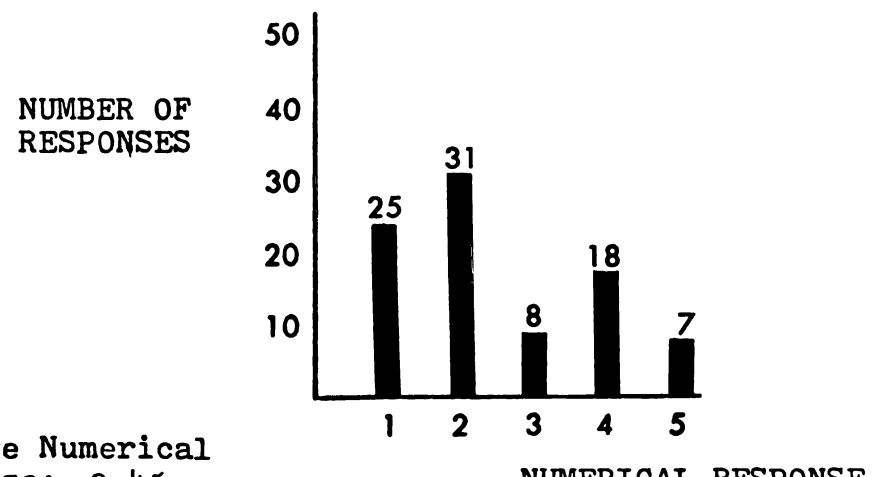


Average Numerical Response: 1.76

Item Identification: Tampered Sample 9265 - Plastic Overwrap

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

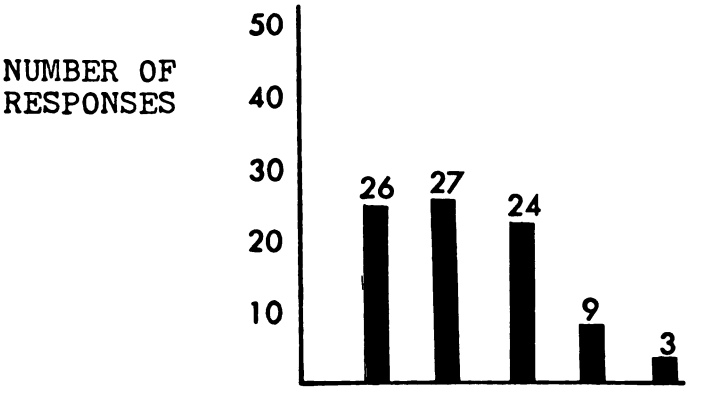


Average Numerical Response: 2.45

Item Identification: Control Sample 5634-Membrane Seal

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

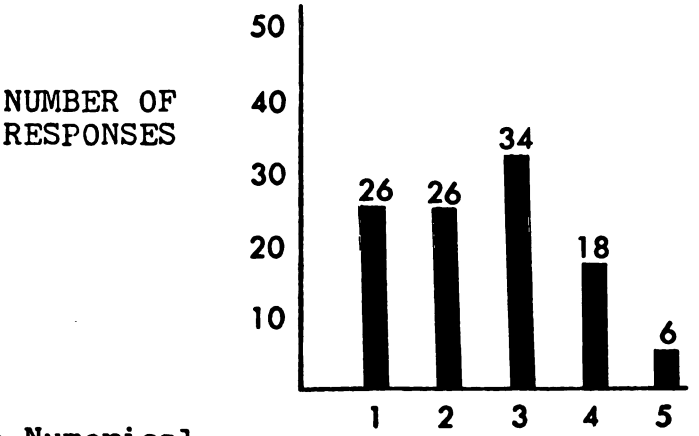


Average Numerical Response: 2.28

Item Identification: Tampered Sample 3710 - Membrane Seal

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

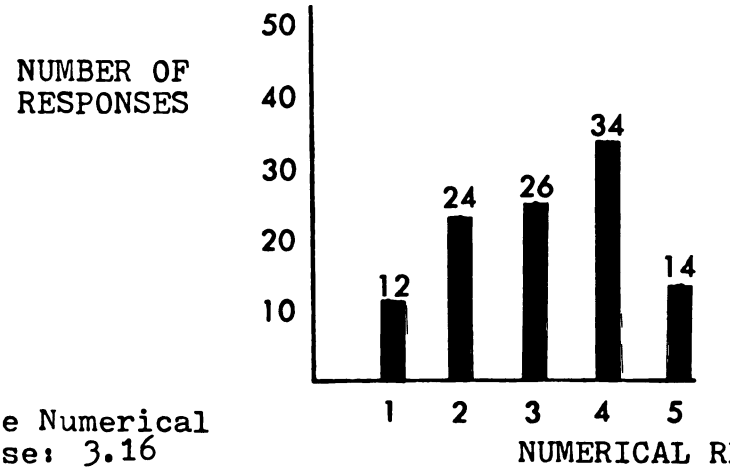


Average Numerical Response: 2.56

Item Identification: Control Sample 8723- Glued End Box

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

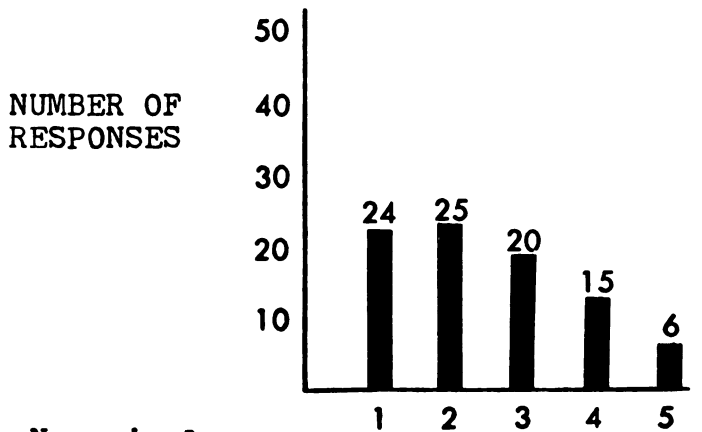


Average Numerical Response: 3.16

Item Identification: Tampered Sample 4036- Glued End Box

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

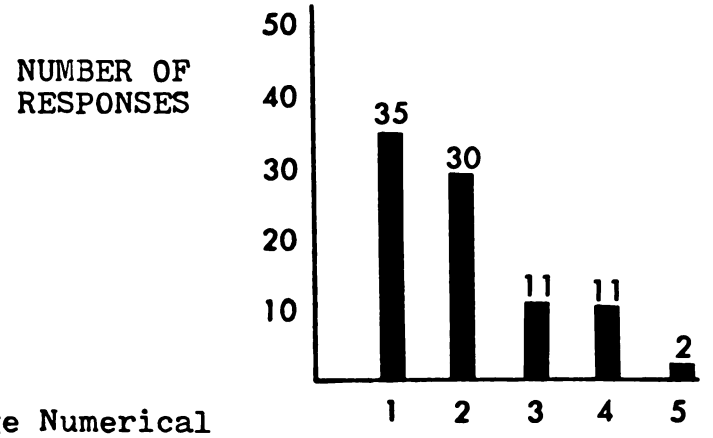


Average Numerical Response: 2.52

Item Identification: Control Sample 5042 - Delamin.Tape

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

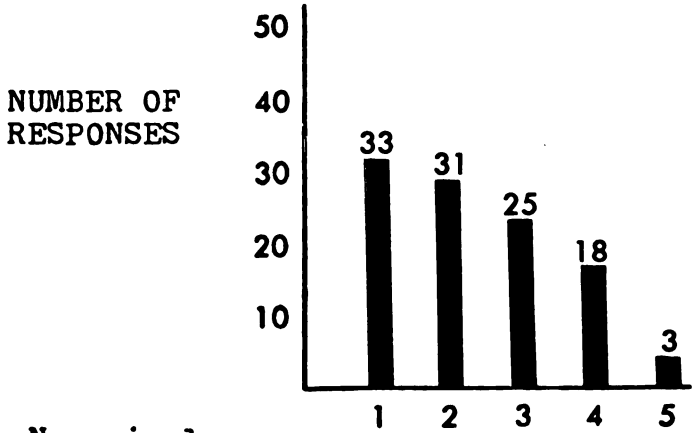


Average Numerical Response: 2.44

Item Identification: Tampered Sample 6251 - Delamin.Tape

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES



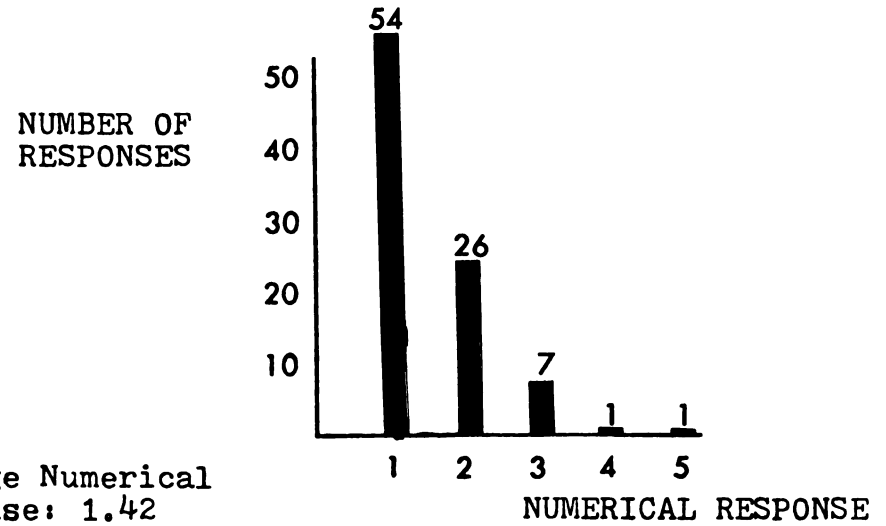
Average Numerical Response: 2.34

TAMPER IDENTIFICATION STUDY

Item Identification: Control Sample 4765- Plas. Overwrap

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

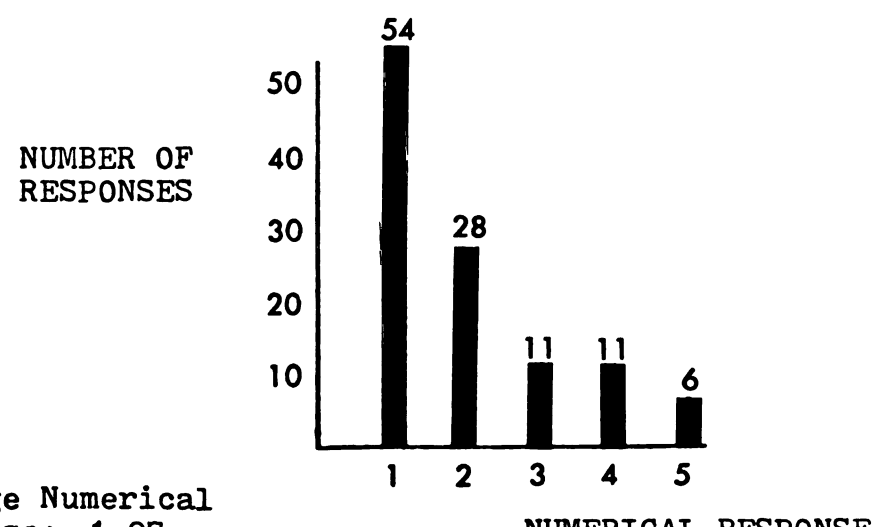


Average Numerical Response: 1.42

Item Identification: Tampered Sample 1429 - Plas. Overwrap

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

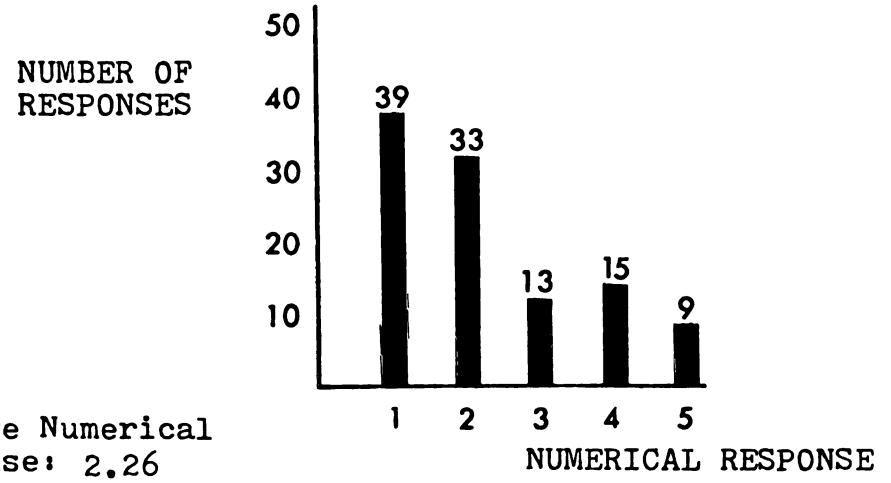


Average Numerical Response: 1.97

Item Identification: Control Sample 8278 - Tape Seal

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

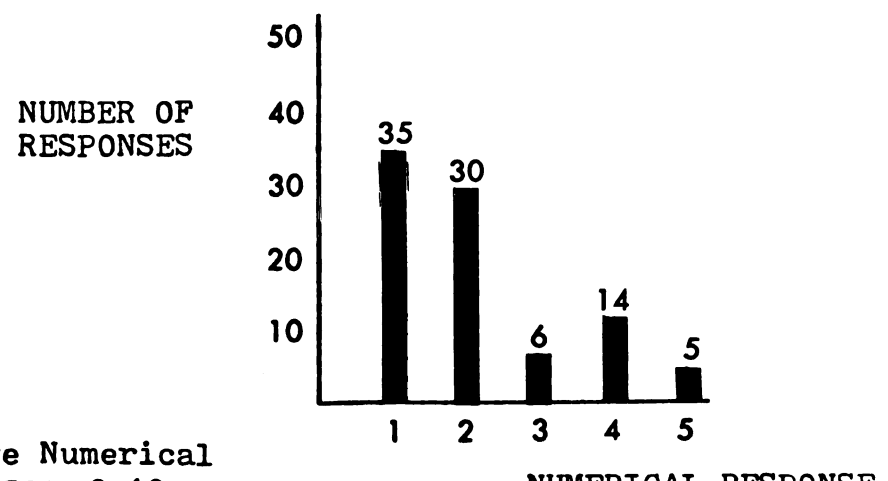


Average Numerical Response: 2.26

Item Identification: Tampered Sample 4082 - Tape Seal

Question: "Having observed this package, do you think it has been tampered with?"

1	2	3	4	5
NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES



Average Numerical Response: 2.12

APPENDIX E :

STATISTICAL COMPUTATIONS - TAMPER IDENTIFICATION TEST

Control Sample Number: #2572

Tampered Sample Number: #5021

Tamper-Resistant Package Type: Membrane Seal

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	33	31	27	14	7	110
Tampered	22	26	17	16	7	88
Column Total	52	57	44	30	14	198

EXPECTED RESPONSES:

	1	2	3	4	5
Control	28.89	31.67	24.44	16.67	7.78
Tampered	23.11	25.33	19.56	13.33	6.22

TEST STATISTIC = 1.870

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

ACCEPT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	27.3	28.2	24.5	12.7	6.7
Tampered	25.0	29.5	19.3	18.2	8.0

Control Sample Number: #3190

Tampered Sample Number: #2494

Tamper-Resistant Package Type: Vert. Perf. Shrink Band

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	28	27	20	22	13	110
Tampered	22	26	17	16	7	88
Column Total	50	53	37	38	20	198

EXPECTED RESPONSES:

	1	2	3	4	5
Control	27.78	29.44	20.56	21.11	11.11
Tampered	22.22	23.56	16.44	16.89	8.89

TEST STATISTIC = 1.300

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

ACCEPT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	25.5	24.5	18.2	20.0	11.8
Tampered	25.0	29.5	15.5	18.2	7.95

Control Sample Number: #9034

Tampered Sample Number: #9069

Tamper-Resistant Package Type: Paper Overwrap

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	35	33	12	4	2	86
Tampered	46	26	18	14	4	108
Column Total	81	59	30	18	6	194

EXPECTED RESPONSES:

	1	2	3	4	5
Control	35.91	26.15	13.30	7.97	2.66
Tampered	45.09	32.85	16.70	10.02	3.34

TEST STATISTIC = 7.337

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

ACCEPT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	40.7	38.4	13.95	4.7	2.3
Tampered	42.6	24.1	16.7	13.0	3.7

Control Sample Number: #6715

Tampered Sample Number: #2826

Tamper-Resistant Package Type: Metal Breakaway Ring Cap

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	39	23	12	9	6	89
Tampered	15	19	15	16	44	109
Column Total	54	42	27	25	50	198

EXPECTED RESPONSES:

	1	2	3	4	5
Control	24.27	18.88	12.14	11.24	22.47
Tampered	29.73	23.12	14.86	13.76	27.53

TEST STATISTIC = 40.61

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

REJECT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	43.8	25.8	13.5	10.11	6.7
Tampered	13.76	17.4	13.8	14.7	40.4

Control Sample Number: #2861

Tampered Sample Number: #1930

Tamper-Resistant Package Type: Dist. Design Shrink Band

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	42	32	7	6	3	90
Tampered	63	27	13	1	4	108
Column Total	105	59	20	7	7	198

EXPECTED RESPONSES:

	1	2	3	4	5
Control	47.73	26.82	9.09	3.18	3.18
Tampered	57.27	32.18	10.91	3.82	3.82

TEST STATISTIC = 8.574

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

ACCEPT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	46.7	35.6	7.8	6.7	3.3
Tampered	58.3	25.0	12.0	.93	3.7

Control Sample Number: #3492

Tampered Sample Number: #9265

Tamper-Resistant Package Type: Clear Plastic Overwrap

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	54	39	10	3	4	110
Tampered	25	31	8	18	7	89
Column Total	79	70	18	21	11	199

EXPECTED RESPONSES:

	1	2	3	4	5
Control	43.67	38.69	9.95	11.61	6.08
Tampered	35.33	31.31	8.05	9.39	4.92

TEST STATISTIC = 21.31

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

REJECT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	49.1	35.5	9.1	2.7	3.6
Tampered	28.1	34.8	9.0	20.2	7.9

Control Sample Number: #5634

Tampered Sample Number: #3710

Tamper-Resistant Package Type: Styrene Membrane Seal

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	26	27	24	9	3	89
Tampered	26	26	34	18	6	110
Column Total	52	53	58	27	9	199

EXPECTED RESPONSES:

	1	2	3	4	5
Control	23.26	23.70	25.94	12.08	4.03
Tampered	28.74	29.30	32.06	14.92	4.97

TEST STATISTIC = 3.575

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

ACCEPT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	29.20	30.30	27.0	10.10	6.70
Tampered	23.60	23.60	31.0	16.4	5.50

Control Sample Number: #8723

Tampered Sample Number: #4036

Tamper-Resistant Package Type: Glued End Box

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	12	24	26	34	14	110
Tampered	24	25	20	15	6	89
Column Total	36	49	46	49	20	199

EXPECTED RESPONSES:

	1	2	3	4	5
Control	19.9	27.09	25.43	27.09	11.1
Tampered	16.1	21.91	20.57	21.91	3.94

TEST STATISTIC = 10.366

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

REJECT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	10.9	21.8	23.6	30.9	12.7
Tampered	27.0	28.1	22.5	16.9	6.7

Control Sample Number: #5042

Tampered Sample Number: #6251

Tamper-Resistant Package Type: Delaminating Tape Seal

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	35	30	11	11	2	89
Tampered	33	31	25	18	3	110
Column Total	68	61	36	29	5	199

EXPECTED RESPONSES:

	1	2	3	4	5
Control	30.41	27.28	16.10	12.97	2.24
Tampered	37.59	33.72	19.90	16.03	2.76

TEST STATISTIC = 5.950

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

ACCEPT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	39.3	33.7	12.4	12.4	2.2
Tampered	30.0	28.2	22.7	16.4	2.7

Control Sample Number: #4765

Tampered Sample Number: #1429

Tamper-Resistant Package Type: Clear Plastic Shrink Overwrap

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	54	26	7	1	1	89
Tampered	54	28	11	11	6	110
Column Total	108	54	18	12	7	199

EXPECTED RESPONSES:

	1	2	3	4	5
Control	48.3	24.15	8.05	5.37	3.13
Tampered	59.7	29.85	9.95	6.63	3.87

TEST STATISTIC = 10.778

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

REJECT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	60.7	29.2	7.9	1.1	1.1
Tampered	49.0	25.5	10.0	10.0	5.5

Control Sample Number: #8278

Tampered Sample Number: #4082

Tamper-Resistant Package Type: Tape Seal

OBSERVED RESPONSES:

	1	2	3	4	5	Row Total
Control	39	33	13	15	9	109
Tampered	35	30	6	14	5	90
Column Total	74	63	19	29	14	199

EXPECTED RESPONSES:

	1	2	3	4	5
Control	40.53	34.51	10.41	15.88	7.67
Tampered	33.47	28.49	8.59	13.11	6.33

TEST STATISTIC = 2.318

CRITICAL VALUE ($\chi^2_{.05,4}$) = 9.488

ACCEPT H_o

RESPONSE PERCENTAGES:

	1	2	3	4	5
Control	35.8	30.3	12.0	13.8	8.3
Tampered	38.9	33.3	6.7	15.6	5.6

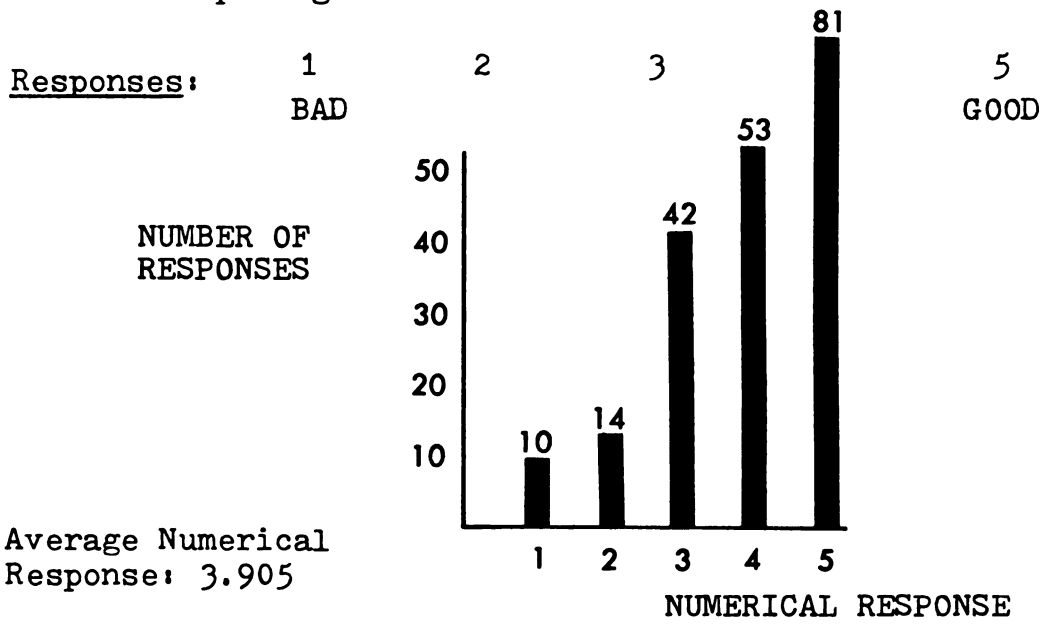
APPENDIX F :

HISTOGRAMS - CONSUMER PERCEPTION SURVEY

CONSUMER PERCEPTION SURVEY

Group Identification: K - SHRINK BANDS

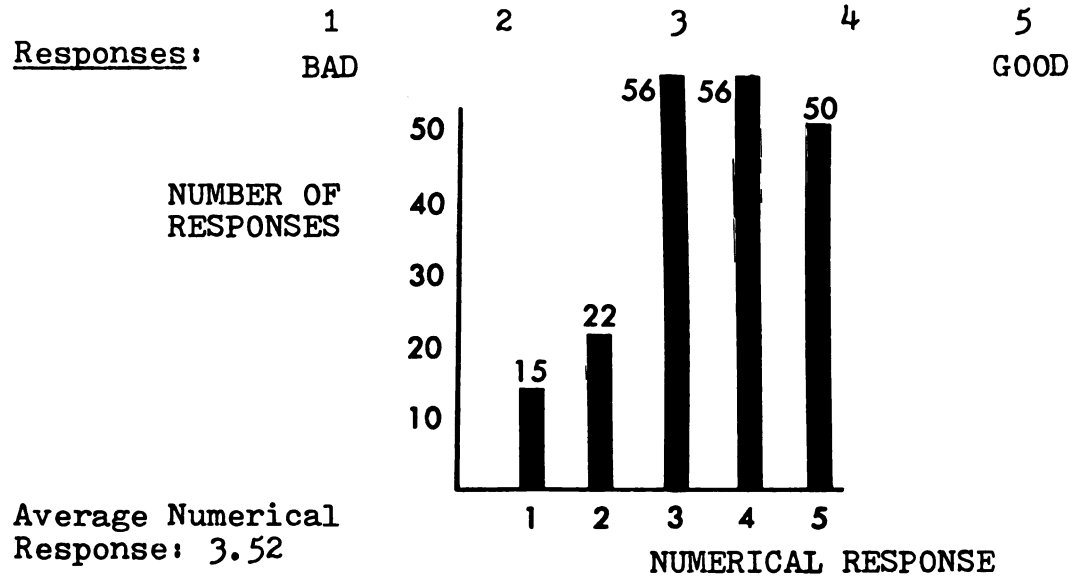
Question: "How do you rate this group of tamper-resistant packages?"



Average Numerical Response: 3.905

Group Identification: V - WRAPS

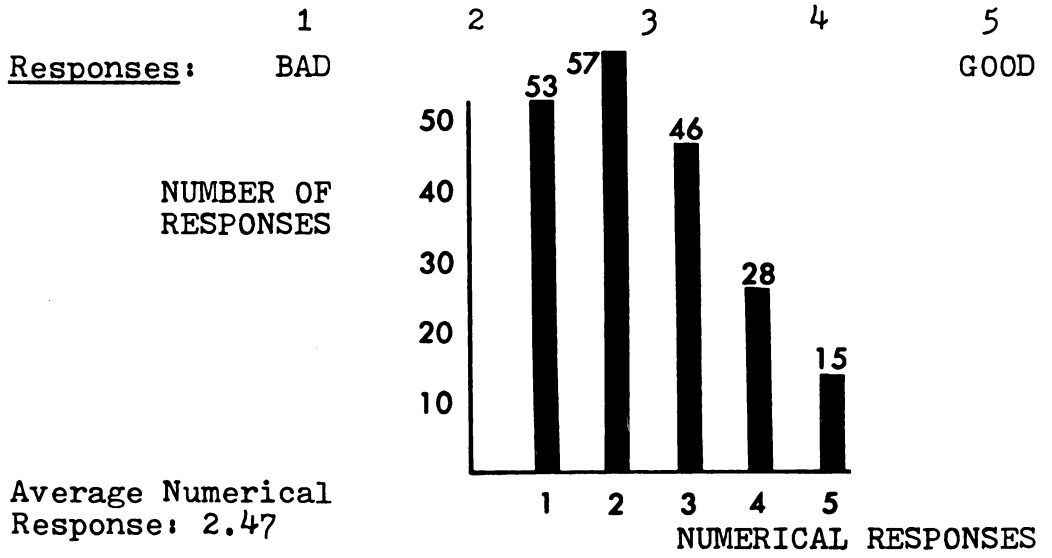
Question: "How do you rate this group of tamper-resistant packages?"



Average Numerical Response: 3.52

Group Identification: I - GLUED END BOXES

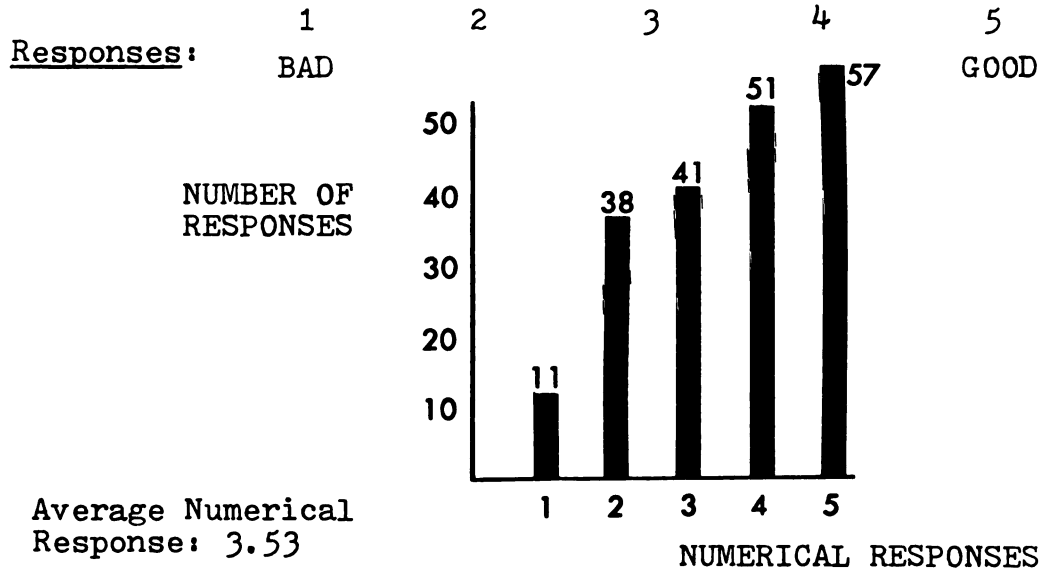
Question: "How do you rate this group of tamper-resistant packages?"



Average Numerical Response: 2.47

Group Identification: N - Breakaway Caps

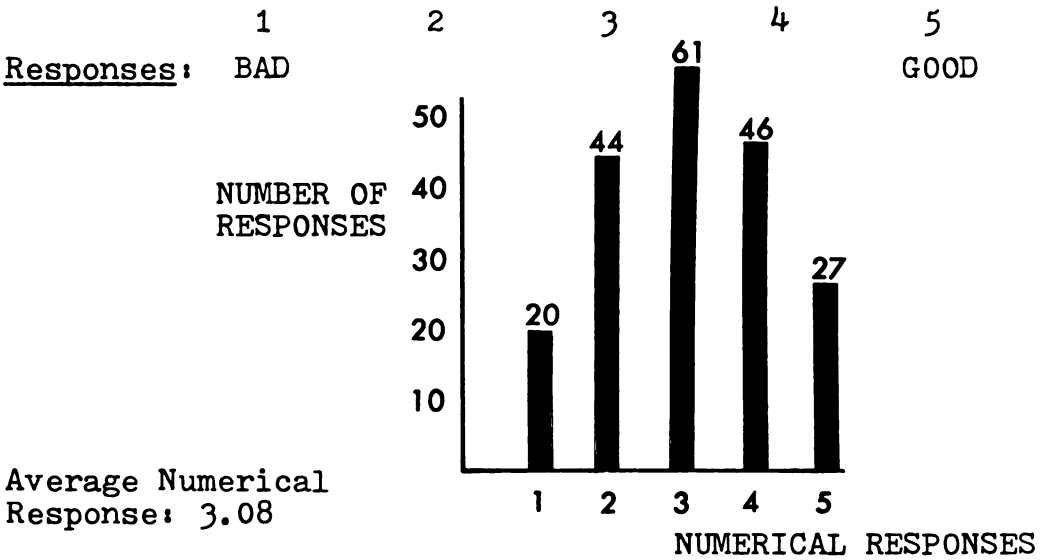
Question: "How do you rate this group of tamper-resistant packages?"



Average Numerical Response: 3.53

Group Identification: R - TAPE SEALS

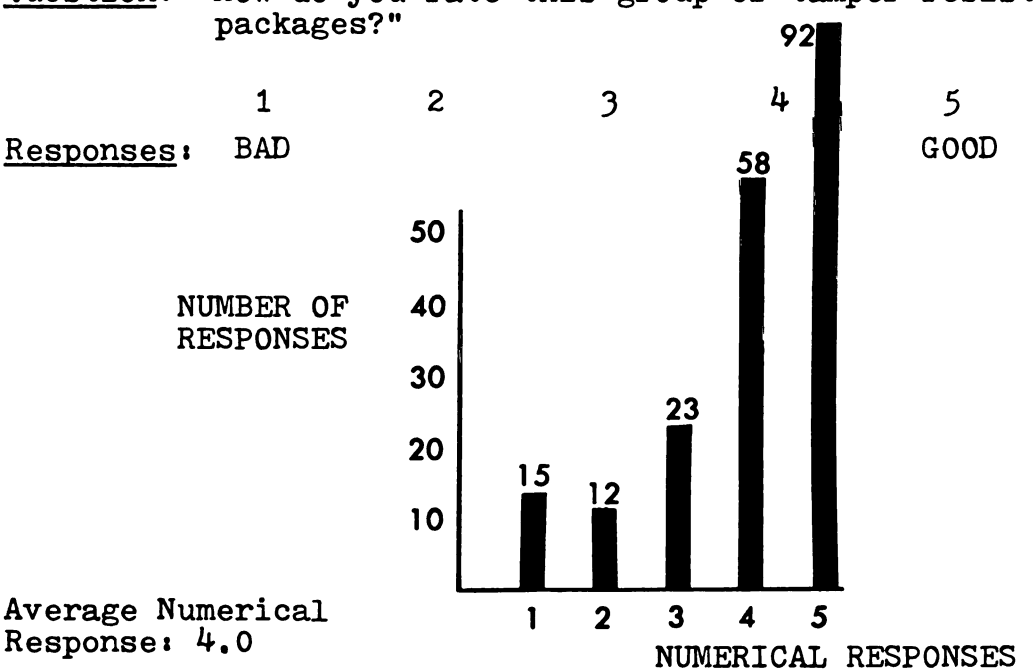
Question: "How do you rate this group of tamper-resistant packages?"



Average Numerical Response: 3.08

Group Identification: F - Blister Packs

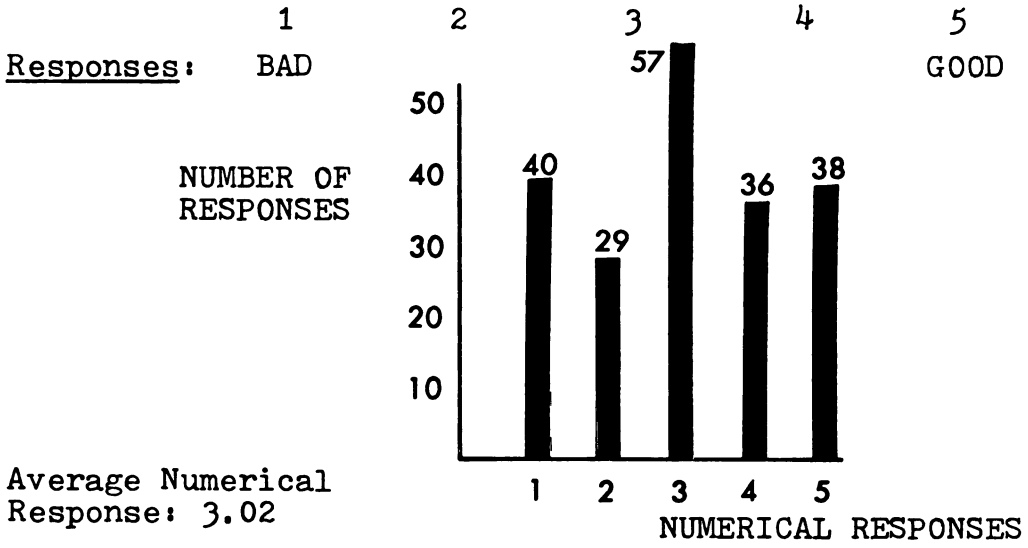
Question: "How do you rate this group of tamper-resistant packages?"



Average Numerical Response: 4.0

Group Identification: T - MEMBRANE SEALS

Question: "How do you rate this group of tamper-resistant packages?"



Average Numerical Response: 3.02

APPENDIX G:

RAW DATA - ATTITUDE SURVEY

RAW DATA: TAMPER RESISTANT PACKAGING SURVEY

I.D.	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q12A	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q20A	SX	AG	ED	CITY/STATE
1000	4	6	7	7	7	7	7	7	7	7	7	2	0	7	3	7	5	5	1	5	1	2	2	4	2	AL/PK MICH
1001	2	6	6	6	7	7	7	7	7	7	1	2	0	4	2	4	4	5	1	4	1	3	2	2	3	LN/PK MICH
1003	2	4	6	5	7	7	7	7	2	2	3	2	0	5	2	2	2	2	2	4	1	1	2	1	4	AL/PK MICH
1004	2	3	4	6	7	7	7	5	5	5	5	2	1	2	2	4	5	5	1	4	1	2	2	2	3	W/LND MICH
1005	3	6	7	7	7	7	7	7	7	7	7	2	0	7	3	7	7	7	1	7	2	0	2	3	2	LN/PK MICH
1006	3	6	7	7	7	1	1	7	7	7	7	2	1	7	2	7	7	7	1	1	1	1	2	5	2	STH/GT MICH
1007	5	6	7	4	7	7	7	7	7	7	4	2	1	3	3	7	3	6	1	3	1	2	2	3	2	TYL MICH
1008	2	6	7	7	7	7	7	7	7	7	7	1	1	7	3	7	5	5	1	7	2	0	2	4	2	AL/PK MICH
1009	3	4	7	7	7	7	3	7	7	7	7	2	1	7	4	6	7	6	1	7	1	3	2	4	2	LN/PK MICH
1010	3	5	7	7	7	7	7	7	7	7	7	1	1	7	1	7	4	4	1	3	1	0	2	4	2	STHFLD MICH
1011	3	5	7	7	7	7	7	7	7	7	7	2	1	7	3	4	6	6	1	6	1	3	2	4	3	STH/GT MICH
1012	4	4	7	7	7	7	7	7	7	7	7	1	1	7	1	7	7	1	1	7	2	6	2	4	2	TYL MICH
1013	3	6	6	6	7	7	7	7	7	7	7	2	0	7	4	5	4	5	1	4	1	2	2	3	2	TYL MICH
1014	2	6	7	7	7	7	7	7	7	7	7	2	0	7	4	7	7	7	1	7	1	2	2	5	2	AL/PK MICH
1015	3	4	7	7	7	7	7	7	7	7	7	2	1	7	2	7	1	1	2	7	2	0	2	0	2	NONE
1016	4	4	6	6	4	6	4	6	6	4	4	2	0	2	3	4	5	4	1	4	1	2	2	1	3	DRBRN MICH
1017	4	6	7	7	7	7	5	7	7	7	7	2	0	5	3	5	5	5	1	5	1	1	2	4	3	AL/PK MICH
1018	2	6	7	7	7	7	7	7	7	7	7	2	0	7	3	7	7	7	1	1	1	6	2	4	2	RMLUS MICH
1019	3	6	6	6	5	7	7	6	6	7	7	1	1	7	3	6	5	5	1	5	1	1	2	2	4	AL/PK MICH
1020	6	6	7	7	4	7	7	7	7	7	7	2	0	7	3	7	4	3	2	4	2	0	2	5	3	STHGT MICH
1021	3	6	7	7	7	7	7	7	7	7	6	2	0	5	2	6	1	1	2	4	2	0	2	2	3	TYL MICH
1022	3	6	7	6	7	7	7	7	7	7	7	2	0	6	2	7	7	7	2	2	1	3	2	1	2	TYL MICH
1023	3	5	7	7	7	7	7	7	7	7	7	2	0	7	3	7	6	5	1	6	2	0	2	4	3	TYL MICH
1024	3	6	7	6	6	6	7	7	7	7	7	2	0	7	3	6	7	3	1	4	1	3	2	5	2	STHGT MICH
1025	5	6	7	7	7	7	7	7	7	7	7	2	0	7	2	6	6	6	1	6	1	2	2	3	1	STHGT MICH
1026	4	6	7	2	6	7	7	7	7	7	7	2	0	7	3	4	4	4	1	5	2	0	2	5	3	MICHIGAN
1027	3	6	7	7	6	7	6	7	7	6	7	2	0	7	2	4	5	5	1	5	1	3	2	2	3	STHGT MICH
1028	2	5	7	7	7	7	6	7	2	7	3	2	1	6	2	3	3	3	1	7	1	3	2	2	2	AL/PK MICH
1029	3	6	7	7	7	7	5	7	7	7	7	2	0	7	3	7	7	7	1	5	1	3	2	1	3	TYL MICH
1030	3	6	7	7	7	7	7	7	5	7	7	1	1	7	3	5	1	4	1	5	1	3	2	2	2	TRTON NJ
1031	3	5	7	7	7	7	7	7	2	5	7	2	0	5	3	1	5	6	2	2	1	2	2	2	3	WYNDT MICH
1032	3	6	7	7	7	7	1	7	7	7	7	2	0	7	3	7	6	5	1	1	2	0	2	5	2	RVRVW MI
1033	3	6	6	6	7	7	7	7	7	7	7	2	0	6	3	4	4	4	1	4	1	4	2	3	3	TRNTN NJ
1034	2	6	7	2	7	1	1	7	7	7	1	2	2	1	1	1	7	7	1	1	2	1	2	4	2	AL/PK MICH
1035	2	6	7	7	7	7	7	7	7	7	7	1	1	7	3	6	5	5	1	6	1	2	2	2	3	MNRO MICH
1036	3	5	7	4	7	7	7	7	7	7	7	2	0	7	3	7	4	4	1	1	1	2	2	2	2	WDHVN MICH
1037	3	6	7	7	7	7	7	7	7	7	1	2	0	1	2	1	7	7	1	2	2	0	2	1	2	TRNTN NJ
1038	3	6	3	3	7	7	7	7	6	7	7	2	0	7	3	0	7	2	2	7	1	3	1	4	2	AL/PK MICH
1039	3	5	7	7	7	7	7	7	7	7	7	2	1	7	4	7	7	3	1	7	1	3	1	5	3	DRBRN MICH
1040	2	4	7	7	7	5	5	7	3	5	7	2	0	7	1	7	7	1	2	4	1	4	1	1	1	OKMS MICH
1041	3	4	5	4	7	7	7	7	3	5	7	2	0	4	3	7	6	5	1	4	1	5	2	1	3	E/LNS MICH
1042	2	6	5	5	7	7	7	5	6	7	2	2	0	2	2	4	5	5	1	5	1	1	1	1	3	BRN/CT MICH
1043	1	4	6	6	6	7	7	7	7	7	1	2	2	6	3	7	2	2	2	4	2	1	1	1	4	MRSH MICH
1044	1	5	6	2	6	6	6	6	4	6	5	2	0	6	1	3	3	3	0	3	1	1	1	1	3	E/LNS MICH
1045	2	6	7	7	5	6	6	6	4	5	7	2	0	3	1	1	6	6	1	7	1	4	2	1	3	OKMS MICH
1046	2	6	7	5	7	7	7	7	7	7	7	2	1	6	4	6	3	4	1	7	1	2	1	1	3	TECSH NY
1047	2	6	6	4	7	7	7	7	7	7	1	2	0	1	2	2	5	6	1	1	2	0	1	2	3	LNS MICH
1048	3	6	7	7	7	7	6	6	6	6	7	1	1	7	2	5	5	5	1	2	2	0	2	1	3	BUFLO NY
1049	2	5	7	6	7	7	7	7	7	7	7	2	0	6	3	5	6	6	1	5	2	0	2	1	3	BUFLO NY
1050	3	4	3	1	7	7	7	7	5	5	1	2	0	3	3	1	7	7	2	7	1	0	2	1	4	WRN MICH
1051	1	4	5	4	7	7	7	7	7	7	1	2	0	1	1	7	1	1	2	7	1	0	2	1	3	NONE
1052	3	6	7	6	6	7	7	7	7	7	1	2	0	4	2	7	1	1	2	5	2	0	1	2	3	LNS MICH

RAW DATA: TAMPER RESISTANT PACKAGING SURVEY

I.D.	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q12A	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q20A	SX	AG	ED	CITY/STATE
1053	2	5	6	5	6	6	6	6	6	6	6	2	0	5	3	2	1	1	2	5	2	0	1	1	3	E/LNS MICH
1054	3	6	7	5	7	3	7	7	3	7	5	2	0	7	2	5	6	3	1	4	1	2	1	1	3	MT/CLMS MIC
1055	3	5	7	7	7	7	7	7	7	7	7	2	0	7	3	4	5	5	1	4	1	1	2	1	3	NONE
1056	3	6	6	6	7	7	7	7	7	7	5	2	0	6	1	1	6	7	2	5	1	2	2	2	4	LNS MICH
1057	3	6	7	1	7	7	5	7	7	7	4	2	0	4	3	1	5	5	2	5	1	6	1	1	4	LK/ORN MICH
1058	3	5	6	7	7	7	7	5	5	6	4	2	0	4	2	4	2	4	1	5	1	1	1	1	4	GR MICH
1059	1	5	7	7	7	7	7	7	7	7	7	2	0	7	2	7	7	7	1	4	1	1	1	4	4	LNS MICH
1060	3	6	5	4	7	7	7	7	7	7	7	2	1	7	2	6	2	2	2	3	1	1	2	3	4	LNS MICH
1061	1	4	7	7	7	7	7	7	7	7	5	2	0	6	2	4	5	6	1	5	1	3	2	1	3	LNS MICH
1062	3	4	4	3	7	7	7	6	4	5	5	2	0	6	2	2	6	6	1	5	1	3	1	2	3	E/LNS MICH
1063	3	6	5	6	7	7	7	7	7	7	7	1	1	7	3	7	4	4	1	5	1	3	2	1	3	FRM/HLS MIC
1064	3	6	7	7	7	7	7	7	7	7	7	1	1	7	2	7	4	4	1	6	1	1	1	1	3	E/LNS MICH
1065	3	6	7	7	7	7	7	7	7	7	7	1	0	7	3	6	7	3	1	5	1	3	2	1	3	E/LNS MICH
1066	6	2	4	1	7	4	1	7	7	7	1	2	0	6	1	5	7	4	2	6	2	0	1	1	3	E/LNS MICH
1067	2	5	3	5	7	7	7	7	3	4	5	1	1	5	2	3	5	5	2	6	1	2	2	1	4	TROY MICH
1068	3	4	7	7	7	7	7	7	5	6	7	2	0	7	2	7	5	4	1	6	1	2	1	1	3	E/LNS MICH
1069	2	5	7	1	7	7	7	7	7	7	4	2	0	7	2	2	1	1	1	2	1	6	1	1	3	NONE
1070	3	5	5	5	6	7	7	6	6	6	5	2	0	6	2	4	5	4	1	4	1	1	1	1	3	HWLL MICH
1071	2	6	6	7	7	7	6	7	6	7	3	2	0	2	3	3	4	4	2	5	1	1	1	1	3	E/LNS MICH
1072	2	6	7	7	7	7	7	6	6	6	7	2	0	4	3	4	5	5	1	4	1	2	1	1	3	GRS/PT MICH
1073	3	5	7	7	5	1	1	7	5	7	7	2	0	4	2	4	4	2	1	2	1	3	2	1	3	CSS CTY MIC
1074	4	5	6	4	6	6	7	7	7	7	6	2	0	6	3	1	6	4	1	5	1	1	1	1	3	BNGHM MICH
1075	4	4	4	2	4	7	4	7	7	7	1	2	0	5	1	6	3	3	1	1	2	0	2	1	3	STRGS MICH
1076	2	5	5	4	7	7	7	7	7	7	5	2	0	5	2	6	6	6	1	3	1	1	1	1	3	BRNGHM MICH
1077	2	4	5	5	3	6	1	7	3	6	7	2	0	6	1	1	7	7	1	3	2	0	2	1	3	DT MICH
1078	3	6	7	7	5	6	7	7	5	6	7	2	0	6	2	4	6	6	1	5	1	5	2	1	3	AL/PK MICH
1079	3	5	7	7	7	6	7	7	7	7	6	1	1	7	2	5	4	5	1	5	1	0	2	1	3	STGS MICH
1080	4	4	5	6	3	4	7	7	4	6	2	2	1	3	3	4	3	2	1	5	1	1	1	1	3	ATHENS GA
1081	4	4	6	5	6	6	6	7	7	7	5	2	0	6	2	4	4	4	1	4	1	4	1	1	3	FNG/HLS MIC
1082	2	4	7	1	7	4	4	7	2	7	4	2	0	5	2	2	1	3	1	5	2	1	2	1	3	UTICA MICH
1084	2	6	5	3	7	7	4	7	7	7	4	2	1	4	3	4	5	5	1	4	1	2	1	1	3	GR MICH
1085	2	6	7	6	5	7	7	7	5	5	4	1	0	5	1	4	4	5	1	4	1	6	2	1	3	E/LNS MICH
1086	1	4	7	7	7	7	7	7	7	7	0	2	0	7	3	3	2	2	1	2	1	1	1	1	3	E/LNS MICH
1087	3	5	6	5	6	6	6	6	2	5	3	1	2	5	1	6	6	4	1	4	2	0	1	1	3	E/LNS MICH
1088	3	4	5	1	7	7	6	7	7	7	6	2	0	4	3	0	6	6	1	3	1	1	1	1	3	LVNA MICH
1089	3	6	7	3	6	7	7	7	6	5	6	2	0	4	3	5	6	5	1	3	1	1	2	1	3	E/LNS MICH
1090	2	6	6	5	6	2	7	7	7	7	4	1	1	6	2	5	7	7	2	5	1	4	2	1	3	E/LNS MICH
1091	3	5	7	5	6	7	3	4	4	4	6	2	0	5	3	6	4	4	1	4	1	4	2	1	3	E/LNS MICH
1092	3	6	7	5	7	7	7	7	7	7	7	2	0	7	3	5	3	2	1	6	1	4	2	1	3	E/LNS MICH
1093	3	4	7	7	7	7	7	7	7	7	6	2	0	6	3	5	7	7	1	7	1	1	1	1	4	GR MICH
1094	3	5	7	7	7	7	7	7	7	7	5	2	0	4	2	6	1	1	1	2	2	0	2	1	3	E/LNS MICH
1095	3	4	2	4	7	7	7	6	3	5	2	2	0	2	1	2	6	6	1	5	1	3	2	2	3	E/LNS MICH
1096	2	6	5	4	7	7	7	7	7	7	5	2	0	5	3	4	7	7	1	4	1	4	1	1	3	RCHSTR NY
1097	3	6	5	5	7	7	7	7	7	7	1	2	0	1	2	4	2	2	2	4	2	0	1	3	4	LNS MICH
1098	3	6	6	6	7	7	7	7	7	7	6	2	0	4	2	6	3	3	2	5	2	0	1	1	3	NONE
1099	5	6	2	5	7	7	7	6	6	6	3	2	0	2	2	5	5	4	1	6	1	3	2	3	3	E/LNS MICH
1100	3	5	6	5	6	7	7	5	5	5	2	2	0	2	1	6	4	4	2	3	2	0	1	1	3	NONE
1101	4	5	3	5	7	7	7	7	6	6	2	2	0	3	2	5	2	2	1	6	1	2	1	2	4	OKMS MICH
1102	3	6	6	6	7	7	7	7	7	7	7	2	1	5	2	4	6	7	1	5	1	3	2	1	3	BAY CY MICH
1103	3	6	3	3	7	7	7	5	5	5	3	2	0	4	2	6	3	3	2	6	2	0	1	1	3	E/LNS MICH

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I.D.	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q12A	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q20A	SX	AG	ED	CITY/STATE
1104	3	6	6	6	7	7	7	7	1	7	1	2	0	2	7	6	5	1	6	1	3	1	1	1	3	NONE
1105	3	5	3	2	7	7	7	6	6	6	2	2	0	4	2	5	2	2	2	6	2	0	1	1	3	NONE
1118	3	6	7	1	7	7	7	7	7	7	2	2	0	1	4	1	7	7	1	6	1	1	1	1	4	GR MICH
1119	3	6	7	4	7	7	7	7	3	7	7	2	0	4	3	7	5	5	2	5	1	2	1	4	4	GR MICH
1121	4	6	5	5	6	7	7	7	7	7	6	2	0	7	3	3	4	5	1	3	1	3	2	5	3	GR MICH
1122	3	0	6	7	4	7	7	7	7	7	7	2	0	7	2	4	3	3	1	4	1	1	1	4	4	GR MICH
1123	3	6	7	5	6	7	7	7	7	7	6	2	0	7	2	7	1	1	1	5	1	2	1	4	4	GR MICH
1141	4	6	5	6	5	6	5	5	6	5	5	2	0	7	3	6	5	5	1	5	1	3	1	5	2	AL/PK MICH
1142	2	4	3	6	7	7	7	7	7	7	7	2	0	7	1	3	5	6	1	1	1	3	1	4	3	AL/PK MICH
1143	5	6	7	7	7	7	7	7	7	7	7	0	7	1	1	7	7	7	1	1	1	2	2	4	2	AL/PK MICH
1144	3	6	6	7	7	1	7	7	7	7	7	1	1	1	2	5	7	7	2	5	2	0	2	4	3	AL/PK MICH
1145	2	6	5	5	7	6	6	7	7	7	5	1	1	2	2	4	7	7	2	5	2	0	1	1	3	AL/PK MICH
1146	4	6	4	3	3	7	1	7	7	7	7	2	0	1	2	1	4	4	2	3	2	0	1	4	3	AL/PK MICH
1147	4	6	6	5	7	7	7	7	7	7	6	2	0	6	2	3	6	6	1	7	2	0	2	3	3	STHGT MICH
1148	3	5	7	7	6	7	7	7	5	5	7	2	0	5	3	7	4	4	1	5	1	1	1	4	4	STHGT MICH
1149	2	6	7	7	5	5	6	7	4	6	2	2	0	7	1	3	1	2	1	5	2	0	1	1	3	STHGT MICH
1150	2	6	7	7	7	4	7	7	4	7	7	1	1	7	2	5	5	5	1	4	1	3	2	1	3	AL/PK MICH
1151	3	6	7	7	3	7	7	7	5	7	7	2	0	7	2	6	7	7	1	3	1	2	2	2	4	AL/PK MICH
1152	3	6	7	7	7	7	7	7	7	7	7	2	0	7	2	7	7	7	1	4	1	2	2	4	2	AL/PK MICH
1153	3	6	7	7	7	7	7	7	6	7	6	1	1	2	4	2	3	5	1	5	2	0	2	3	2	AL/PK MICH
1154	3	6	7	7	7	7	1	7	5	7	7	2	0	1	4	6	3	4	1	1	2	0	2	1	3	AL/PK MICH
1155	2	2	7	1	7	7	7	7	1	1	4	1	1	7	2	7	3	7	1	5	2	0	1	1	2	AL/PK MICH
1156	2	5	4	6	7	7	5	7	7	7	7	2	0	7	3	7	5	5	1	7	1	3	1	5	1	LNC/PK MICH
1157	3	6	6	4	7	7	7	7	7	5	5	2	0	5	3	5	6	5	2	6	1	2	1	1	3	LNC/PK MICH
1158	3	6	7	7	7	7	7	7	7	7	7	2	0	6	2	5	6	5	1	6	1	1	2	2	4	LNC/PK MICH
1159	4	5	7	7	7	7	7	7	7	7	7	2	0	7	4	7	7	7	1	3	1	4	1	5	4	STHFLD MICH
1160	3	6	5	5	6	7	7	7	7	6	5	2	0	5	2	6	6	3	1	5	1	2	2	1	3	MDSN WISC
1161	4	6	4	3	3	7	1	7	7	7	7	2	0	1	2	1	4	4	2	3	2	0	1	4	3	OKMS MICH
1162	4	6	7	7	4	7	7	4	4	7	7	2	0	5	2	5	5	5	1	4	2	0	2	2	3	E/LNS MICH
1163	2	6	5	5	7	6	6	7	7	7	5	1	1	2	2	4	7	7	2	5	2	0	1	1	3	
1164	3	5	7	7	6	7	7	7	5	5	7	2	0	5	3	7	4	4	1	5	1	1	1	4	4	STHGT MICH
1165	2	6	7	7	7	4	7	7	4	7	7	1	1	7	2	5	5	5	1	4	1	3	2	1	3	
1166	3	6	7	7	7	7	7	7	5	7	7	2	0	7	6	7	7	1	3	1	2	2	2	2	4	AL/PK MICH
1167	3	6	7	7	7	7	7	7	6	7	6	1	1	2	2	2	3	5	1	5	2	0	2	3	2	E/LNS MICH
1168	3	6	7	7	7	7	1	7	5	7	7	2	0	1	3	6	3	4	1	1	2	0	2	1	3	
1169	2	2	7	1	7	7	7	7	1	1	4	1	1	7	2	7	3	7	1	5	2	0	1	1	2	OKMS MICH
1170	3	6	6	4	7	7	7	7	7	5	5	2	0	5	3	5	6	5	2	6	1	2	1	1	3	
1171	4	5	7	7	7	7	7	7	7	7	7	2	0	7	4	7	7	7	1	3	1	4	1	5	4	DET MICH
1172	4	5	6	6	7	7	4	7	7	7	7	2	0	7	3	6	5	5	1	4	1	2	1	1	3	E/LNS MICH
1173	3	5	5	5	7	6	3	7	7	7	7	2	0	7	2	6	4	4	1	5	1	5	2	1	4	DRBN MICH
1174	4	6	7	7	7	7	7	7	7	7	7	2	0	7	1	7	4	4	1	1	2	0	1	1	4	MTCLMS MICH
1175	1	4	1	1	7	6	1	4	3	1	7	1	1	7	2	4	5	5	1	3	2	0	1	1	3	WRN MICH
1176	4	5	7	7	7	7	7	3	2	2	4	2	0	3	3	2	3	3	2	5	1	2	2	3	3	NONE
1177	3	6	5	5	7	7	7	5	5	5	7	2	0	3	3	6	6	6	1	6	1	2	2	2	3	DRBN MICH
1178	3	6	3	5	3	7	5	7	7	7	7	2	1	4	3	4	1	1	1	2	2	1	1	3	3	NONE
1179	3	6	7	7	7	7	7	7	4	5	6	2	0	6	3	6	7	6	1	6	1	1	2	1	3	DET MICH
1180	2	5	7	7	7	7	7	7	4	4	4	2	1	1	2	3	6	3	1	3	2	0	1	3	3	DET MICH
1181	3	6	7	7	7	7	7	7	7	7	7	1	1	7	4	1	7	7	2	3	1	1	2	2	3	BRMNHM MICH
1182	3	6	4	4	1	7	1	2	1	1	6	2	0	7	2	2	7	5	1	5	1	1	2	3	2	AL/PK MICH

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I.D.	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q12A	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q20A	SX	AG	ED	CITY/STATE
1183	3	5	7	7	6	6	6	7	7	7	7	1	2	7	3	7	5	5	1	5	1	5	2	2	3	DRBRN MICH
1184	3	5	7	7	7	7	7	7	7	7	7	2	0	7	3	1	7	7	1	7	1	5	2	5	2	STHGT MICH
1185	3	4	7	5	4	7	7	7	7	7	7	2	0	7	2	7	6	4	1	5	1	1	2	6	2	INKSTR MICH
1186	3	6	7	3	2	7	7	7	7	7	7	2	0	7	2	4	6	6	1	3	1	1	2	4	2	TYL MICH
1187	3	6	7	7	4	6	1	1	1	1	4	2	0	1	2	7	1	1	2	7	2	0	2	4	2	DRBRN MICH
1188	6	6	7	7	7	7	7	7	7	7	7	2	0	7	3	6	1	1	1	1	2	0	2	4	2	NONE
1189	3	5	3	4	7	7	6	7	5	7	2	2	0	4	2	2	5	5	2	3	1	0	2	1	3	MTCLMNS MIC
1191	3	5	6	5	7	7	7	7	7	7	5	2	0	5	2	6	7	6	1	2	1	1	1	2	4	DET MICH
1192	2	6	7	7	7	7	7	7	7	7	7	2	1	6	2	6	6	6	1	6	1	6	2	4	2	CANTN OHIO
1193	3	6	7	7	7	7	4	7	7	7	7	1	1	7	4	7	4	4	1	4	1	1	2	4	2	TYL MICH
1194	2	5	7	7	7	7	7	7	7	5	7	2	0	6	3	3	4	5	1	4	1	1	2	4	4	GRS/IL MICH
1195	4	6	6	6	5	7	7	6	4	7	3	2	0	6	1	4	3	4	1	4	1	1	2	1	1	TRNTN NJ
1196	3	6	7	7	7	7	7	7	7	7	7	2	0	7	3	5	7	6	1	5	2	0	2	5	3	TRNTN NJ
1197	3	6	7	7	7	7	6	7	7	7	7	2	0	6	3	5	6	5	1	7	1	2	0	5	2	WYNDT MICH
1198	3	6	6	7	7	7	1	7	4	7	7	2	0	7	3	7	7	5	1	5	1	1	2	4	3	TYL MICH
1199	3	6	6	5	7	7	6	6	5	6	6	2	0	4	2	3	3	5	1	5	2	0	2	1	2	TRNTN NJ
1200	3	0	7	7	1	7	1	7	7	7	7	2	0	7	1	0		7	1	2	1	1	2	5	2	LNCN PK MIC
1201	2	6	4	1	7	7	7	7	5	7	7	2	0	7	3	7	7	1	1	6	2	0	1	1	3	RSVLE MICH
1202	2	3	4	4	7	7	6	7	5	7	7	2	1	5	3	5	4	4	1	5	1	3	2	2	4	TRNTN NJ
1222	2	4	7	7	7	7	7	7	7	7	7	2	0	7	3	1	5	5	1	3	1	2	1	2	4	LNS MICH
1223	3	3	2	7	7	7	7	7	7	7	7	2	0	7	3	5	3	3	1	3	1	1	1	4	4	BUCHN MICH
1224	3	6	6	6	7	7	7	7	7	7	7	2	0	6	3	2	6	2	2	3	1	4	2	4	4	BUCHN MICH
1225	4	6	7	7	6	7	7	5	5	6	7	2	0	6	3	6	6	6	1	6	1	2	2	1	4	NLS MICH
1226	2	4	6	6	7	7	5	7	7	7	5	2	1	5	2	5	5	5	1	6	1	2	1	2	3	FRTPRT MICH
1227	3	4	7	7	6	2	7	7	7	7	7	1	1	7	1	7	4	4	1	3	1	3	2	1	4	DET MICH
1228	3	4	7	7	7	1	7	1	7	7	1	2	1	1	1	1	7	7	1	1	1	6	1	1	4	DRBRN MICH
1229	2	4	7	4	7	7	7	7	7	7	3	2	1	7	3	7	5	6	1	5	1	2	0	3	4	DRBRN MICH
1230	4	6	5	6	6	5	3	7	7	7	7	2	0	7	2	7	4	5	1	5	1	1	1	3	4	NONE
1231	4	6	7	7	7	7	6	7	7	7	6	2	1	7	3	3	5	5	1	5	2	0	2	3	4	DRBRN MICH
1232	4	6	7	7	7	7	7	7	7	7	7	2	1	7	3	5	6	6	1	3	2	1	2	1	4	RYLOK MICH
1233	3	6	7	7	7	7	7	7	7	7	7	2	0	7	3	6	2	2	1	3	1	1	2	2	4	CRSWL MICH
1234	3	6	7	6	7	4	7	7	7	7	7	2	0	7	3	7	4	1	1	4	1	4	2	3	4	KZOO MICH
1236	3	6	7	7	7	6	7	7	6	7	7	2	0	7	3	6	6	5	1	7	1	3	1	4	4	FMTNHLS MIC
1237	2	6	7	7	7	7	7	7	7	7	7	2	0	7	4	7	7	7	0	7	2	0	1	2	4	WASH STATE
1239	4	4	7	7	6	6	6	7	7	7	7	2	0	7	3	5	4	4	0	0	1	1	2	3	4	MATTWN MICH
1240	2	6	7	7	6	7	6	7	7	7	7	1	0	7	2	7	7	7	1	7	1	2	2	3	2	FNVL MICH
1241	3	5	7	7	7	7	7	7	7	7	7	1	1	7	3	7	4	4	1	1	1	2	2	2	3	SAG MICH
1242	2	6	7	6	7	7	5	7	7	7	7	2	0	7	2	7	1	1	1	4	1	1	2	4	4	SAG MICH
1243	3	6	7	7	7	3	3	7	7	7	6	2	0	6	2	6	5	6	1	6	1	3	2	3	3	SAG MICH
1244	3	6	7	7	7	7	7	7	7	7	4	2	0	7	2	6	5	5	1	6	1	2	2	3	4	SAG MICH
1245	3	5	4	4	6	6	6	6	6	6	5	2	0	4	1	4	4	4	0	4	1	1	1	3	4	LNS MICH
1246	4	6	7	7	6	7	7	7	7	7	7	1	1	7	3	6	5	4	1	6	1	1	2	2	4	STHHVN MICH
1247	3	5	7	7	7	7	7	7	7	7	7	1	0	7	4	7	7	1	3	1	4	2	2	2	4	FLNT MICH
1248	3	6	4	3	7	7	7	7	5	7	6	2	0	5	3	4	6	6	1	4	1	4	2	2	4	YPSI MICH
1249	3	5	5	5	6	7	7	6	5	5	6	2	0	4	3	3	6	6	2	5	2	4	2	2	4	STHFLD MICH
1250	3	6	7	7	7	7	7	7	7	7	4	2	2	5	2	2	1		1	2	1	1	2	4	4	FRMTN MICH
1251	3	6	7	7	7	7	4	4	7	7	1	1	1	7	3	7	5	5	1	6	1	1	2	2	4	W/BLMFLD MI
1252	3	3	6	7	5	6	5	7	6	6	7	2	0	7	2	5	4	5	2	7	2	0	2	2	4	TROY MICH
1253	3	6	4	4	7	7	7	7	7	7	7	2	0	7	3	7	7	7	0	0	1	4	2	2	4	STHFLD MICH
1254	3	6	4	7	1	6	7	7	7	7	7	1	0	7	3	0	4	2	1	2	1	6	2	4	4	W/BLMFLD MI
1255	3	6	7	7	7	7	7	7	7	7	2	2	0	7	2	7	7	1	1	2	1	2	2	2	4	PWPW MICH

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I.D.	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q12A	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q20A	SX	AG	ED	CITY/STATE
1256	2	6	4	7	7	7	7	8	6	6	2	0	7	4	7	5	5	1	6	1	1	2	4		4	CHI ILL
1257	2	6	7	7	5	7	5	6	6	5	7	1	1	7	3	7	6	5	1	7	1	3	1	6	4	KZOO MICH
1258	2	6	1	4	7	7	7	7	7	7	6	2	0	6	0	6	6	6	1	6	1	2	0	3	4	HLND MICH
1259	3	6	7	7	5	7	1	6	4	5	4	2	1	5	3	2	4	3	2	3	1	1	2	1	3	FMTNHLS MIC
1260	3	4	7	7	7	4	7	7	7	7	2	0	7	2	4	2	3	1	6	1	1	2	2	3	4	FMTNHLS MIC
1261	4	6	7	7	7	7	7	7	7	7	1	2	0	7	3	3	3	4	1	3	1	1	2	4	2	SAG MICH
1262	3	6	6	5	7	7	1	7	7	7	2	0	7	3	2	4	4	2	2	1	1	1	1	4	2	SAG MICH
1263	3	6	6	6	7	7	7	7	7	7	6	1	1	7	2	6	5	6	1	5	1	2	2	1	4	SAG MICH
1264	3	6	7	6	7	7	7	7	7	7	7	2	0	7	3	5	6	5	1	6	1	1	2	5	3	SAG MICH
1265	3	6	7	7	6	6	6	7	7	7	6	2	1	6	2	6	5	5	1	4	1	1	1	5	2	SAG MICH
1266	4	6	7	7	7	7	7	7	7	7	1	2	1	1	3	4	6	7	1	6	1	2	1	1	4	SAG MICH
1267	4	6	7	4	4	7	7	7	7	7	7	2	1	7	3	3	6	7	1	5	2	0	1	5	3	SAG MICH
1268	4	6	7	4	4	7	7	7	7	7	7	2	1	7	3	4	6	7	4	4	2	0	1	2	2	SAG MICH
1269	2	6	6	7	7	7	7	7	7	7	7	2	2	7	3	7	5	6	1	5	1	3	1	4	2	SAG MICH
1270	3	6	6	6	7	7	7	7	7	7	2	2	0	2	2	6	4	3	2	5	2	0	1	2	3	SAG MICH
1271	1	1	3	1	6	7	6	7	7	7	2	2	0	6	2	2	7	7	1	5	2	0	1	1	1	SAG MICH
1272	3	5	7	7	7	7	7	7	7	7	4	2	1	3	3	5	3	5	1	2	1	5	2	5	4	SAG MICH
1273	3	5	7	7	5	7	7	7	7	7	7	2	0	7	3	7	4	4	1	5	1	2	1	5	2	SAG MICH
1274	3	5	7	4	7	7	7	0	7	7	7	2	1	7	3	0	6	6	1	6	1	2	2	5	1	SAG MICH
1275	4	5	7	6	7	7	7	7	7	7	4	2	0	7	2	7	5	1	1	4	2	0	2	2	2	SAG MICH
1276	4	5	7	6	7	7	7	7	7	7	4	2	0	7	3	7	5	1	2	4	2	0	1	2	3	SAG MICH
1277	3	6	7	7	7	7	7	7	7	7	1	2	0	1	2	1	4	4	2	2	2	0	1	4	3	SAG MICH
1278	3	6	7	7	7	7	7	7	7	7	1	2	0	1	2	1	5	1	2	2	2	0	2	3	2	SAG MICH
1279	4	6	7	7	7	7	7	7	7	7	7	2	0	7	4	7	6	6	1	7	1	1	2	4	4	SAG MICH
1280	1	6	3	2	7	6	1	7	5	4	1	2	1	3	1	2	2	3	2	6	1	1	2	1	1	SAG MICH
1281	3	5	7	5	6	7	7	7	4	5	6	2	0	7	2	4	4	5	1	5	1	3	2	1	4	E/LNS MICH
1282	3	5	7	7	4	7	7	7	7	7	7	1	1	7	2	1	7	7	1	5	2	0	2	1	3	HSLTT MICH
1283	2	6	7	7	7	7	7	7	7	7	7	0	0	7	2	4	7	7	1	5	1	1	2	1	4	FLORIDA
1284	2	4	3	7	7	7	4	7	7	3	1	2	1	2	2	2	3	2	1	3	2	0	2	4	2	LNS MICH
1285	3	6	7	6	7	7	6	7	4	4	5	2	1	4	3	4	1	2	2	4	2	0	2	2	4	KZOO MICH
1285	4	6	6	5	4	5	5	7	7	7	2	1	1	6	3	5	4	6	0	5	1	1	1	4	4	E/LNS MICH
1286	2	6	3	3	2	7	7	5	1	7	7	2	0	4	1	7	7	7	1	5	1	1	2	2	4	LNS MICH
1287	2	6	7	7	5	3	7	7	7	7	2	2	0	7	2	7	3	3	1	5	1	2	2	2	4	DET MICH
1288	4	6	6	6	6	7	7	7	2	4	2	2	1	3	3	5	3	3	2	5	2	0	1	3	4	HSLTT MICH
1289	2	6	5	5	7	7	7	3	3	3	7	2	1	6	3	5	3	6	1	6	0	4	1	3	4	NONE
1290	3	6	7	7	6	7	7	7	7	7	1	2	0	4	3	3	4	4	2	4	1	1	1	1	4	OKMS MICH
1291	3	4	7	7	7	7	7	7	7	7	7	2	0	7	2	5	5	5	1	4	1	3	1	2	4	E/LNS MICH
1292	3	4	7	7	5	2	7	7	5	7	4	2	1	4	1	6	3	4	1	5	2	0	2	1	3	BSTN MASS
1293	2	4	7	7	7	7	7	7	7	7	1	2	0	1	4	7	4	4	1	7	1	2	2	1	3	CRSWL MICH
1294	3	5	5	5	5	7	6	7	7	7	5	2	0	6	3	5	3	3	1	2	1	4	2	1	3	GLDWN MICH
1295	3	4	7	7	7	7	7	7	7	7	5	2	0	4	1	5	3	3	1	5	1	2	2	1	3	GLDWN MICH
1296	3	6	7	5	6	7	7	7	4	6	6	2	0	5	3	5	6	6	1	6	1	3	2	1	2	HNLULU HAW
1297	3	3	7	3	7	7	7	5	4	7	7	1	2	5	2	7	5	5	1	5	1	5	2	1	3	LNS MICH
1298	3	3	4	4	3	7	7	7	5	7	6	2	0	3	2	2	6	5	1	5	1	1	2	1	2	BRMNHM MICH
1299	2	3	5	4	3	7	6	7	5	7	6	2	0	3	2	2	6	5	1	5	1	1	2	1	2	ANARBR MICH
1300	3	6	6	3	7	7	6	3	3	5	4	2	0	4	3	4	3	6	1	3	1	1	2	1	3	WRN MICH
1301	3	6	2	2	7	7	7	7	7	6	3	2	0	3	3	3	7	5	1	3	1	4	1	2	4	OKMS MICH
1302	3	6	5	5	6	7	7	7	6	7	3	2	0	2	1	2	6	6	1	2	1	1	2	2	0	OKMS MICH
1346	5	6	7	7	7	7	7	7	7	7	7	2	0	7	1	7	6	6	1	6	1	1	2	3	4	E/LNS MICH
1347	2	5	7	7	7	7	7	7	6	6	7	1	1	7	3	7	6	6	1	5	1	1	2	1	4	FLINT,MICH
1348	2	5	6	5	7	7	7	7	7	7	5	2	0	7	2	2	7	7	1	4	1	1	1	1	4	LANSING,MIC

RAW DATA: TAMPER RESISTANT PACKAGING SURVEY

I.D.	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q12A	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q20A	SX	AG	ED	CITY/STATE
1256	2	6	4	7	7	7	7	8	6	6	2	0	7	4	7	5	5	1	6	1	1	2	4		4	CHI ILL
1257	2	6	7	7	5	7	5	6	6	5	7	1	1	7	3	7	6	5	1	7	1	3	1	6	4	KZOO MICH
1258	2	6	1	4	7	7	7	7	7	7	6	2	0	6	0	6	6	6	1	6	1	2	0	3	4	HLND MICH
1259	3	6	7	7	5	7	1	6	4	5	4	2	1	5	3	2	4	3	2	3	1	1	2	1	3	FMTNHLS MIC
1260	3	4	7	7	7	4	7	7	7	7	2	0	7	2	4	2	3	1	6	1	1	2	2	3	4	FMTNHLS MIC
1261	4	6	7	7	7	7	7	7	7	7	1	2	0	7	3	3	3	4	1	3	1	1	2	4	2	SAG MICH
1262	3	6	6	5	7	7	1	7	7	7	2	0	7	3	2	4	4	2	2	1	1	1	1	4	2	SAG MICH
1263	3	6	6	6	7	7	7	7	7	7	6	1	1	7	2	6	5	6	1	5	1	2	2	1	4	SAG MICH
1264	3	6	7	6	7	7	7	7	7	7	7	2	0	7	3	5	6	5	1	6	1	1	2	5	3	SAG MICH
1265	3	6	7	7	6	6	6	7	7	7	6	2	1	6	2	6	5	5	1	4	1	1	1	5	2	SAG MICH
1266	4	6	7	7	7	7	7	7	7	7	1	2	1	1	3	4	6	7	1	6	1	2	1	1	4	SAG MICH
1267	4	6	7	4	4	7	7	7	7	7	7	2	1	7	3	3	6	7	1	5	2	0	1	5	3	SAG MICH
1268	4	6	7	4	4	7	7	7	7	7	7	2	1	7	3	4	6	7	4	4	2	0	1	2	2	SAG MICH
1269	2	6	6	7	7	7	7	7	7	7	7	2	2	7	3	7	5	6	1	5	1	3	1	4	2	SAG MICH
1270	3	6	6	6	7	7	7	7	7	7	2	2	0	2	2	6	4	3	2	5	2	0	1	2	3	SAG MICH
1271	1	1	3	1	6	7	6	7	7	7	2	2	0	6	2	2	7	7	1	5	2	0	1	1	1	SAG MICH
1272	3	5	7	7	7	7	7	7	7	7	4	2	1	3	3	5	3	5	1	2	1	5	2	5	4	SAG MICH
1273	3	5	7	7	5	7	7	7	7	7	7	2	0	7	3	7	4	4	1	5	1	2	1	5	2	SAG MICH
1274	3	5	7	4	7	7	7	0	7	7	7	2	1	7	3	0	6	6	1	6	1	2	2	5	1	SAG MICH
1275	4	5	7	6	7	7	7	7	7	7	4	2	0	7	2	7	5	1	1	4	2	0	2	2	2	SAG MICH
1276	4	5	7	6	7	7	7	7	7	7	4	2	0	7	3	7	5	1	2	4	2	0	1	2	3	SAG MICH
1277	3	6	7	7	7	7	7	7	7	7	1	2	0	1	2	1	4	4	2	2	2	0	1	4	3	SAG MICH
1278	3	6	7	7	7	7	7	7	7	7	1	2	0	1	2	1	5	1	2	2	2	0	2	3	2	SAG MICH
1279	4	6	7	7	7	7	7	7	7	7	7	2	0	7	4	7	6	6	1	7	1	1	2	4	4	SAG MICH
1280	1	6	3	2	7	6	1	7	5	4	1	2	1	3	1	2	2	3	2	6	1	1	2	1	1	SAG MICH
1281	3	5	7	5	6	7	7	7	4	5	6	2	0	7	2	4	4	5	1	5	1	3	2	1	4	E/LNS MICH
1282	3	5	7	7	4	7	7	7	7	7	7	1	1	7	2	1	7	7	1	5	2	0	2	1	3	HSLTT MICH
1283	2	6	7	7	7	7	7	7	7	7	7	0	0	7	2	4	7	7	1	5	1	1	2	1	4	FLORIDA
1284	2	4	3	7	7	7	4	7	7	3	1	2	1	2	2	2	3	2	1	3	2	0	2	4	2	LNS MICH
1285	3	6	7	6	7	7	6	7	4	4	5	2	1	4	3	4	1	2	2	4	2	0	2	2	4	KZOO MICH
1285	4	6	6	5	4	5	5	7	7	7	2	1	1	6	3	5	4	6	0	5	1	1	1	4	4	E/LNS MICH
1286	2	6	3	3	2	7	7	5	1	7	7	2	0	4	1	7	7	7	1	5	1	1	2	2	4	LNS MICH
1287	2	6	7	7	5	3	7	7	7	7	2	2	0	7	2	7	3	3	1	5	1	2	2	2	4	DET MICH
1288	4	6	6	6	6	7	7	7	2	4	2	2	1	3	3	5	3	3	2	5	2	0	1	3	4	HSLTT MICH
1289	2	6	5	5	7	7	7	3	3	3	7	2	1	6	3	5	3	6	1	6	0	4	1	3	4	NONE
1290	3	6	7	7	6	7	7	7	7	7	1	2	0	4	3	3	4	4	2	4	1	1	1	1	4	OKMS MICH
1291	3	4	7	7	7	7	7	7	7	7	7	2	0	7	2	5	5	5	1	4	1	3	1	2	4	E/LNS MICH
1292	3	4	7	7	5	2	7	7	5	7	4	2	1	4	1	6	3	4	1	5	2	0	2	1	3	BSTN MASS
1293	2	4	7	7	7	7	7	7	7	7	1	2	0	1	4	7	4	4	1	7	1	2	2	1	3	CRSWL MICH
1294	3	5	5	5	5	7	6	7	7	7	5	2	0	6	3	5	3	3	1	2	1	4	2	1	3	GLDWN MICH
1295	3	4	7	7	7	7	7	7	7	7	5	2	0	4	1	5	3	3	1	5	1	2	2	1	3	GLDWN MICH
1296	3	6	7	5	6	7	7	7	4	6	6	2	0	5	3	5	6	6	1	6	1	3	2	1	2	HNLULU HAW
1297	3	3	7	3	7	7	7	5	4	7	7	1	2	5	2	7	5	5	1	5	1	5	2	1	3	LNS MICH
1298	3	3	4	4	3	7	7	7	5	7	6	2	0	3	2	2	6	5	1	5	1	1	2	1	2	BRMNHM MICH
1299	2	3	5	4	3	7	6	7	5	7	6	2	0	3	2	2	6	5	1	5	1	1	2	1	2	ANARBR MICH
1300	3	6	6	3	7	7	6	3	3	5	4	2	0	4	3	4	3	6	1	3	1	1	2	1	3	WRN MICH
1301	3	6	2	2	7	7	7	7	7	6	3	2	0	3	3	3	7	5	1	3	1	4	1	2	4	OKMS MICH
1302	3	6	5	5	6	7	7	7	6	7	3	2	0	2	1	2	6	6	1	2	1	1	2	2	0	OKMS MICH
1346	5	6	7	7	7	7	7	7	7	7	7	2	0	7	1	7	6	6	1	6	1	1	2	3	4	E/LNS MICH
1347	2	5	7	7	7	7	7	7	6	6	7	1	1	7	3	7	6	6	1	5	1	1	2	1	4	FLINT,MICH
1348	2	5	6	5	7	7	7	7	7	7	5	2	0	7	2	2	7	7	1	4	1	1	1	1	4	LANSING,MIC

APPENDIX H:

PROCTOR INSTRUCTIONS FOR COMPLETION OF TESTING

PROCTOR INSTRUCTIONS - TAMPER IDENTIFICATION EXPERIMENT

Sample Presentation

Samples will be placed on a flat surface in an organized manner. Be sure samples have been placed far enough apart to allow participants access to the samples one at a time. Each sample will be assigned a random number and a corresponding information card will be displayed in front of the sample. Make sure these cards are displayed with the appropriate samples. The samples should be displayed in good lighting. All sample settings should be maintained in a similar manner to eliminate any bias.

NOTE: Be sure to remove and replace any sample that becomes damaged through test participant handling. Do not allow participants to pull, pluck, or damage samples.

Samples that require removal of a primary package or closure system to display the systems "tamper-resistant feature" must be presented adequately. Blisters will be removed from their carton and displayed next to each other. Caps over membrane seals will be removed and placed next to the bottle. Other samples in this category will be displayed similarly.

TEST PARTICIPANTS

Feel free to use any individual (test participant) for this test that is not a member of your immediate

family, has had no technical training in the field of packaging and is generally above the age of 18.

Please do not administer the test to persons you have discussed the topic of tamper-resistant packaging with. You should apply the test to as many different age and sex groups as possible.

Sample Evaluation

Test participants will recieve a sheet of paper consisting of scales that contain a range of answers. These scales correspond to the question asked about each sample:

"Having observed this package, do you think it has been tampered with?"

Scale:	1	2	3	4	5
	NO	NOT LIKELY	DON'T KNOW	MOST LIKELY	YES

Participants will be asked to respond to the answer that best describes their thoughts. Sample identification numbers will already be entered on each form. Be sure the numbers match up with the samples.

TEST INSTRUCTIONS TO PARTICIPANTS

When preparing a test participant to take the test make sure you give instructions carefully. Each participant should be informed of the nature of the test. This is done in a very general manner only. Let the individual know that it is a test regarding tamper-resistant packaging and

that they will be shown some samples and asked some related questions. Inform test participants that it is for a graduate research project at Michigan State University. Their answers are totally anonymous and will be greatly appreciated.

If they agree to participate, give them a test sheet and further instructions. After showing them all the samples together, tell them that the individual packages they look at may or may not have been tampered with. Based on that statement, have them answer the question asked as if they were in a store and about to purchase the products displayed. They are also to be told that they can pick the packages up and handle them if they feel it is necessary. Again, please ask them not to mishandle the samples. (Ask them not to peel, pluck, or pull at the sample packages.)

Let them know that secondary closures and packages have been removed on some samples for display purposes only and it should not influence their answers.

Please ask them not to speak to anyone while taking the test and that you cannot provide answers to any questions until after they have completed the test. Be sure to thank each participant for their contribution.

Good organization makes for good results!!!
Thank you for your participation. GOOD LUCK!!!

BACKNOTES

[1] Senate Subcommittee Hearing, Health and Environment Committee. Tamper-Resistant Packaging, Washington, D.C., 15 October 1982.

[2] Ibid.

[3] Ibid.

[4] Ibid.

[5] Food and Drug Administration. "Tamper-Resistant Packaging Requirements; Certain Over-the-Counter Human Drugs and Cosmetic Products; Contact Lens Solutions and Tablets; Final Rules", Office of the Federal Register, volume 47, No. 215, p.50444.

[6] Modern Packaging, November 1950. "Four Roses", p.84.

[7] Modern Packaging, August 1973, p.78.

[8] Modern Packaging, December 1949, p.138.

[9] Modern Packaging, October 1961, "Background for Packaging", p.44.

[10] Modern Packaging, November 1965, "New ways to tamper-proof", p.107.

[11] Modern Packaging, October 1961, "Background for Packaging", p.44.

[12] Package Engineering, April 1979, "Show and Tell Closures", p.37.

[13] The 1981 Packaging Encyclopedia, "Safe and Legal Packaging", p.40.

[14] U.S. Department of Health, Education, and Welfare, Public Health Service/Food and Drug Administration. "Grade A Pasteurized Milk Ordinance (1978 Recommendations)", p.31.

[15] Ibid.

[16] U.S., Statutes at Large, Public Law 85-859, 72 Statute 1358.

[17] Bureau of Alcohol, Tobacco, and Firearms, 27 Code of Federal Regulations 19.663.

[18] Food and Drug Administration, 21 Code of Federal Regulations 200.50.

[19] Food and Drug Administration,"Tamper-Resistant Packaging Requirements; Certain Over-the-Counter Human Drugs and Cosmetic Products; Contact Lens Solutions and Tablets; Final Rules", Office of the Federal Register, volume 47, No. 215, p.50443.

[20] Ibid.,p.50444.

[21] Ibid., p.50450.

[22] Church, George J., "Murder by Remote Control", Time, October 18, 1982, p.18.

[23] Ibid.

[24] Ibid.

[25] "Copycat criminals weak-ego type", State Journal, October 28, 1982.

[26] "Tainted goods may be result of a grudge", State News, October 28, 1982, p.10.

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