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IDENTIFICATION AND PRELIMINARY EVALUATION OF THE MOST VIABLE SHORT AND LONG TERM SOLUTIONS REGARDING TAMPER-EVIDENCE FOR AN ASEPTIC PUREE PACKAGED IN PLASTIC

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IDENTIFICATION AND PRELIMINARY EVALUATION OF THE MOST VIABLE SHORT AND LONG TERM SOLUTIONS REGARDING TAMPER-EVIDENCE FOR AN ASEPTIC PUREE PACKAGED IN PLASTIC

By

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ABSTRACT

IDENTIFICATION AND PRELIMINARY EVALUATION OF THE MOST VIABLE SHORT AND LONG TERM SOLUTIONS REGARDING TAMPER EVIDENCE FOR AN ASEPTIC PUREE PACKAGED IN PLASTIC

By

Julia Corinna Breisinger

Tamper evident (TE) features have been mandatory for over-the-counter drug products since 1982. For the vast majority of food products no such legislation exists, and most efforts made are voluntary. Presented research evaluates current commercial TE technologies and promising technologies relevant to tamper evidency and explores the feasibility of a gas sensor as a possible solution. To do so, headspace gas concentration of an aseptic puree packaged in plastic was measured using gas chromatography. The analysis defines the initial headspace gas concentration (O_2, CO_2) of four types of puree and the gas concentration after two different tampering methods; the opening of the container and the prick of a needle. Results suggest that a sensor can be used to detect tampering that is similar to opening of the container. Although the gas composition of the unopened product was significantly different from the product that had its lid removed and reaffixed ($P= 0.0004$ for O_2 and $P= 0.0046$ for CO_2), the unopened product compared with a sample penetrated with a needle was not significant ($P= 0.95$ for O_2 and $P= 0.29$ for CO_2). This suggests that oxygen and carbon dioxide sensors may be a plausible design in gross tampering, but will not provide protection against ingresses which are minimally invasive.

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Key to Symbols or Abbreviations

cGMP	Current Good Manufacturing Practice
FATA	Federal Anti-Tampering Act
FDA	Food and Drug Administration
GC	Gas Chromatograph
MAP	Modified Atmosphere Packaging
MEMS	Micro-Electro-Mechanical System
OTC	Over-the-counter
OTR	Oxygen Transmission Rate
TCD	Thermal Conductivity Detector
TE	Tamper Evidence
TTI	Time Temperature Integrator
RFID	Radio Frequency Identification

1 Introduction

Tampering incidents of packaged consumer goods have been a regular occurrence, especially since 1982, when Tylenol, an over-the-counter drug, was tampered in Chicago. The 1982 event was highly publicized, and helped to spur copy-cat events in varied products in the time since. The concern is present not only for OTC drugs, but for all products that are meant to be ingested. Certain products, such as baby food, incite particular concern. Babies don't have a strong immune system and can be harmed very easily. As recently as 2009, baby food, manufactured by Earth's Best and Gerber Products, was involved in tampering incidents. In both cases, glass jars were tampered with at the store (see Appendix A, Table 8. Tampering incidents of food and pharmaceutical products). On the other hand, tampering threats also occurred in combination with extortion. In 2005, a tampered Snickers bar was sent to Masterfoods in Australia along with extortion threats.

If concerns like these cannot be eliminated, the popularity of e.g. homemade baby food will increase and the growth of prepared baby food, such as purees, will decrease [1]. For baby food manufacturers, this trend would be critical and drop their sales drastically. Food manufacturers, therefore, try to secure themselves by implementing new technologies that help consumers to identify a tampered package more easily or remove consumer involvement by applying techniques that work at the retail level.

Literature review on the history of tampering and government regulations proposes that the implementation of tamper evident regulations for OTC drugs did not prevent tampering from happening (see 2.1 History of tampering). As mentioned earlier, baby food and OTC drugs were targeted by tamperers in the past (see also 2.1 and Table 8). Food products, however, are not required by law to have tamper evident features. Although, they have tamper evident features integrated voluntarily. Their implementation is good business practice and utilizing a dedicated approach to protect and secure the product can create consumer confidence.

For OTC drugs, FDA recommends several tamper evident packaging designs in the Compliancy Policy Guide (CPG) 7132a.17 (see 2.3.2 Drugs, p. 22). Many of these recommended tamper evident features can also be employed for food products. However, there is no compliance guide of tamper evident technologies for food products. This enables researchers to look into new and incremental tamper evident solutions and their possible implementation (see 3 Literature Review: Identification and Analysis of Promising New and Established Technologies Relevant to TE). There has been little research on tamper evident technologies after FDA published the CPG for drugs. Ohio State University researchers evaluated a new tamper evident closure system in 2006, which is most likely designed for the use with beverage containers (see 2.2).

This thesis covers the state-of-the-art in tamper evidence with a close look at commercial tamper evident packaging solutions and provides a basis for incremental and "leap" solutions for an aseptic puree packaged in plastic. The

current tamper evident feature of the aseptic puree can be described as a blister pack according to the CPG (see p. 24). Here, a blister pack is defined as one having individually sealed dosage units in clear plastic sealed with foil or paper baking that must be broken or torn to obtain the product.

One tamper evident design that is further analyzed in this research is the use of a gas sensor as a new tamper evident solution. Gas detectors are already in use for food packaging, however, not as tamper evident feature (see 3.3.2.2 Gas Detectors). To examine the feasibility of a gas sensor as tamper evident technology, a product (puree) with a modified atmosphere in its headspace is evaluated. Headspace analysis provides information which has the potential to garner insights for future tamper evident features (see 5 Characterizing the product: Headspace Analysis).

2 Literature Review

2.1 History of tampering

2.1.1 Level and Types of Tampering

Tampering is defined in the Federal Anti Tampering Act (FATA) of 1983 as "tainting any consumer product or rendering materially false or misleading the labeling of, or container for, a consumer product with intent to cause serious injury to the business of any person" [2].

There are three points at which a foreign object or other contaminants can get into a product; during manufacturing, while the product is in distribution, and after purchase. Tampering during manufacturing is generally the most harmful scenario, in that large amounts of product can be accessed at this point, possibly by angry employees. By contrast, tampering that occurs within the distribution chain, is more likely to be committed by extortionist threatening the government or a company or by individuals wanting to harm a single victim. Tampering after purchase, on the other hand, is frequently related to "false report cases", such as the Pepsi tamperings in 1993 (see 2.1.3) [3].

"Modifying Criminogenic Products" [4], indicates four main types of intrusion to guard against:

- terrorism or random attacks (such as the 1982 Tylenol case),
- pilfering or damaging of items enclosed in the packaging,

- tampering during manufacturing and
- counterfeiting

This project, limits its focus to random attacks on the consumer unit-level in post-production environments.

2.1.2 Reasons for product tampering

Park Elliott Dietz, a forensic psychiatrist and expert on criminal behavior, did an analysis of tampering incidents in the U.S. which led him to the conclusion that most tampering offences spring from "greed, anger, and hatred among immature and antisocial people". Dietz also indicates "real product tampering is usually done by political terrorists or by people who are mentally ill" [5].

There are three different types of random acts of tampering that companies must concern themselves with; initial acts, copycat incidents and threats of tampering. All three types present problems that companies must manage [6].

The initial act is usually a true tampering, where an offender places a contaminated product back into the distribution system. In faked tamperings, someone contaminates a product in their household and makes it look as though they are the victim of random tampering (false reports). Threats of tampering are mostly coupled with product extortion, threatening to tamper with a product if the demands (usually money) are not met [7]. Extortion tampering can be political or social, where terrorist call the news to make threats to reduce the confidence in either the government or the company. Another category is "politically motivated

and malicious tampering", where terrorism groups were behind the threats [8] (see 2.4 – Bioterrorism Act).

2.1.3 How product tampering occurred in the past

"Reports of tainted goods causing harm and resulting in litigation date back to the late 19th century" [9]. Tampering of packaged goods, however, became prominent after the 1982 Tylenol incident in Chicago, Illinois. Prior to this, "the phenomenon of product tampering was virtually unknown and no homicides as a result of product tampering has happened" [7]. Seven people died after ingesting Extra Strength Tylenol capsules that had been laced with potassium cyanide. The perpetrator placed the capsules in the original package and back on the shelves [10]. This case is still unsolved, but interest was reignited in February 2009 when the Federal Bureau of Investigations (FBI) searched the condominium of a leading suspect in Cambridge, Massachusetts. Still seen as the prime suspect, James W. Lewis denies committing any crime [11].

Since the Tylenol poisonings, there have been periodic product tamperings (see Appendix A, Table 8, p. 80). The problem, however, peaked in the United States in 1986, after a second tampering of Tylenol and other consumer products occurred, reigniting media attention (see Figure 1).

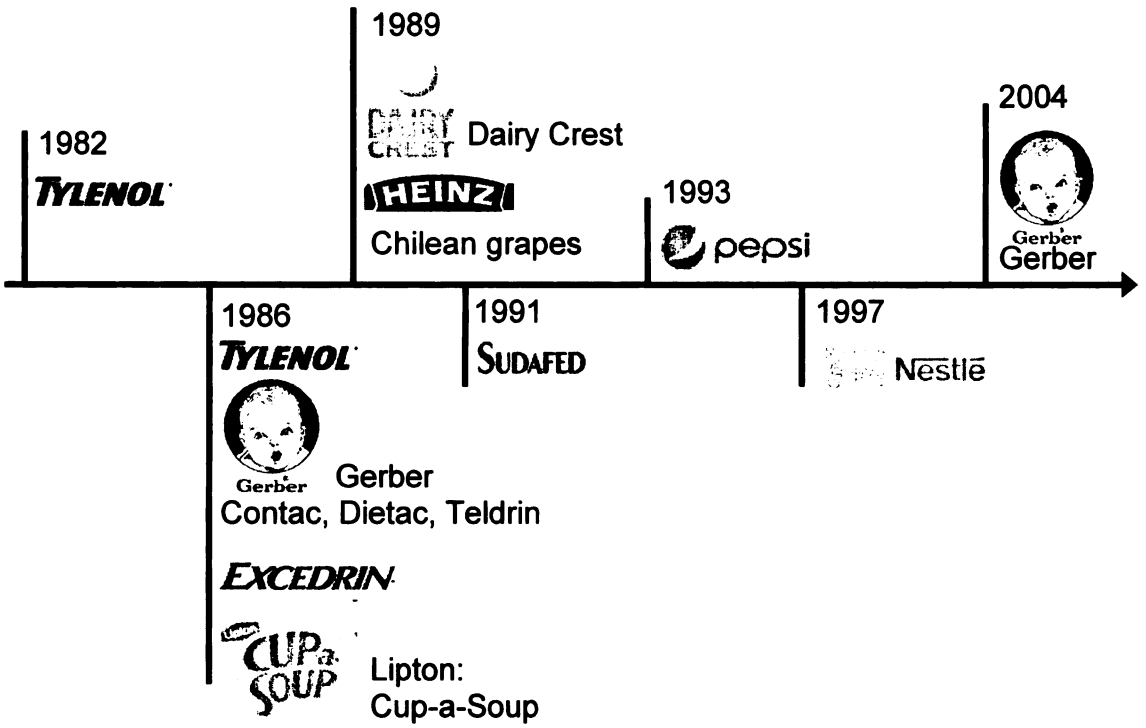

Figure 1. Various Tampering incidents after 1982

In February 1986, a 23 year old woman died after ingesting Tylenol that had again been laced with cyanide [12]. Tampering complaints reached an all-time high of "1,900 during the six weeks following the death", the largest increase recorded since FDA started tracking tampering reports in the late 1970s [13; 14]. During this same period of history, Gerber received over 200 complaints of glass shards in their baby food jars. This marked the third time Gerber had been alarmed by such reports. In 1984, they recalled baby food twice after receiving unconfirmed reports of glass in the packages. During the 1986 scare, the US Food and Drug Administration (FDA) inspected 36,000 unopened jars and failed to discover anything that would justify a recall [15]. Gerber was sued for $800,000 "for the pain and suffering caused to an Ohio mother whose child might or might not have swallowed glass" [16].

One month later, in March, the SmithKline products: Contac, Dietac and Teldrin were immediately recalled after traces of the rat poison warfarin were detected in nine capsules [16]. In the same year, two people died after taking adulterated Excedrin, manufactured by Bristol-Myers. In the Excedrin case, the wife of the second victim, Stella Nickell, placed cyanide in the extra strength Excedrin capsules, repackaged them, placed three of the bottles in area stores and kept two bottles to use as a means to kill her husband. She was found guilty of murder and sentenced to 90 years. She was also the first person to be tried and convicted for committing murder by means of product tampering [10]. In September 1986, another person died after eating Lipton Cup-A-Soup that was also tainted with cyanide [17]. The tampering complaints during 1986 most often cited Tylenol, Gerber baby food and SmithKline products. However, over "800 complaints involved a multitude of other products, from soft drinks to peanut butter" [13]. It was suggested that nationally publicized tamperings correlated with complaint rates (see 2.4 Reactions of the Public: Post-tampering) [4; 7; 13]. For instance, prior to the 1982 Tylenol tampering, "all recorded tampering complaints totaled 37" and in the three years after, the number of complaints was around 800 [13].

But the problem of tampering is not limited to the US. In the United Kingdom, for example, there were two cases of food tampering in 1989 alone. Dairy Crest, a large butter producer, had to take all its butter off the shelf after traces of mercury were discovered in one pack [18]. During the same year, a single jar of

Heinz baby food was identified to contain caustic soda and two large metal drawing pins and others slivers of glass [4; 19].

"Political and social causes" have acted as a motive for product tampering around the world [8]. One such threat occurred in the form of imported Chilean grapes that were intended for wine and table use in the US in 1989. Terrorists phoned the US Embassy in Santiago de Chile and claimed that all Chilean grapes had been poisoned with cyanide. The threat was related to a protest over unspecified policies of the Pinochet Government. After it appeared that American consumers were at risk, food stores pulled tons of grapes and other fresh fruit from their shelves. Investigators found two grapes that had a white ring of crystalline dust around a puncture hole, where cyanide was "injected". However, each grape contained 0.003 mg cyanide, whereas the lethal dose is considered to be 200 mg for an adult [20].

By the late 80s, many documented tamperings employed the use of chemicals, like Cyanide. Recognizing this, the FDA changed its Elemental Analysis Research Center to focus on forensic research with the primary focus on "what happens when poisons are added to food and drugs" [3]. This center became the FDA Forensic Center, which was intended to "provide the agency with a team of forensic science experts who can respond immediately to all tampering incidents and provide expert advice and scientific evidence to FDA officials" [21].

Despite the new tools being embraced by the Agency, the tampering of products with cyanide continued, and in 1991 and 1992 the OTC drugs Sudafed

and Goody's headache powder were targeted. At least six packages of the cold remedy "Sudafed 12-Hour" were identified as adulterated. The capsules were laced with cyanide, resulting in two deaths and a national recall [22]. This incident happened after 1989, the year in which changes were made to the tamper evidence packaging regulations of hard gelatin capsules (see 2.3.2 Drugs). In the case of Goody's Headache Powder, an over-the-counter Headache remedy, the product was recalled after the death of a 51 year old man who ingested the tampered product. This poisoning occurred despite the presence of a tamper evident feature (a plastic seal) [23].

Food products were targeted again in 1993 when Pepsi had to cope with more than 60 reports of objects (like syringes and even a mouse) in their Diet Pepsi cans. It started with a report from Tex (82) and Mary (78) Triplett, who claimed to find a syringe in their Pepsi can. After four days of publicity the complaints had increased to a total of 9. Even so, Pepsi's crisis counselors "decided to fight the media crisis with media". They set up a crisis command center in the company's TV room to make the statement that cans were 99.9% safe and explained that in 50 ways. In the end it turned out, the syringe found by the Tripletts likely belonged to a diabetic relative [21; 24].

In 2004, Gerber's Banana Yogurt Dessert was tainted with non-lethal amounts of ricin. Two jars contained the poison and warnings inside that the jars were contaminated. As a result, Gerber added an additional tamper-evident feature, a plastic seal, to the jars [25].

As mentioned earlier, the UK baby food market also suffered after a tampering incident in 1989. In 1994, bottles of UK Safeway's tonic water were found to be laced with atropine, a form aptly named deadly nightshade. Eight people became ill after consuming the product, with four of them being quite seriously ill. Consumers didn't see that the seal on the bottle was broken. The genesis of the situation was a man who attempted to murder his wife by administering the poison in the tonic water. The overall cost for the recall added to at least £44,000 [4].

Nestlé Germany has been the target of several extortionists. In early 1996, police found tubes of Thomy mustard and mayonnaise that had been laced with cyanide. In 1998 and 1999 jars of "Alete" brand baby food were laced with pesticide and placed on several grocery stores. Fortunately, no injuries resulted from any of the events. A German-Romanian who confessed to the contamination of the Thomy products, which were tampered between August 1996 and September 1998, was sentenced to 11 years in prison [14; 26].

Like other countries throughout the world, Australia's food and pharmaceutical companies have faced big recalls of their products as the result of extortion attempts. In 1997, Arnott recalled its biscuits after extortionists threatened to poison the product with a pesticide [27].

Another Australian recall in 2000 involved Herron pharmaceutical group. Herron capsules were removed from shelves after 2 people were poisoned in an extortion attempt. The capsules, packaged in tamper-evident packaging, had been laced with strychnine, a highly toxic poison used to kill rats [28]. Five years

later, Masterfoods recalled all Snickers and Mars Bars in New South Wales, when they received a contaminated Snickers bar, laced with a substance similar to pest poison, along with extortion threats [29].

2.2 Research on Tampering

There was never again a wider influence on tamper evidence packaging than after the Tylenol tamperings in 1982. One year later, Sneden published "Testing of tamper-resistant packaging: Consumer attitudes and perceptions on tamper evident packaging" [30]. For this work, the researcher employed an attitude survey designed to determine the effect of the Tylenol incident on consumer awareness of TE packaging. Survey findings and a performance evaluation of eleven tamper evident packages suggested that consumers were aware of tamper evident packaging, but unsure or unable to detect tampered packages.

A subsequent study examined a specific tamper evident closure that was introduced in 1983 by TBL development (Livingston, NJ) [31; 32]. The closure changed color when twisted, indicating that the container had been opened. The plastic cap, which was applicable for container closure systems that requires a rotational motion to remove the closure, such as jars and bottles, featured a "transparent, modified standard cap and a laminated liner". Small tines in the cap rip the upper foil away and expose the red paper liner under the foil, which is intended to protect and warn the consumer of a prior opening [32]. When this container/closure system was tested, a majority of survey respondents (57.4%) indicated that they were unsure that they would be able to detect tampering.

Because many tamper-evident features are only effective if the consumer is aware of the feature, attends to it and understands its meaning this result was concerning [31].

Another survey, conducted in 1983 for DuPont Co. (Wilmington, DE), questioned 500 consumers about their preference between two types of tamper evident packaging [33]. The study compared two packaging systems in two different configurations,

- cartons covered with an overwrap were compared to the same cartons sealed with glue and
- bottles with an overwrap were compared to bottles sealed with shrink bands around the neck.

The survey revealed that 95% of the people preferred the overwrap to the glued carton. The perception was that an overwrap provided more indication of tampering attempts and was a higher barrier to tampering, with the rationale being that special machinery needed to be used in order to reseal. When solutions focused on applying TE technology to the bottle itself, 69.5% chose the overwrap compared to 27.5% who indicated a preference of shrink neck bands (the remaining 3% indicated no preference).

The magazine 'Package Engineering' published the results of two focus group sessions focused on TE technologies during this same timeframe. One of the two focus groups consisted of 10 women and the other 9 men. The study differed from DuPont's study, which provided a quantitative sample of consumer opinion,

because it qualitatively observed the perception of consumers regarding tamper evident packaging [33].

The female panelists in this research felt that carded packages (see also Figure 2, p. 26) were the most secure and most expensive package, and also the one they would be willing to pay more for. The group also felt somewhat safe with inner seals, provided the seal left behind a residue. Feelings about shrink bands were mixed, with one person of the opinion that the band shouldn't be transparent to increase the noticeability. Plastic or paper pouches made the consumers feel "fairly comfortable", but blister packs were generally approved by the female panelists.

The focus group consisting of men shared the women's disapproval of that tape seals. The observation of one man was that a package must be completely destroyed in order to open it and that the "self-destruction" secures it. Clear overwrap was discussed as needing some printing to prevent duplication and was accepted, with care. Glass bottles were mentioned as among the best tamper evident packages, because "you can't stick a needle through glass" [33]. As with the women's panel, men expressed favorable opinions of blister packaging. However, offering pharmaceuticals in a blister instead of a bottle, one man mentioned that consumers might rather stay with a package they know.

Hotchkiss and Gravani surveyed commercially available packaging for the purposes of assessing the security of food products in commerce in 1984 [34]. They surveyed supermarket shelves, in order to categorize different food products and determined the level of tamper evidence for various food groups.

The purpose of the field survey was to provide information to the food packaging and manufacturing industry "on the status and vulnerability of food packaging to tampering" [34]. One goal was to quantify the different types of packaging used at the time to assign a "relative rating on the degree of protection against tampering afforded by each product" [34]. Another goal was to create a ranking of susceptibility to tampering. The survey was conducted by collecting data in 5 "super" retail grocery stores owned and operated by different companies. Their conclusion was that less than 1% of the food surveyed in these markets had tamper evident packaging which would meet the FDA regulation for OTC drug products. To compare the safety features of baby food packages with findings of this study, the present study repeated the work for this category in a single store (see Appendix B, p. 85).

The effectiveness of tamper evident packaging was evaluated by researchers at Michigan State University in 1989. The MSU researchers evaluated the overall effectiveness of current, selected tamper resistant packages by measuring the consumer's ability to detect tampering and by surveying packaging professionals involved with tamper evident packaging. The consumer study included about 200 people from various age groups and educational backgrounds that were given four tampered and four untampered packages for observation. The study revealed that the participants did "a poor job overall in correctly identifying packages which had been tampered" [35] or in differentiating between tampered and untampered packaging. The opinion of packaging professionals surveyed during the course of the study regarding tamper evident

packaging was split. Some indicated the current TE features are good indicators of possible tampering, while others felt that many TE features can be repaired without detection and, therefore, recommended better consumer education. Ultimately, the research team recommended that new designs be evaluated using two approaches: consumer testing (80%) and the professional evaluation of the TE design feature (20%) "in order to cover all possible effectiveness criterion in an appropriate proportion of importance" [35]. Therefore, they combined both industry concerns and the consumer's ability to detect tampering in their evaluation procedure.

By contrast, Rosette (1985), recommended that design effectiveness for tamper evidence be evaluated based on industry concerns. He started the evaluation of tamper evident features in his Master Thesis "Development of an Index for Rating the Effectiveness of Tamper-evident Packaging" in 1985 [36] and continued studying on this topic in his dissertation "Improving the Effectiveness of tamper-evident packaging" completed in 1989 [37]. The system that he developed is now published as the "Rosette Protocol" (see 2.5 Evaluation Methods) and is a ranking protocol that intends to provide the users and producers of TE packaging an objective technique for evaluating protective measures.

Closely tied to the previously mentioned studies conducted at Michigan State University, another thesis "An Evaluation of Tamper-resistant Packaging: A method for measuring tamper-evidence" was published by Iwaszkiewicz in 1991 [38]. For this study, researchers presented three packages that incorporated five

different tamper evident technologies (film overwrap and blister, foil membrane seal and plastic shrink band, vacuum button) in a tampered and untampered condition to 96 consumers. Overall, they found out that the tamper-evident packages failed to protect the consumer, because consumers didn't know how to use the tamper-evident packaging. The emphasis of the experiment, however, was placed on the reaction of the subjects during their decision making process of "tampered" or "untampered" package and the developed methodology provides "the degree to which tampering is apparent to the observer" [38]. The researchers studied the consumer behavior and showed the consumers' inability to detect tampered packages. As result, they suggested that the store be used as a "control point" in the prevention of tampering. Specifically, they suggested the use of a magnetized strip or ink that is demagnetized after purchase be used to alert the retailer or consumer that "the package had been previously purchased" [38].

In 1996, two years before packages for OTC drugs offered in capsules (see also 2.3.2) were required to have at least two tamper evident features, another study examined the consumer preference for solid oral dosage forms for OTC pharmaceuticals [39]. Three hundred and eighty-eight students, of which 16.5% were pharmacy students, were questioned about their usage or perception of tablets, capsules and caplets. The questionnaire concluded with questions that focused on tamper evidency. Data suggested that respondents believed capsules were not tamper evident or safe, but effective. However, female pharmacy students thought that tablets were not tamper evident and capsules

were of high quality. Studies such as this, which suggested a lack of confidence in capsule technology, were likely considered as the regulation 21CFR211.132 was changed.

In the time since 1998, no regulation changes have been made to the tamper evidence requirements for OTC drugs, but further studies on tamper evident technologies have been conducted. In 2006, a focus group study, conducted at the Ohio State University (OSU) explored consumer understanding and experiences with tamper evident packaging devices [40]. The study was used as guidance for the development of a new tamper evident packaging technology that changes color. The device is not clearly described, but the TE feature is most likely employed in the closure as a "flagging device" (see also ONE LOOK® in 3.3.1 Current commercial solutions). OSU researchers provided 130 female participants with a questionnaire which asked about their experiences with TE packaging. Among other things, the research team asked if participants usually checked for an intact TE feature before buying or using a food product, or if they had ever eaten food from a package with a broken TE device. The participants answered that they usually check for TE features on a package at the store, but if these are hidden or they are in hurry or shopping with their children, they would examine the package before usage at home. In cases of an urgent need for a product, however, they would also buy a product with a broken TE feature if no indication of spoilage was apparent. Participants also mentioned that they did not examine every product in the same way, but paid more attention to liquids or semisolids, such as milk or baby food, with the reason that spoilage can occur to

the product after opening and that especially infants are at a higher risk regarding illnesses.

The OSU research found that consumers associate a TE device with food spoilage, instead of the concept of product security. Regarding the development of the new, color changing TE device, the consumers were skeptical about its necessity and how to interpret a triggered device. Their suggestion was a "point-of-purchase signage" to help the consumer understand the features properly [40]. After an educational session on the device's use and meaning, participants that were first doubtful about a color changing TE features changed their mind.

The OSU study, as well as those mentioned previously, indicates the importance of consumer education regarding TE device design and use (see also 2.4). OSU researchers go further, suggesting, "consumer education is often lacking in the product development cycle" [40]. In conclusion, the researchers mentioned that their participants could identify a triggered TE device, even though they did not check the products they buy consistently.

Most consumers are familiar with at least some level of tamper evident packaging, but how can they know what a tamper evident device is, if it is not indicated on the package? "Labeling and instructions to consumers are frequently unclear" and information is often "buried in the fine print or is completely missing", Roger Johnston states in his publication on tamper-indicating seals [41]. He says the reason for this is that manufacturers don't want their products to be associated with product tampering.

Even though, OTC drug products require a label statement (see 2.3.2) referring to the TE feature, the warning is often unheeded. The warning is, by regulation (21CFR 211.132) required to be "prominent" so that consumers are encouraged to read the warning at the point-of-purchase [42]. A study published in the *Proceedings of the National Academy of Science of the United States* used eye tracking to examine the prominence of warning labels, among them the required TE warning, on OTC pain relievers of 5 different drugs containing acetaminophen [43]. Dependent variables analyzed included standardized time (time per typographical character) spent on varied portions of the label (brand name, tamper evident warning, child resistant warning, claims statement and drug facts box). The study presents evidence that two required warnings, the TE warning and child-resistant warning are not prominent when compared with other elements of tested labels. The TE warning was particularly problematic; researchers indicate that "more than 80% of study participants failed to record time in the TE warning gaze zones across all packages tested" [43]. This means that just 20% of participants registered any time in the "warning zone" despite the fact that regulations require it to be prominent.

2.3 Government Reaction to Tampering - US Legislation and Regulation

In October 2007 the FDA issued an updated "Guidance for Industry Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" indicating tampering of products as a major threat to consumer health and safety (Section 4). The document recommends actions in cases of

tampering or other malicious, criminal, or terrorist actions to minimize their risk. Companies should have a strategy regarding the appropriate response to product tampering, which also implies that the evidence of tampering should be easily visible or obvious.

Liquor, drugs and milk are required to have tamper evidence devices that show that provide evidence to the consumer that the container has been tampered with. The existing tamper evident regulations for these products are discussed in the following subchapters.

2.3.1 Liquor

Legislation and regulation of tamper-evident packages is nothing new, it has been used ever since the repeal of Prohibition in the United States [30; 44]. During the early years of Prohibition Repeal (after 1933), when the sale of alcohol was again legalized, whiskey distillers developed tamper-resistant packages in the form of "foil-covered, metal-end fibre cans" to reassure the consumers that their product was "the real thing" [45]. The primary purpose of the distilled spirits regulation (27 C.F.R. § 19) at its inception, however, dealt with revenue tax stamps. The current regulation also mandates distilled spirits to be closed with a tamper-evident device (§ 19.662). Liquor, in containers having a capacity of one gallon (3.785 liters) or less, are required to have an "Affixed closure". The closure (or other device) shall be securely affixed to the containers, to leave a portion remaining on the container when the container is opened and the closures shall be constructed in such a manner as to require that they be broken to gain access to the contents of the containers [46].

2.3.2 Drugs

The first Tylenol incident led to the massive recall of 31 million containers of Tylenol. Following the recall, Johnson & Johnson (J&J) conducted a $150 million "advertising blitz to restore consumer confidence". This action is still considered to be a model public relations response to a product harm crisis.

Widespread public concern motivated the creation of tamper evident regulations for OTC products. In 1982, the FDA implemented 21CFR211.132, "Tamper-evident packaging requirements for over-the-counter (OTC) human drug products". The rule required, among other things, tamper-resistant packaging for selected cosmetic products such as oral hygiene products and many over-the-counter (OTC) drugs. According to this regulation, "each manufacturer and packer who packages an OTC drug product for retail sale shall package the product in a tamper-evident package, if this product is accessible to the public while held for sale." A tamper-evident package is defined as "one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred."

In the year following the poisonings (1983), Congress passed the Federal Anti-Tampering Act (FATA), which made it a crime to tamper with consumer products. Certain other behaviors, such as falsely reporting that a consumer product has been tainted, also became chargeable under the provisions of the Act. These felonies are punishable by three years to life imprisonment and a fine of up to $250,000.

In the wake of several other publicized incidents of tampering (e.g. Excedrin – see Figure 1), the regulations were revised. Capsules, consisting of two or more pieces, were now required to have at least two tamper evident features, or to have at least one tamper evident packaging feature if a tamper evident capsule seal was employed. The main regulation, 21CFR211.132, includes the requirement of tamper evident packages for most OTC pharmaceuticals and was amended in 1989 and 1998. In 1998, 21CFR211 changed the packaging requirements for OTC drugs in an attempt to further decrease the risks posed from product tampering. Two highlights of the final rule are:

- Sealing of all two-piece, hard gelatin capsules that were regulated as OTCs (1989) are mandated. Since capsules were the choice of many tamperers, the agency initiated this rulemaking to reduce the potential for tampering with vulnerable two-piece, hard gelatin capsules. However, Johnson & Johnson phased out capsules entirely after the second Tylenol tampering and replaced them with either capsule-shaped tablets (caplets) or gelatin-covered tablets (gelcaps) [22]. Another requirement for the packages of two-piece, hard gelatine capsules was the use of at least two tamper-resistant packaging features or at least one tamper-resistant packaging feature if a tamper-evident capsule seal was employed.
- Another change to the regulation was the terminology used throughout the agency's regulatory program. The term "tamper-resistant" was changed to "tamper-evident" to more accurately characterize the role of tamper-evident packaging in protecting consumers. Tamper resistance in this case, can be

defined as "the degree to which it is difficult to tamper and repair a packaging without leaving evidence". On the other hand, Tamper evidence can be defined as "the degree to which tampering is apparent to the observer" [38].

The amendments to 21CFR211.132 also required labels to reference all TE features employed by the packaging, including those present in the secondary packaging. Tamper-evident warnings must be "prominently placed" on the package, so they are unaffected if the tamper-evident feature of the package is breached or missing. Dermatological products, denitrifies, insulin and lozenges are exempted from the TE requirements and, therefore, the labeling as well. For products that did require TE features, the features were dictated to be "distinctive by design." This means that they "cannot be duplicated with commonly available materials", or distinctive by the use of at least one indicator like e.g. a registered trademark, logo or pattern (21CFR211.132 (b)).

The FDA Compliance Policy Guide (CPG) 7132a.17, part of the current good manufacturing practice (cGMP), "Tamper-Resistant Packaging Requirements for Certain Over-the-Counter (OTC) Human Drug Products" indicates that these designs meet the requirements of 21CFR211.132 (see Figure 2):

1. Film Wrappers: Transparent film wrapped around the entire product that must be cut or torn to open the container and that employs an identifying characteristic.
2. Blister/ Strip packs: Dosage units individually sealed in clear plastic with foil or paper baking that must be broken or torn to obtain the product.

3. Bubble Pack: Product and container are sealed in plastic and mounted in or on a display card to be torn or broken to remove the product.

4. Heat shrink bands/ wrappers: Band or wrapper, heat shrunk applied to a portion of the container must be cut or torn to open the container and employing an identifying characteristic. The use of a perforated tear strip can enhance tamper-evidence.

5. Foil, Paper or Plastic Pouches: Sealed individual pouch that must be torn or broken to obtain the product.

6. Container inner mouth seal: Film, foil, or a combination thereof, sealed to the mouth of a container (e.g., bottle) under the cap that must be torn or broken. Polystyrene (PS) foam container mouth seal are not considered tamper-evident.

7. Tape seals: Rely on an adhesive to bond them to the package and are only considered capable as TE feature if an identifying characteristic that cannot be readily duplicated is employed.

8. Breakable Caps: Plastic or metal cap with a band that either breaks away completely when the cap is removed from the container or leaves part of the cap attached to the container.

9. Sealed metal tubes or plastic blind-end heat sealed tubes: Bottom of tube is heat sealed and mouth or blind-end must be punctured to obtain the product. Crimped ends can be used if they cannot be breached by unfolding and refolding without visible evidence of entry.

10. Aerosol containers: Tamper resistant by design with the preference of direct printing.

11. Metal and Composite Cans: Top and bottom must be joined to the can walls such that they cannot be pulled apart and reassembled without visible evidence of entry with the preference of direct printing.

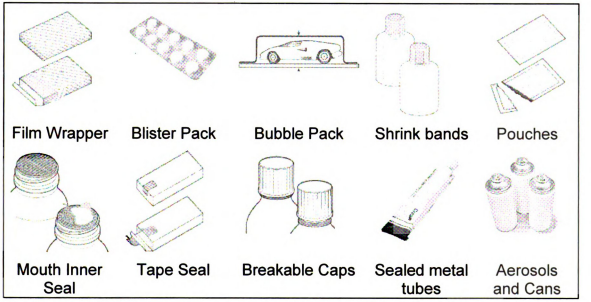

Figure 2. Packaging examples complying with the FDA TE requirements [47-50]

2.3.3 Milk

The requirement for tamper evidence has not been limited to drugs and alcohol. In January of 2006, the Center for Food Safety and Applied Nutrition (CFSAN) at FDA and the US Public Health Services (USPHS) began enforcing a requirement for tamper-evident packaging for plastic containers of fluid milk. Item 19p of the Grade "A" Pasteurized Milk Ordinance (Grade "A" PMO) states,

"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 regard to fluid product containers, removal cannot be made without detection."

A major driver for the TE requirement was the fact milk has the potential to serve as a vehicle of disease transmission and has, in the past, been associated with disease outbreaks of major proportions. Item 19p of the PMO "help(s) to assure the consumer that the milk and milk products have not been contaminated after packaging" [51].

2.4 Reactions of the Public: Post-tampering

As mentioned (2.1.3), a publicized tampering event is frequently followed by a surge in complaints for all types of products and copy-cat events. Complaints range from "strange-tasting items to swollen cans, discoloration or insect parts in packages" [13].

According to a consumer survey [30] conducted at Michigan State University shortly after the 1982 Tylenol Poisonings, 75% of respondents (n=270) believed that the new Anti-tampering regulation (21CFR 211.132) should also apply to food and beverage products (see also Figure 2 and 2.2 Research on Tampering). The FDA, however, did not go further in introducing TE features for food packages because of the much greater diversity of the food products as compared to those in the pharmaceutical sector [4]. Despite the fact that the regulation didn't apply to food packages, the food industry actively reviewed its packaging and recall procedures during this period of history. Many food companies voluntarily introduced TE packages in order to make their products less vulnerable to tampering [52], to protect their consumers and to shield themselves from liabilities associated with "foreseeable risks".

When the TE system requires information processing on the part of the consumer, companies have a duty to educate the consumer and to routinely warn them to inspect packages and tamper evident indicators before using the contents [9]. The theory is that "if consumers inspect their packages before use, incidents of injury from product tampering will decline" [8] when consumers notice that distinctive, tamper evident features are missing. When consumers are asked about TE systems, some suggest that they prefer TE packages and are "willing to pay slightly more" for "products that are resistant to tampering and have shelf-visible features" [30; 31].

Protecting consumers from potential tampering is not just the right thing to do in an ethical sense; it is also good business practice. Packaging must provide protection against foreseeable events under product liability laws [37]. Although, a federal product liability law doesn't exist, but the United States Department of Commerce has promulgated the Model Uniform Products Liability Act (MUPLA) for voluntary use by the states (for foreseeable risk see also [9]). Manufacturers and their insurers, however, favor one federal law that replaces the 50 state products liability laws [53].

In addition, a tampering event is often followed by great public scrutiny that can distress companies, who have to expend tremendous resources on a variety of things. Publicity causes a resurgence of consumer anxiety about product tampering and publicity surrounding legitimate cases of tampering is documented to encourage copycat incidents [7]. To prohibit unnecessary publicity, responsible reporting is crucial and begins with obtaining accurate information

[8]. In cases of extortion, the extortionists seek media attention to increase the pressure on the business. But the journalist's duty is to inform the public with precise information and should not be blinded by the willingness to create a story.

Heightened concerns for threats have resulted since the terrorist events of 9/11. To help companies facing a tampering threat, the Food Marketing Institute released an advisory guide [54], with step-by-step instructions regarding how to examine and deal with threats or possible hoaxes. In the time since, the Bioterrorism Act of 2002 was enacted. The intention of the Act was to improve the ability of the US to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act developed "a crisis communications and education strategy with respect to bioterrorist threats to the food supply" [55].

2.5 Evaluation Methods

An index developed by Jack Rosette and published as the "Rosette Protocol" is a tool for evaluating the effectiveness of TE features of a package [37]. He rates the factors that are involved in package tampering and detectability on a basis of their effectiveness. The test is constructed to serve both package suppliers and industry users. For the test at least three participants should be used for reliable results. The TE features of a package are then rated by:

- The knowledge level of the participant (violator),
- The TE feature material (how feature was reused, reproduced, or replaced),
- The quickest required time for a successful violation,

- The equipment used to violate the package and
- The visibility of the TE feature (determined by a panel of 3-5 people).

For the rating, one of the participants has to violate the package successfully. This is achieved if an inspector doesn't detect evidence of tampering. The inspector (e.g. manager, who leads the test) is given three packages, one of them violated. Out of these three, the violated package has to be identified within five minutes [37]. The test was carried out by the present researchers to rate the effectiveness of an aseptic puree packaged in plastic (see Appendix C, p. 89).

If a security feature isn't already present, the ASTM Standard F 1448 can provide guidance in determining a suitable security technology. The ASTM standard F 1448 is a "Guide for the Selection of Security Technology for the Protection against Counterfeiting, Alteration, Diversion, Duplication, Simulation, and Substitution (CADDSS) of Products or Documents" [56]. The guidance provides a procedure to accomplish the proper selection of a security system, and encompasses the six following steps:

- Define the CADDSS problem
- Determine requirements using the CADDSS matrix
- Compare the user's matrix and the technology matrix in order to make the appropriate technology selections
- Test for effectiveness (using a test such as the Rosette protocol, referenced above)
- Implement the technology

- Institute educational programs so that the technology is used effectively

This procedure can be repeated with every available technology and can be helpful in evaluating features of technologies available for use with the application. The guidance also assists in determining the requirements by completing the user's specific CADDSS versus parameters matrix included in the standard [56].

In this research a similar approach was done. A matrix was created to compare various commercial and incremental tamper evident solutions and their effectiveness against different tampering methods (see Appendix G Matrix Development, p. 105).

3 Literature Review: Identification and Analysis of Promising New and Established Technologies Relevant to TE

The market of security technologies specific to consumer products is flourishing, and many technologies have been developed as a result. The food industry, with its great diversity of products, is not regulated in terms of tamper-evident packaging and therefore needs more attention, because their products may be involved in "criminal activities such as tampering, relabeling, unauthorized diversion, and counterfeiting" [57]. This chapter includes a short introduction to technologies other than tamper evident technologies; some technologies discussed are commercially available at the time of writing, others require refinement and research prior to any implementation.

Securing the supply chain against threats is a comprehensive issue. Tools for enhanced security include: authenticators, anti theft tags, and track and trace technologies, as well as tamper evident packaging. Such tools make a package more intelligent. Intelligent packaging can sense and inform [58] and can be described as packaging containing external or internal indicators to provide information about the product and/or package [59]. Intelligent packaging has the potential to work on issues like product quality and safety, package integrity and tamper evidence. They can also serve as authenticators, anti-theft and track-and-trace technologies [59].

3.1 Authentication

Authenticators are tools or techniques that are used to verify that the packaged product is genuine, and sometimes provide the added benefit of being difficult to reproduce because of their complexity.

Authentication technologies are generally divided into three categories: overt, covert and forensic. Overt authentication features do not require special readers or detectors; they are perceptible in nature (generally visible) so that the general public can identify them. Examples include: embossed holograms or color changing inks as well as retroreflectives. Since Glaxo first used a tamper-evident hologram to seal packages of Zantac in 1989, holograms have been utilized frequently by the pharmaceutical and medical industry. They are used in the form of labels, seals, hot-stamped patches and blister-pack foils [60].

Covert authentication encompasses technologies "that are not readily apparent, but instead require a simple reader or verifier to detect" [61]. To notice UV ink, for instance, a UV lamp is required, while the detection of microprinting mandates a source of magnification. The most secure authentication features, however, are at the forensic level. They are extremely covert and provide information on a "need to know" basis. Forensic technologies include "unique Taggants or other imperceptible changes that require sophisticated equipment to read and recognize" [61].

3.2 Antitheft and Track-and-Trace

To prevent theft, retail shops currently employ electronic article surveillance (EAS) systems. EAS tags are particularly attractive for high-cost goods, such as cosmetics and electrical and entertainment products, and are not as common for food products [57]. They are attached to the product they are intended to protect and can set off an alarm, when the active device is passed through an EAS detection system. Current developments include anti-theft tags that can be directly integrated in the packaging material during manufacturing [62] or that are "paper-thin" and the size of a post stamp [59]. Built-in anti-theft tags also have the advantage that a possible thief can't visualize and remove them.

A study conducted by The Freedonia Group Inc., a Cleveland-based industrial market-research firm, suggests that the US smart-label industry, including EAS, RFID and interactive packaging labels, however, will no longer be dominated by EAS labels but rather by RFID and smart labels[1] ("Smart Labels", 2006). [64].

Radio frequency identification (RFID) surged in popularity after Walmart mandated RFID tags on the pallet level for its suppliers. RFID is a wireless automatic identification and data capture technology. RFID tags can be programmed with unique information for identification and tracking. An RFID tag can also include data about a product such as its color, size and model number and act as Electronic Product Code (EPC). Wal-Mart, which is already using

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[1] According to the 'Adhesives & Sealants Industry', smart labels include RFID, EAS and interactive packaging [63]

EPCs, states that an EPC is nothing more than an "electronic version of a bar code, but with greater capacity" [65]

With dropping cost for radio frequency identification tags, they can be the key to electronic item level track-and-trace packaging. "Traceability is the ability to track a product's flow or attributes throughout the production process and supply chain" [66]. Especially in cases of recalls or as anti-counterfeiting technology, item level tagging can be a solution.

3.3 Tamper evidence

As mentioned previously, tamper evident features are defined as 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 (21CFR211.132). Tamper evident features should be "distinctive by design" so that duplication is challenging. In other words, packaging that cannot be duplicated with commonly available materials or through commonly available processes. Examples include features with identifying characteristics (e.g., a pattern, name, registered trademark, logo or picture). Tamper evident packaging may involve an immediate container and closure system or secondary container or any combination thereof and provides a visual indication of package integrity. Features are designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution and retail display.

3.3.1 Current commercial solutions

Some technologies recommended by FDA that meet the requirements of 21CFR211.132 (TE for OTC products) (see 2.3.2) are also very common in the food industry. Shrink bands around the necks of tubs and breakable caps on bottles (e.g. milk or colas) are examples (see Figure 2, p. 26).

3.3.1.1 Closures

A two-piece, flip-top neck closure with two independent TE features, introduced by Bericap in 2007 for the vinegar market, is another example (see Figure 3).

Figure 3. Bericap Galileo II, 2-pieces flip top pourer closure [67]

To open the cap, the consumer must first break the over-cap seal before being able to remove the pull-up ring to break the second seal [68]. Another TE closure invention launched by Heinlein, Germany is the ONE LOOK®. After the first opening, four open windows on top of the closure change their color and snap into position. As a result, they cannot be moved back when the cap is retightened [69].

Fresh food products have been packed in tamper evident packages, like the "Safe-T-Fresh" design. The tear strip lock keeps the container leak resistant and

eliminates the need for shrink banding. After removing the strip, the container stays intact and is reclosable [70]. A similar technique for a tamper evident closure equips a molded plastic container with a manually removable tear band (see Figure 4). The band is constructed such that after tearing off the band, one side of the cap still remains attached to the container (see Figure 4) [71].

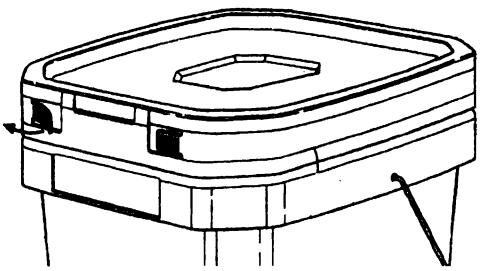

Figure 4. Tamper-evident container with tear band [71]

3.3.1.2 Labels, films and polymers

A tamper evident package patented by Rexham Corporation is the invention of a TE folding carton [72] with a "flagging device" incorporated in the carton (see Figure 5). The carton shows a message or a change in window color at the carton end if the flaps have been opened. A blank panel changes upon opening e.g. opened by the use of tamper indicating labeling materials.

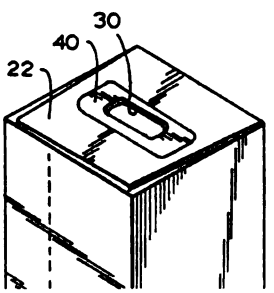

Figure 5. TE folding carton (22: front flap, 30: window, 40: tamper indicating seal)

A tamper evident label offered by 3M presents a "film that fractures when attempting label removal from many surfaces" [73]. The indication can appear as text or shape or just as destructible facestock.

As mentioned previously, printed overwrap film around a carton is used as tamper evident element (see Figure 2), but wrapping the entire product in printed film can increase the package price substantially. One solution to this is the use of preprinted tape, eliminating the need for preprinted overwrap film. The tape can also bear standard or custom holograms [74]. An easy tearing strip of film over the opening of a package can also serves as anti-counterfeit and tamper-evident attribute. The film retains its tensile strength and, therefore, is suitable for automatic processing but fragments if removal is attempted [75].

Resealable, flexible packaging has grown popular in recent years and these technologies can also provide tamper evidence. One example is the "Zip Pak" (Zip Pak: division of ITW) used by the manufacturers of fresh meat, dry and frozen food as well as pet food. A similar invention, with the same closing mechanism, is the "tamper-evident, reclosable flexible package" [76]. The package consists of an "inner, hermetic peel seal and a reclosure seal comprised of interlocking closure strips" as well as an outer peelable seal. The TE feature has to be visibly disrupted to gain access to the reclosable seal.

A new material manufactured by Evonik (Essen, Germany) utilizes a polymer compound called XT 375, which can be used in extruded, thermoformed and blow molded packages. This acrylic-based, multipolymer compound is advertised as having the ability to exhibit evidence of tampering such as tearing,

cutting, or needle pricking and seal integrity [77]. A test with the mentioned material showed a shift in color (transparent blue to opaque) around the hole that was drilled through the plastic plaque. A thermoformed tray, for example, can change from a transparent blue tint to a highly visible, opaque white in the location of a breach. Separating the lid stock from the tray also changes the optical properties of the thermoformed compound and makes seal separation evident by an apparent color change [77; 78].

3.3.1.3 RFID

Pliant Corporation offers a pallet-level solution for tamper evidence. Pliant has constructed a tamper evident, stretch film that utilizes silver ink (nanoparticles). This creates an electrically conductive trace that is embedded in the stretch film. The conductive trace is printed in two parallel lines, 1 to 1.5 inches wide and 6 inches apart. After the load is fully unitized, the end points of the conductive trace are attached with a conductive adhesive, creating a circuit to which a battery-powered circuit board is electrically connected that contains a passive EPC Gen 2 tag. The GEN2 tag is only readable when the circuit is intact. As such, an unreadable tag becomes an indicator of possible tampering [79].

Like the Pliant solution, manufacturer MIKOH also uses an RFID tag to detect tampering. Smart&Secure™ is a physical security technology for RFID tags that detects tampering or rather the removal of the tag. MIKOH offers two configurations, differing from each other in their price and construction. The simpler feature detects tampering, when the tag is deactivated and the more

expensive configuration continues to operate after tampering, but alerts the next reader that it has been tampered with. The TE feature is a "tamper-release layer", printed next to the conductive ink antenna layer, causing the antenna to break when the tag is removed [80]. Breakage of the TE layer is guarantee by a special multi-layer adhesive design. The tag can be used to seal a single product, e.g. its opening or even a whole case.

3.3.2 Commercially available incremental systems

Some technologies are commercially available, but require modifications to be effectively employed as tamper evident packaging solutions.

The company ArjoWiggins, a leading banknote manufacturer, developed a synthetic tamper evident security substrate (STES), which is susceptible to delamination. A tampering attempt will delaminate the facestock (biaxially oriented film of HDPE), making repositioning and reuse impossible [81].

3.3.2.1 Dyes and inks

Other technologies have the potential to be used in a TE fashion, but require further refinement or research before doing so. One such technology incorporates a mix of conventional polymers and small amounts of tailored, fluorescent dyes. The dyes function as "natural molecular sensors, creating light-emitting polymer blends" that show mechanical stress like tearing, pin-holing or deformation of the formed polymer container by changing their color of the fluorescence. For example, the fluorescence of the package might change from orange to green or from yellow to blue after being exposed to the mechanical

stresses induced by tampering. This technology is covert, because an ultraviolet light is required to detect the change. The amount of fluorescent dyes added to the resin is 0.2 percent, similar to the quantity of additives such as ultraviolet stabilizers or antioxidants. This development, led by Christoph Weder at Case Western Reserve University, has been indicated not change the polymer's characteristics [82; 83].

Another indicator is the Food Sentinel System® by SIRA Technologies (Pasadena, US). The indicator is a barcode that is printed with irreversible thermochromic ink, turning the barcode into a time temperature integrator (TTI) [84; 85]. The thermochromic ink barcode is coupled with a standard ink barcode and becomes unreadable after the thermochromic ink is exposed to a temperature change. This activates the thermochromic ink and results in a thermally-induced color change. Changes in the ink could make this technology a tamper-evident feature. Consider, for instance, if the ink were formulated to detect oxygen at a certain level. By printing with this ink inside the package behind the barcode, exposure to oxygen could render the barcode unreadable. A label containing a gas-sensitive dye has already been designed, where different gas concentrations lead to different colors. The label could e.g. be inserted into a carbon dioxide flushed package and would detect the decline of the carbon dioxide content if the dye color changes from blue to a permanent yellow [84].

3.3.2.2 Gas Detectors

Ageless Eye, a product of the Mitsubishi Gas Chemical Corporation, is an oxygen indicating sachet, which includes an oxygen sensitive tablet [84]. In the

absence of oxygen, the tablet has a pink color (≤ 0.1 %) and turns blue after about 5 minutes of exposure to oxygen (≥ 0.5 %) [86].

Similar technologies exist to measure the carbon dioxide level inside a package. Although these detectors have the potential to measure CO_2 and are used to do so in modified atmosphere packages that have been flushed with carbon dioxide, [84] and offer a potential technology for TE, some products could be problematic if this approach were employed. Many perishable products respire, resulting in the production of carbon dioxide. The release of carbon dioxide could lead to false positives of TE indicators based on this type of approach, as such, the usage of such indicators needs careful consideration.

A fluorescence-based oxygen sensor, called OxySentry by OxySense, Inc (Dallas, TX) is an oxygen monitoring and control system for modified atmosphere packaging (MAP) [87]. It consists of a control unit and a passive oxygen sensor based on the "fluorescence quenching of a dye immobilized in a gas permeable hydrophobic polymer" [88]. The presence of oxygen results in a change in the emitted intensity of the dye. In this case, the control system analyzes the optical signal of the passive oxygen sensor and converts the signal into oxygen concentration data. The OxySense system could be used as TE technology, if the package that needs to be secured doesn't contain of oxygen in the headspace. The detection of violation can then possibly be determined by changes in the oxygen content of the packages headspace gas. An oxygen sensor present in the headspace would trigger when air from the atmosphere made contact with the sensor if the package was destroyed. However, this

technology would need a separate control unit to check the passive detector, and at least semi-transparent package and also depends on the oxygen variation of the packaged product (see 5 Characterizing the product: Headspace Analysis). Nevertheless, a control unit could be directly integrated in the check-out system at the retailer.

3.3.2.3 Biobased Sensors

A commercially available solution for the detection of pathogens, Toxin Guard, has the potential to be modified as a tamper evident indicator. This diagnostic system detects pathogenic bacteria in food and indicates them by displaying a visual signal to alert the consumer. When the bacterial toxin is in contact with the immobilized antibodies integrated into the packaging material, it will be bound to these antibodies, which are then identified by a printed characteristic pattern. The Toxin Guard test is printed on polyethylene-based packaging material and can be used for detecting freshness degradation, the presence of specific food hazards, pesticides, or indicators of genetic modification [84; 89].

3.3.3 Potential "leap" solutions

Leap technologies are ideas for tamper evidence that will require significant effort to make them commercially feasible.

Solutions suggested by Food Science Australia utilize a visible change of color to alert consumers to potential product tampering that is triggered from the photochemical oxidation that occurs in the presence of light and air reacting with

the red-colored flexible film used as package. The technology acts like the bruising of an apple and is a form of intelligent packaging. [90].

Newly developed by scientists at the University of Southampton (UK) and the Deutsches Kunststoff-Institut (DKI) (Darmstadt, Germany), is a color changing film based on photonic crystals. This film is a "class of photonic crystals that change color in various chemical conditions" [91]. It is made of arrays of spheres that reflect the light and also contains tiny carbon nanoparticles wedged between the spheres that scatter off the light.

Putting nanotechnology "fingerprints" into products is a new method that can be applied to (drug) packages or the pills themselves (see Draft Guidance for Industry on "Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting" [92]). Nanoscale materials can be embedded to distinguish the medicines from counterfeits or to detect hazardous material such as bacteria. For the package, nanomarkers are mixed with inks or coatings that change color and are applied onto labels, cartons or closure seals. The markers can also be highlighted by shining an ultraviolet ray on the package. For a single pill, the markers are added to the components and confirmed by "simple field-testing kits" [93].

Nanotechnology can also be used inside fibers or garments embedding magnetic nanoparticles to "create a unique but invisible signature". Remarkable fibers are potentially capable of filtering out viruses, bacteria, and hazardous particles. Fabricating a textile that could look like a sponge and act as a sensor could detect the presence of hazardous bacteria by wiping the surface of the

product. If a contaminant is detected, the fibers would capture it and alert the user by changing color or becoming fluorescent [94].

Since the use of radio frequency identification (RFID) technology is increasing [64], there are also possibilities of connecting oxygen and pressure sensors with RFID tags. RFID-based sensors can be micro-sized and enable the storage of data during shipping. One method for the detection of oxygen could be the integration of an oxygen sensitive conducting polymer incorporated in a RFID tag. Changes in the packages pressure due to tampering could be detected with MEMS-based (Micro-Electro-Mechanical System) pressure sensors that are also integrated in a RFID tag.

4 Focus group

A focus group is a small group of people discussing a specific topic and whose response is studied to "determine the response that can be expected from a larger population" [95]. To garner insights regarding the topic of package tampering, a focus group was conducted in accordance with procedures approved under IRB 09-225 (see Appendix D). The focus group was conducted on the campus of Michigan State University and consisted of subject-matter experts in the areas of packaging, food processing and manufacturing.

4.1 Focus Group characterization

A group of Michigan State University faculty, involved in packaging, food industry representatives and students was composed for a single session. The group of nine participants, aged 21 to 80, shared their experiences and attitudes related to tampering (see Appendix F. Data Collection Sheet and Results).

Three of the nine participants were students in their senior year at School of Packaging and one student was in the graduate program of the biosystems engineering department at the time of the meeting (1 female, 3 male; average age, 22.5 years; SD, 1.3 years).

The group had notably different backgrounds with regard to tampering incidents and tamper evident packaging (3 female, 6 male; average age, 36.4 years; SD, 21.4 years, two ages missing; see Table 1, p. 48).

One of the packaging students mentioned his awareness of the issue of product tampering comes from the media. Another packaging student stated that his parents warned him to examine Halloween candy, and he also worked on a study where tamper-evident research was involved. Most participants mentioned that they had heard of, or were actively engaged in issues regarding the Tylenol tampering. One participant, a former professor at the School of Packaging, was working on research regarding tampering in 1982, when the Chicago poisonings occurred. He presented to the media at that time, and that his experience suggested that even a "knowledgeable lab technician with a background on tampering can be fooled". His feeling was also that peoples' overall knowledge about tampering is limited. Another faculty member participating in the focus group had conducted his Master's research in tampering and consumer awareness in the early 1990s. As such, he too, was familiar with the history of tampering, regulations, tamper evident features and the techniques that have been used. Yet another member of the focus group represented the company for the studied product. She indicated experience with glass and poison in a packaged product and addressed the importance of tamper evident features and the need of a company to be a good steward by addressing such issues. Faculty working with packaging stated their awareness of the Tylenol incident. One of them taught a class during the Tylenol incident, where students did a series of projects; one group focusing on consumer education. That mentioned, he stated that the understanding of tampering for average consumer is limited and that

Halloween candy provided to children within the household are inspected for breaks in the wrapper.

Table 1. Focus group panelist's background on tampering

Gender	Age	Background with regard to tampering
Male	80	Performed research at the School of Packaging in 1982 when the Chicago poisonings occurred. This created the 1st National presence of the issue and a media and public frenzy. Happened again in 1986. Asked "Could a knowledgeable lab technician with a background be fooled? Answered yes. Feels people don't know much about tampering.
Male	22	Tylenol
Male	43	MS Thesis focused on tampering of packaging.
Male	23	Parents warned to examine Halloween candy. Performed a study of the OneTouch pharmaceutical strips.
Female	42	Has experience with tampered products such as glass and ricin in product. Addresses the importance for a company to be a good steward by addressing the issues. Is familiar with a 2004 tampering incident and a recent unsubstantiated internet threat from a blogger
Female	24	Aware of the Tylenol poisonings and of tampering in pharmaceuticals.
Male	21	His awareness of the issue comes from the media.
Female	-	Aware of the Tylenol Incident
Male	-	Mentions that Halloween candy provided to children within household are inspected for breaks in wrapper. But the sensitivity to tampering is not very high. During the Tylenol incident, he taught a class, where students did a series of projects; one group focused on consumer education. He doesn't believe that the average consumer understands the issue.

4.2 Procedure

Before the beginning of the focus group, consent forms, approved under IRB 09-225/ APP# i032704, were signed and collected (see Appendix E.

Consent Form Consent Form). The focus group lasted about two hours and a half and participants were asked a series of questions from an IRB approved moderator guide (see Appendix D, p. 93) about product tampering. During the session, researchers took notes.

As a warm-up activity, participants were asked to introduce themselves and provide the group with any background or experiences that they had had with tampered products or tamper evident packaging. Following the initial warm-up, a series of questions were introduced to establish the group's baseline understanding of the state-of-the-art in tamper evidency.

After approximately 30 minutes of discussion around the guided questions, the group was split into pairs; each pair was moved to varied locations that were isolated from other groups. Each pair was provided with: • basic household tools, • the food product, a plastic, aseptically processed puree and • a liquid (sports drink), • solid (bbs) and • powder (a powdered juice drink). Participants were tasked with four objectives for this portion of the focus group: (1) to find the least detectable way to introduce the solid (bbs) (2) to find the least detectable way to introduce the powder (a single serving drink mix) (3) to find the least detectable way to introduce the liquid (a brightly colored energy drink), and, finally (4) to find the most ways to get into the packages provided. One hour was allotted and then the group was reconvened.

After reconvening the group, they discussed the methods they used to introduce the solid, powder and liquid into the provided product. The debriefing

lasted about 20 minutes followed by general questions about tamper evident packaging features.

4.3 Background and experiences of participants

In order to benchmark current protective features of a given product and derive insights into the full range of techniques that might be attempted to tamper this product, a group of experts was recruited for the focus group. The fundamental principle of the concept was that people with significant backgrounds in packaging, food production and tampering would provide rich insights into the techniques that could be used by the general public with regard to tampering.

Using the moderator guide, the focus group moderator led the group in discussion around a series of questions related to tampering (see Appendix D).

- What comes to your mind when you hear the phrase "tamper evident" packaging?

When asked for their thoughts and impressions on the phrase "tamper evident packaging", one group member mentioned, "things" that are put into place to help the consumers to identify whether or not tampering has possibly occurred. Another theme that emerged as a result of this question was that it was the consumers' responsibility to check for intact tamper evident packaging. A recurrent theme with this question and others was that the involvement of the consumers in recognizing tampering should be minimized.

Discussing the terms "tamper evident" and "tamper resistant" revealed that everyone had heard both terms, but did not necessarily know the differences between them. One former faculty member indicated that although the names were changed in the laws and regulations, the employed technologies were not (see 2.3 Government Reaction to Tampering - US Legislation and Regulation). He felt that the terminology change was largely a marketing move on the part of the OTC industry to say that they are making things evident as opposed to resistant. Following the discussion of the two terms, the participants were asked for their knowledge about their difference. In conclusion, one team member came up with the following definitions:

Table 2. Definition of "tamper evident" and "tamper resistant"

Tamper evident	How obvious something is once tampered
Tamper resistant	How difficult something is to tamper

- How would a consumer know if a product has been tampered?

To explore the self reported behaviors of these individuals, we asked them about whether or not they had ever knowingly consumed a product that showed potential signs of tampering (e.g. a popped seal). Because all participants were selected as subject matter experts from three areas (packaging, food processing or manufacturing), it was expected that they were sensitized to the issues and outcomes associated with product tampering as well as the packaging features employed to mitigate or detect it. Nevertheless, the group consensus was that thorough observation of the package before consumption doesn't always happen.

Additionally, several members of the group indicated that even when they do notice something is awry (e.g. a missing induction seal), that they would frequently not want to be troubled by taking the product back to the store. Further discussion revealed that at least two group members had rationalized incomplete seals or tears as production problems or damage and consumed a product that they thought would be safe anyway (e.g. mustard, cereal). They also expressed that they further rationalized the consumption of the questionable goods with thoughts related to the fact that a fatal tampering would not happen to them and that they were extremely rare.

When asked about the regulations and requirements for tamper evident features, limited participants discussed food products, which are, with the noted exceptions of milk and alcohol, not required to have tamper evident features in the US (see 2.3, p. 20). Discussion then moved to pharmaceuticals, specifically OTC drugs.

As previously discussed, OTCs are required to have at least one tamper evident feature and their packages are required to be prominently labeled so that the product is not consumed in the event that the feature is not intact. A broken feature should therefore be visible to the consumer, so the consumer knows if a product has been tampered. For the package (category: blister with glued paperboard wrap) that was used as "tampering object", the observation was made that when the blister was squeezed and the lidstock bulged, tampering could be detected when the sound of gas escaping was heard. Participants were asked about their familiarity with tamper evident features. The group provided a

list of commonly used technologies which included: shrink bands and sleeves, printed foils over seals, induction seals, tear tapes (e.g. with color that sticks and won't go when removed) and jars with vacuum up closures.

4.4 Reactions

The general consensus of the group was that a tamper evident technology generally has to be detected by the consumer in order to work. However, as noted previously, several group members (of this sensitized team) had admitted that they had ignored or completely disregarded products with broken or missing TE features due to rationalization (it won't happen to me) or laziness (I don't want to hassle with taking this back and I need to use it).

During the experimental phase of the focus group (1 hour), the different teams were tasked with tampering a specific package with the common tools provided by the research team. The group felt that they were able to adequately tamper numerous packages in less than an hour, and felt that it was highly unlikely that their work would be detected. The importance of a tamper evident device on a food package was discussed, and the group expressed the importance of TE features, not only for the consumer, but also for the brand. Any injury or fatality is devastating to the brand, but TE solutions also need to strike a balance, as they can't be too costly. Nevertheless, for manufacturers it is important to comply and to show an effort is made to protect the consumer.

As discussion around the guided questions continued, one of the recurrent themes that emerged from the group was that tamper evident designs should

minimize the need for consumer intervention, and that tamper evident strategies should use the consumer as a "last step." Several members mentioned the possibility of auto-identification technologies as tamper evident strategies. Specifically discussed was the strategy of blocking the bar code if a package is tampered so as to render it "unscanable" and, thus, "unsalable". The group further discussed the idea of rendering the bar code "unscanable" at purchase in order to prevent items from being purchased, tampered and then returned.

Focus group results suggest that a layered approach to tamper evidence, which does not rely solely on the consumer, is warranted. Not every consumer attends to the employed tamper evidence features and, even when attended, at least occasionally, they are disregarded. Technologies which can leverage auto identification or the development of smart materials or sensors are further recommended (see also 3.2 Antitheft and Track-and-Trace).

5 Characterizing the product: Headspace Analysis

Headspace gas analysis was conducted to evaluate the headspace gas from samples of the same product used in the focus group analysis. The product headspace gases were tested at beginning and end of shelf life at three levels of tampering. The levels of tampering, which were informed by focus group findings were: lid removal, syringe, and control (no tampering). The purpose of the analysis was to characterize the amount of two gases: oxygen and carbon dioxide of tampered and untampered product. This was done with the purpose of exploring the feasibility of gas-based detection as a way to detect tampering of two extremes. The researcher asked whether or not a gas-based sensor could be developed that would identify leaks or possible tampering attempts that did not result in false positives. Understanding the inherent variation of these gases is necessary in order to develop such a sensor.

Four different kinds of purees were chosen for the analysis; Applesauce, Bananas, Green Beans and Prunes. A gas chromatograph (TraceGC Ultra, ThermoScientific) was employed to analyze headspace data. Initial tests and calibration of the gas chromatograph (GC) was necessary for accurate and precise measurement of the two gases (see 5.2).

5.1 Gas Chromatograph Trace GC Ultra

The gas chromatograph "TraceGC Ultra" (Manufacturer: ThermoScientific) was used to measure the oxygen and carbon dioxide content in the headspace of

the four different purees. The gas chromatograph (GC) is equipped with a thermal conductivity detector (TCD) and a Carboxen 1010 GC Plot Capillary Column (Manufacturer: Supelco) and uses helium as carrier gas. The porous layer open tubular (PLOT) column that is used as a stationary phase is a type of packed column. This column is more effective in separating oxygen and nitrogen, because its pore structure is larger than other columns and can be used up to temperatures of 250 °C [96].

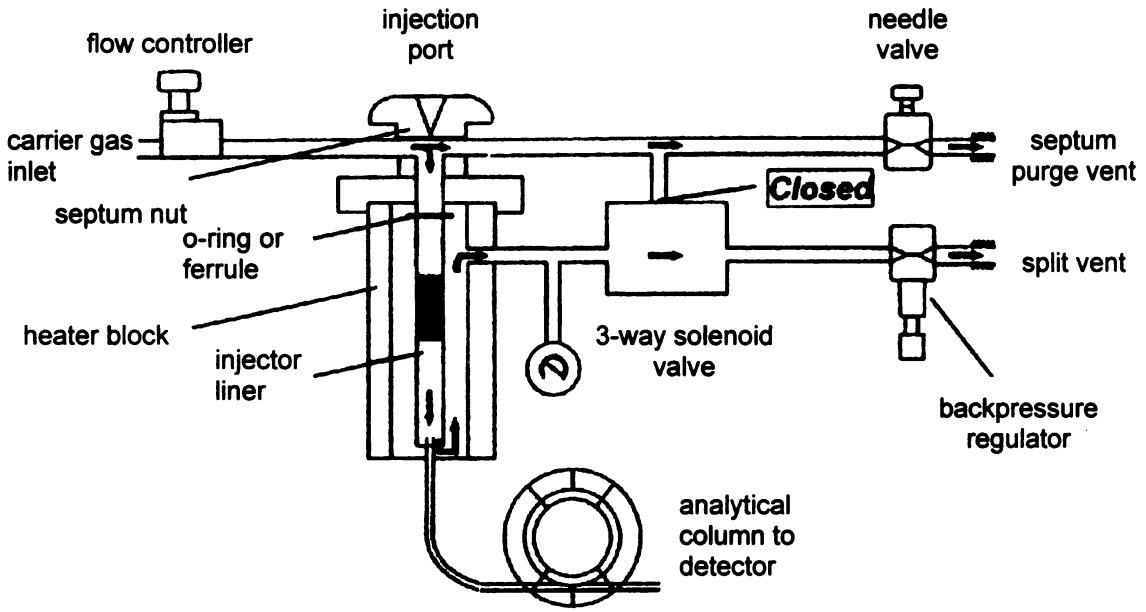

Figure 6. Diagram of GC flows for split injection [97]

The GC injector, which is attached with a nut to the heater block (see Figure 6), consists of an inlet tube for the carrier gas, the heater block to maintain the injector temperature, an inlet (injector) liner, a septum, a septum nut, outlet tubing and a fitting to hold the column in place. The carrier gas is introduced to the head of the column into an unpacked open space above the restraining frit and beneath the septum. The septum seals the top of the column through which the

syringe needle is inserted. The most common way of introducing a sample into a GC is with a syringe. The GC needle needs to be very narrow in order to not destroy the septum disc and to minimize the volume of sample remaining in the syringe. For the injection of the headspace gas as well as the gases for the calibration, a gas tight syringe (1MDR-V-GT, Manufacturer: SGE) with a maximum volume of 1 ml was used. The detector analyzing the gases is a thermal conductivity detector (TCD), which is generally the least sensitive detector, but applied for the analysis of permanent gases [97]. The TCD responds to differences in thermal conductivity of analytes in comparison to a carrier gas, helium, which is highly thermally conductive. The high thermal conductivity of the carrier gas allows the detection of most compounds, which are less thermally conductive. The presence of even a small amount of analyte reduces the thermal conductivity significantly and, thus, the filament with a constantly applied voltage will decrease in thermal conductivity (or increase in resistance), changing the temperature of the detector. This change in conductivity gives a signal which is then represented in the chromatogram [98].

For the instrument method, different modes of injections are available; split and splitless injections. The split injection method (see Figure 6) is used for the analysis. The main purpose of this injection method is to reduce the amount of sample that is injected onto the column. Split ratios can be "as high as 1000 to 1" and were set here to a ratio of 30 to 1. The split ratio refers to the ratio of the gas flow through the inlet versus the gas flow that goes through the column [98]. For

this study, the gas flow was held constant at a flow of 3 ml/min and with a split ratio of 30, resulting in a split flow of 90 ml/min.

5.2 Calibration

To calibrate the GC, different percentages of each gas were injected in order to obtain a calibration curve for each gas of interest (O_2 and CO_2) (see Table 3). The amount of gas injected is limited to 100 µl, because initial tests showed that an injection of >100 µl resulted in overlapping of peaks. For the calibration the following concentrations of each gas were used:

Table 3. Calibration gas concentrations

Oxygen	0%	5%	30%	50%	100%
Carbon dioxide	0%	5%	30%	50%	100%

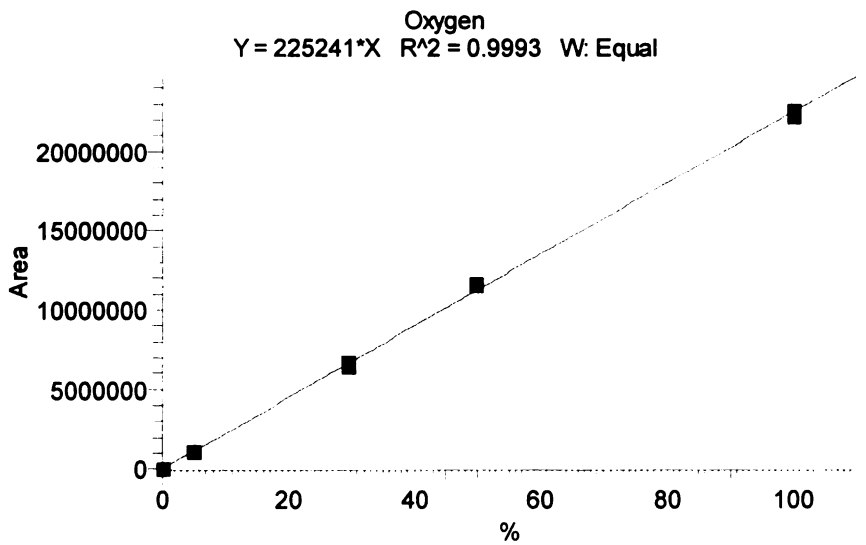

Figure 7. Calibration Curve: Oxygen

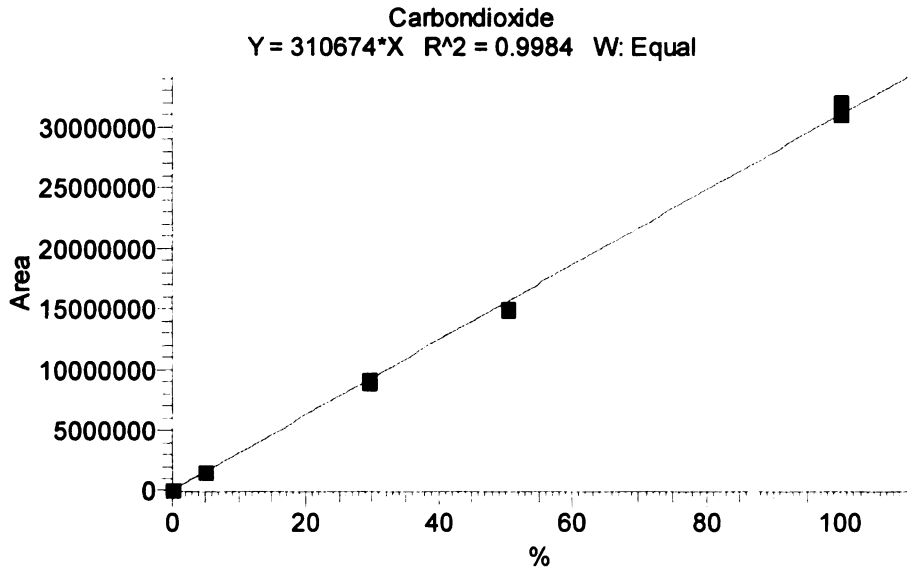

Figure 8. Calibration Curve: Carbon dioxide

The R-Value, or correlation coefficient, of the curve is the quantitative value of the calibration curve and computed as the fraction of the total variation of the Y values of data points that is attributable to the assumed model curve. Possible values of R lie between 0 and 1, with 1 indicating the best fit. In this case, correlation coefficient, or R-value, was 0.9975 or greater with a forced origin (see Figure 7 for oxygen and Figure 8 for carbon dioxide).

5.3 Materials and Methods

The purees tested with this experiment were aseptically packaged in a multilayer plastic cup that incorporated an oxygen barrier layer. The defined oxygen transmission rate (OTR) of the molded container was 0.006 cc/package/day. The cup is sealed with a high barrier lid which contained a layer of aluminum. The labeled net-contents, by volume, were 2.5 oz for Applesauce, Green Beans and Prunes and 3.5 oz for Banana puree. The approximate

headspace volume of the purees was approximately 28 ccs, depending on the density of the product. The area of puree in contact with the headspace was approximately 35 cm^2. The maximum amount of oxygen expected for all purees at its 'beginning of shelf life' stage was expected to be ≤2% based on specifications provided by the product manufacturer. It is likely that oxygen content can increase with shelf life, due to permeation.

Each puree type (four levels) was tested at the beginning and the end of shelf life (see Appendix H. Details of tested product, Raw Data, p. 107). Additional factors that were investigated included "tampering method" at three levels, either 'lid removal' or 'syringe' or no tampering (see Figure 9, p. 61). For the "tampered samples", tampering was either conducted three weeks before testing (delayed) or immediately preceding the analysis of headspace gas (i.e. the same day). All samples selected for the first tampering method were tampered by peeling back the lid halfway and exposing the contents for 30s (+/- 3s) so that the headspace was exposed to the ambient air. Afterwards, the lid was secured again to ensure a closed environment. The samples for the second tampering method were tampered by puncturing the cup wall in the headspace area with the needle of a sterile syringe. Nothing was injected or removed from the headspace, and immediately after puncturing the puncture point was closed. The rationale for the two methods was that they represented extremes in exposure conditions. In contrast to the 'lid removal', the syringe provided the product with a relatively modest exposure to the ambient environment. After every tampering process, the package was gently squeezed to ensure that the lidstock was properly

resecured. Each treatment was repeated three times (triplicates, n = 3) (see Figure 9). Thus, the total number of samples tested was n=120. Run order was randomized across all treatments.

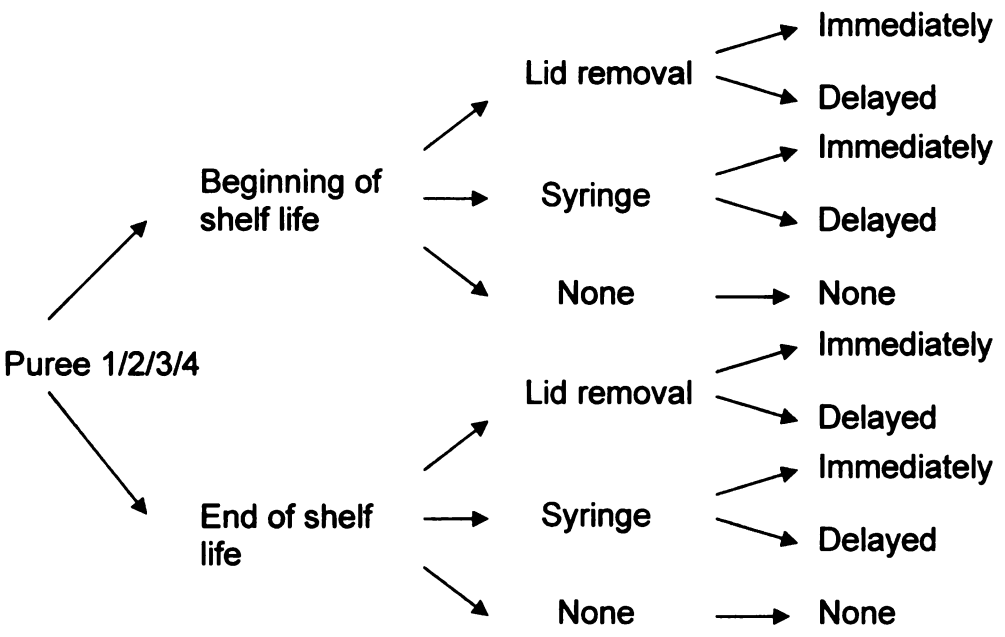

Figure 9. Sample characterization

The dependent variables of interest, oxygen and carbon dioxide content of the headspace, were assayed by gas chromatography (GC; TraceGC Ultra, ThermoScientific; Milan, Italy) using split injection (see 5.1) and a 7 Å PLOT column under the following GC conditions: oven temperature 35°C to 190°C at 25 °C/min.; detector 200°C; injector 125°C. Aliquots of 100 µl were withdrawn using a gas-tight syringe (1MDR-V-GT, SGE; Victoria, Australia) from the headspace of the purees via a rubber septum (Illinois Instruments, Johnsburg, IL) fitted to the composite film (lid of container) in order to eliminate the entry of air into the package.

Statistical analysis

The data obtained were statistically analyzed using a two-way analysis of variance (ANOVA) in a mixed model with the Statistical Analysis System (SAS) software (SAS Institute, Cary, NC). The objective of the analysis was to investigate the effect of tampering on headspace gas concentration (see also 5.4 Null hypotheses) at a confidence level of 95%. Significant two-way interactions represent differences of Least Squares Means. The normality assumption was checked with 'proc univariate' using normal plots (visual assessment) and the equality of variances assumption was checked with 'proc sort' using side-by-side box plots (visual assessment). The responses, oxygen and carbon dioxide, were analyzed separately with unequal variances in the broad model (see 5.5.1) and the narrow one (see 5.5.2). The broad scope analysis accords the factor 'sample type' as a random factor, because the purees were not chosen with great intent, but due to their availability. However, within the available purees there was an objective to include both fruit and vegetable purees. Therefore, the data was also analyzed in a narrow scope according 'sample type' as a fixed effect.

5.4 Null hypotheses

Researchers tested the following null hypotheses:

- There is no effect of tampering method (lid removal, syringe, no tampering) on the headspace gas concentration (O_2, CO_2)
- There is no effect of tampering time (delayed and immediate test) on the headspace gas concentration (O_2, CO_2)

- There is no effect of sample type (applesauce, green beans, prunes and bananas) on the headspace gas concentration (O_2, CO_2) and
- There is no effect of expiration date (beginning of shelf life and end of shelf life) on the headspace gas concentration (O_2, CO_2)

5.5 Results and analysis

For each treatment, triplicates were tested and descriptive statistics were calculated (see Table 5, for raw data see Appendix H)

Table 4. Legend for Headspace Tables and Graphs

A:	Applesauce	**P:**	Prunes
G:	Green Beans	**B:**	Bananas
SL:	Shelf life	**Beg:**	Beginning of shelf life
		End:	End of shelf life
T:	Tampered	**NT:**	Not tampered
LR:	Lid removal	**Syr:**	Syringe
Delay:	Tested after 3 weeks	**Imm:**	Immediate testing

Table 5. Headspace Gas Data for O_2 and CO_2

Abbreviation Label	Average O2	Std.Dev O2	Average CO2	Std.Dev CO2
A, SL: Beg, T: LR, Delay	7.3	5.1	4.2	1.1
A, SL: Beg, T: LR, Imm.	14.2	11.3	1.9	1.7
A, SL: Beg, T: Syr, Delay	0.3	0.6	4.2	0.3
A, SL: Beg, T: Syr, Imm.	0.7	0.4	4.1	0.1
A, SL: Beg, NT	0.6	0.8	4.0	0.4
A, SL: End, T: LR, Delay	8.9	8.0	4.6	3.4
A, SL: End, T: LR, Imm.	19.7	1.0	2.2	0.3
A, SL: End, T: Syr, Delay	0.3	0.2	7.1	0.3
A, SL: End, T: Syr, Imm.	0.1	0.2	7.2	0.3
A, SL: End, NT	1.1	0.6	6.8	0.2
G, SL: Beg, T: LR, Delay	5.6	1.0	5.4	0.6
G, SL: Beg, T: LR, Imm.	15.5	2.3	3.1	1.0
G, SL: Beg, T: Syr, Delay	0.9	0.8	4.5	0.3
G, SL: Beg, T: Syr, Imm.	1.2	0.8	4.2	0.4
G, SL: Beg, NT	0.6	0.6	4.3	0.3
G, SL: End, T: LR, Delay	18.4	2.5	0.7	0.4
G, SL: End, T: LR, Imm.	21.2	0.6	1.9	1.1
G, SL: End, T: Syr, Delay	0.1	0.2	4.9	0.1
G, SL: End, T: Syr, Imm.	0.5	0.8	4.8	0.3
G, SL: End, NT	0.4	0.4	4.7	0.2
P, SL: Beg, T: LR, Delay	8.8	2.1	2.5	0.2
P, SL: Beg, T: LR, Imm.	19.8	1.4	0.7	0.1
P, SL: Beg, T: Syr, Delay	3.6	5.8	2.0	0.3
P, SL: Beg, T: Syr, Imm.	0.6	1.0	2.2	0.1
P, SL: Beg, NT	0.5	0.6	2.2	0.1
P, SL: End, T: LR, Delay	10.7	4.5	2.7	0.8
P, SL: End, T: LR, Imm.	20.3	0.5	1.0	0.3
P, SL: End, T: Syr, Delay	0.4	0.8	3.5	0.4

				Table 5. cont.
P, SL: End, T: Syr, Imm.	0.0	0.0	3.5	0.1
P, SL: End, NT	0.4	0.7	3.7	0.3
B, SL: Beg, T: LR, Delay	7.1	9.8	7.0	2.9
B, SL: Beg, T: LR, Imm.	19.4	1.8	1.2	0.3
B, SL: Beg, T: Syr, Delay	0.2	0.3	3.6	0.1
B, SL: Beg, T: Syr, Imm.	0.0	0.0	3.8	0.4
B, SL: Beg, NT	1.1	0.5	3.3	0.5
B, SL: End, T: LR, Delay	12.8	9.6	5.1	4.9
B, SL: End, T: LR, Imm.	15.9	4.1	4.1	1.7
B, SL: End, T: Syr, Delay	1.0	0.9	8.6	0.7
B, SL: End, T: Syr, Imm.	0.6	0.7	8.9	0.4
B, SL: End, NT	0.3	0.6	8.2	0.5

Figure 10 depicts the average and standard errors associated with oxygen and carbon dioxide concentrations for each treatment combination. Graphs for each type of puree are presented in the Appendix (Appendix H, p. 107).

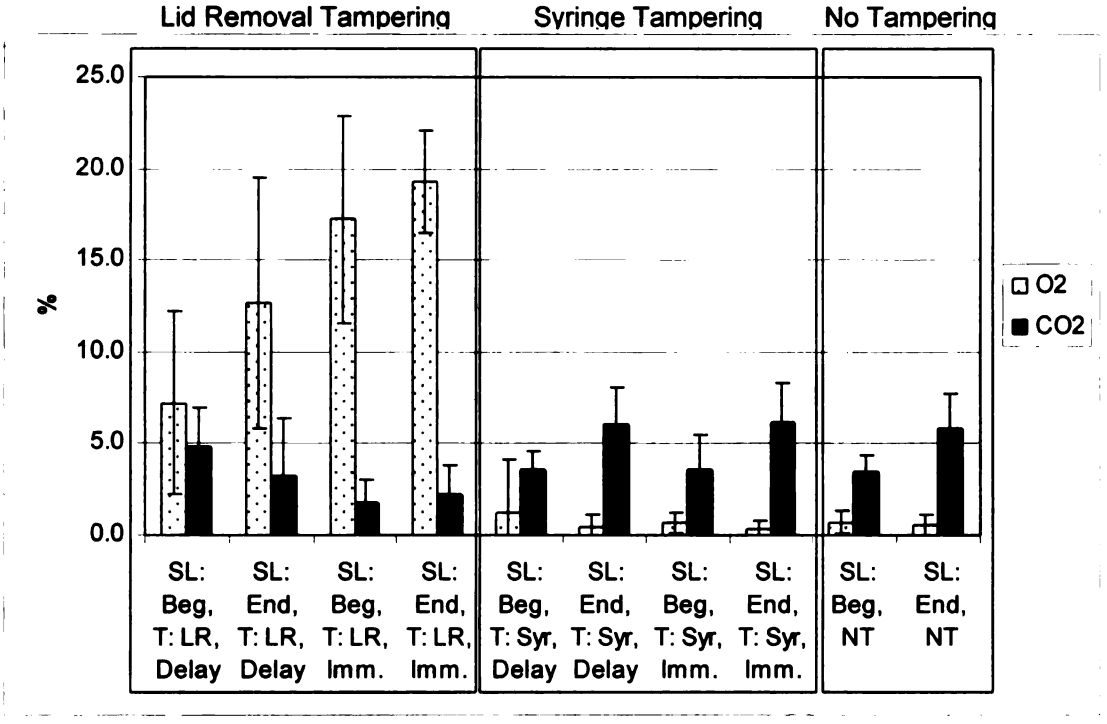

Figure 10. Comparison of oxygen and carbon dioxide concentrations (means of all puree types) for each tampering method per shelf life stage and tampering time (if available)

Two dependent variables, percentage of oxygen and percentage of carbon dioxide, were analyzed using the broad model and the narrow one.

5.5.1 Broad Scope

5.5.1.1 Oxygen

The mixed model design 'Broad scope' treated oxygen as the response variable (dependent variable), 'Sample Type' as a random effect and the following factors as fixed effects:

- Expiration Date (beginning of shelf life and end of shelf life)
- Tampering Method (lid removal, syringe, no tampering)
- Tampering Time (samples tested immediately and 21 days after tampering)
- Expiration Date x Tampering Method
- Expiration Date x Tampering Time
- Tampering Method x Tampering Time
- Expiration Date x Tampering Method x Tampering Time

The first analysis of oxygen content provided no evidence to support significance in any three-way interaction, and only one significant two-way interaction, 'Tampering Method x Tampering Time' ($p<0.0001$) (see Figure 11). The factors 'Tampering Method' ($p<0.01$) and 'Tampering Time' ($p<0.05$) indicated a significant effect at $\alpha= 0.05$. The factor 'Expiration Date' did not provide evidence of a significant effect on the percentage of oxygen as a response.

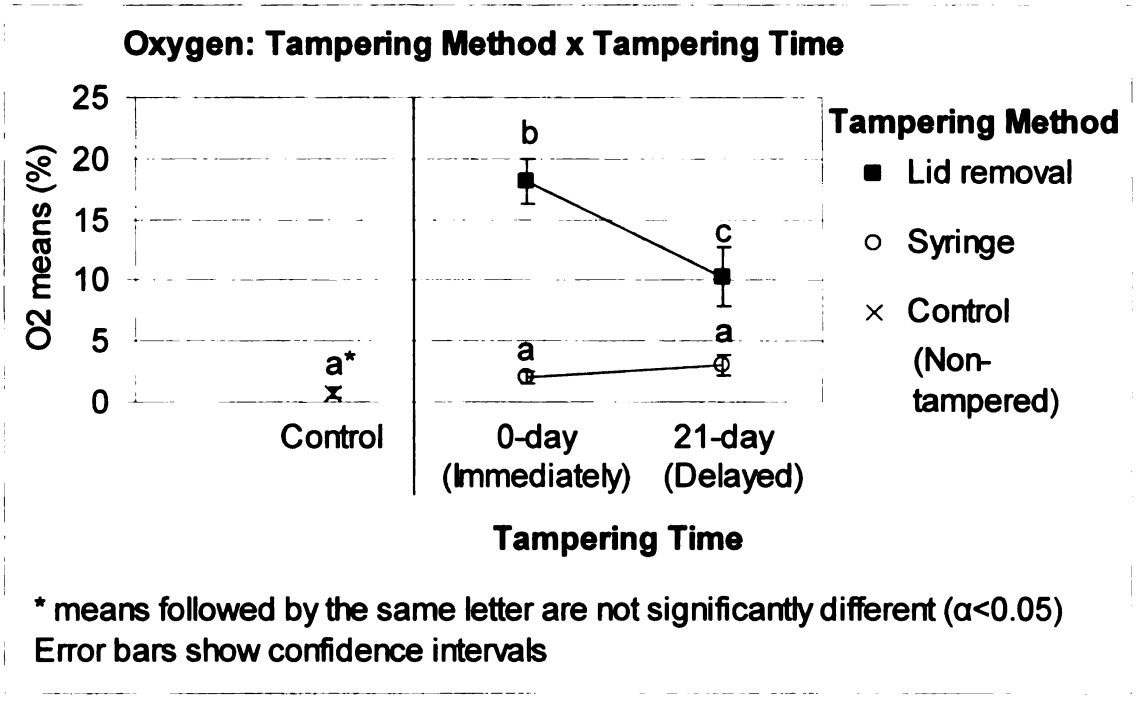

Figure 11. Comparison of O_2 concentrations (means) for Tampering Method x Tampering Time

The analysis indicated oxygen concentrations to be significantly different when the packages with their lids removed were compared with those that were tampered using a syringe and those that were not tampered at all. Within the samples that had their lids removed, a significant difference was also indicated for tampering time. The samples that had their headspace gas tested immediately following tampering (tampered on test day) had almost double the concentration of oxygen of those that had this analysis delayed (tampered 3 weeks before headspace testing) and approximately 10 times the concentration of 'Syringe' tampered samples and not tampered samples. Analysis provided no evidence of difference when the control group and the syringed were compared (in either the 'delayed' or 'immediate' categories).

5.5.1.2 Carbon dioxide

The mixed model design 'Broad scope' was repeated using carbon dioxide as the response variable (dependent variable). As before, 'Sample Type' was a random effect and the following factors as fixed effects:

- Expiration Date (beginning of shelf life and end of shelf life)
- Tampering Method (lid removal, syringe, no tampering)
- Tampering Time (samples tested immediately and 21 days after tampering)
- Expiration Date x Tampering Method
- Expiration Date x Tampering Time
- Tampering Method x Tampering Time
- Expiration Date x Tampering Method x Tampering Time

For carbon dioxide, two two-way interactions, 'Tampering Method x Tampering Time' ($p<0.01$) (see Figure 12) and 'Tampering Method x Expiration Date' ($p<0.05$) (see Figure 13), were significantly different. As with the oxygen analysis, there was no evidence of significance examined for the three-way interaction tested when the dependent variable was the percentage of carbon dioxide present in the headspace. The factors 'Tampering Method' ($p<0.01$) and 'Tampering Time' ($p<0.05$) indicated a significant effect at $\alpha= 0.05$, but tests of the factor 'Expiration Date' did not indicate evidence of significance.

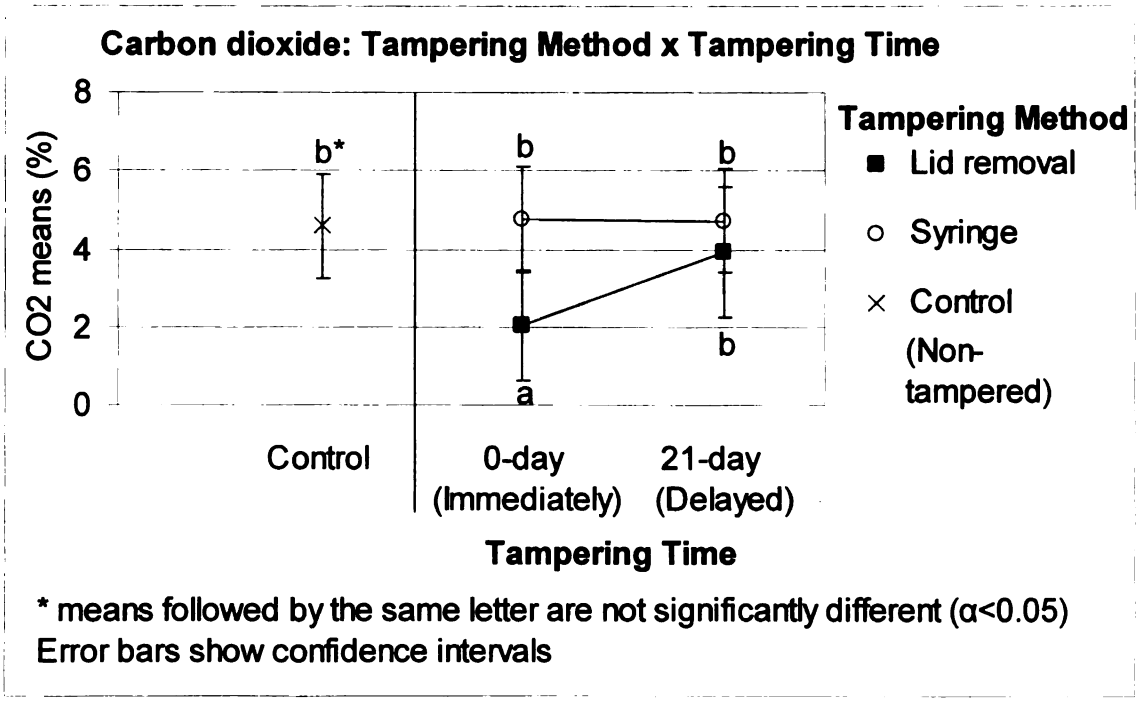

Figure 12. Comparison of CO_2 concentrations (means) for Tampering Method x Tampering Time

The 'Lid removal' tampered samples, tested immediately after tampering, had the lowest average concentration of carbon dioxide (see Figure 12). Their concentration is about 2.5 times less than the average CO_2 concentration of samples that were tested after being tampered with a syringe and those not tampered at all. 'Lid removal' samples, tampered 3 weeks before testing (delayed), didn't provide evidence of a significant difference in their carbon dioxide concentration compared to syringe tampered samples or the control group. However, their average carbon dioxide concentration was twice as much as that of the 'Lid removal' samples that were tampered on test day (immediately). Analysis of the 'Syringe' tampered samples did not provide evidence of a difference in CO_2 concentration when compared with the control group. This was the case for both the delayed and immediate testing.

Multiple mean comparisons using the Least Squares Means also indicated significance of the interaction term 'Tampering Method x Expiration Date' presented in Figure 13. The main difference for this interaction is at the 'End of shelf life' stage. At the 'Beginning of shelf life', all treatments show a similar concentration of carbon dioxide; about 3.3%.

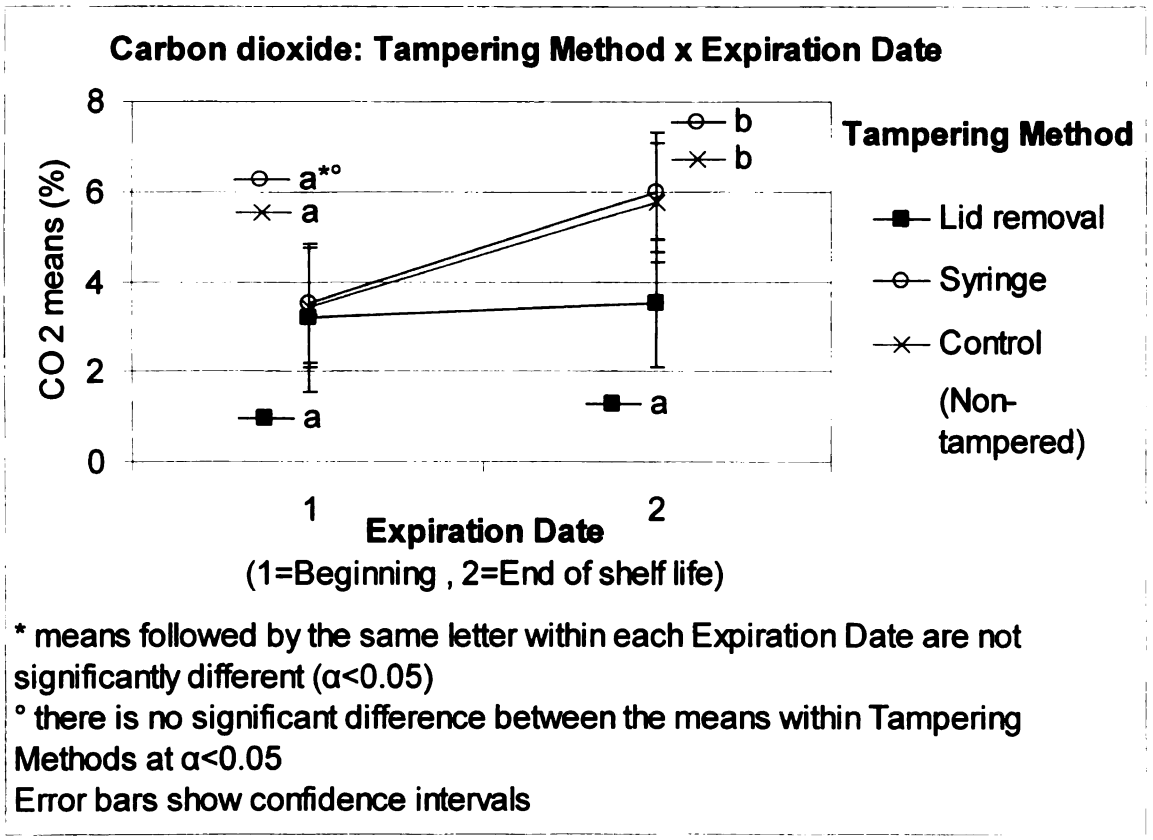

Figure 13. Comparison of CO_2 concentrations (means) for Tampering Method x Expiration Date

Data trends are consistent and a comparison of the averages indicates at the end of shelf life there is about 1.7 times the concentration of carbon dioxide in the product's headspace that there is at the beginning of shelf life. 'Lid removal' tampered samples show about half the concentration of CO_2 when compared with 'Syringe' tampered samples and those that had been not tampered. 'Lid

removal' tampered samples did not provide evidence of a significant difference in their carbon dioxide content between beginning and end of shelf life samples.

5.5.2 Narrow Scope

When the model assumed that the products (applesauce, green beans, prunes and bananas) were chosen purposefully (varied fruits and vegetables with differing acidities), they were considered a fixed effect of the model for analysis, making the scope narrower.

The mixed model design 'Narrow scope' analyzed the control group and treated carbon dioxide as the response variable (dependent variable) and the following factors as fixed effects:

- Expiration Date (beginning of shelf life and end of shelf life)
- Sample Type (applesauce, green beans, prunes and bananas)
- Sample Type x Expiration Date

The narrow scope analysis for all treatments for oxygen and carbon dioxide resulted in no evidence of significance for 'Sample Type'.

The analysis of the control group (not tampered samples), however, provided evidence of a difference for the factors 'Sample Type' ($p<0.001$) and 'Expiration Date' ($p<0.001$) and their interaction 'Sample Type x Expiration Date' ($p<0.001$).

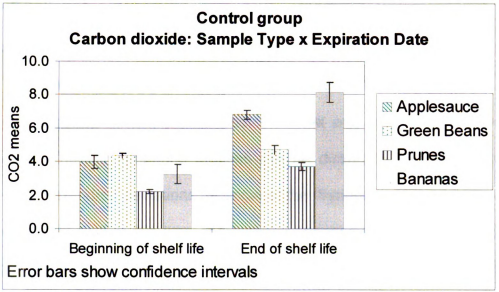

Figure 14. Control group: Comparison of CO_2 concentrations (means) for Sample Type x Expiration Date

Table 6. CO_2 concentrations (means) for Sample Type x Expiration Date

	Applesauce		Green Beans		Prunes		Bananas	
	CO2 (%)	Conf. Interval	CO2 (%)	Conf. Interval	CO2 (%)	Conf. Interval	CO2 (%)	Conf. Interval
Beginning of shelf life	4.0	0.40	4.3	0.31	2.2	0.14	3.3	0.56
End of shelf life	6.8	0.25	4.7	0.27	3.7	0.29	8.2	0.61

In the control group (not tampered samples), 'Green Beans' differ from the other purees in that the analysis does not provide evidence for a significant difference when pairwise comparisons were conducted. The samples, 'Applesauce', 'Prunes' and 'Bananas' show a highly significant difference. The carbon dioxide content of these purees is rising from the beginning to the end of shelf life.

5.6 Discussion

Tampered samples varied significantly in their composition of headspace gas when they were compared to control samples. Finer analysis of this result, using the Least Squares Means method indicates that only samples with their lids removed during the tampering process can be distinguished from the control group. High standard deviations for some of the 'Syringe' tampered samples led to the assumption that this type of tampering cannot be reliably discerned from the control group and could lead to 'false negatives'. 'Syringe' tampering did not result in a sufficient change in the headspace gas concentration.

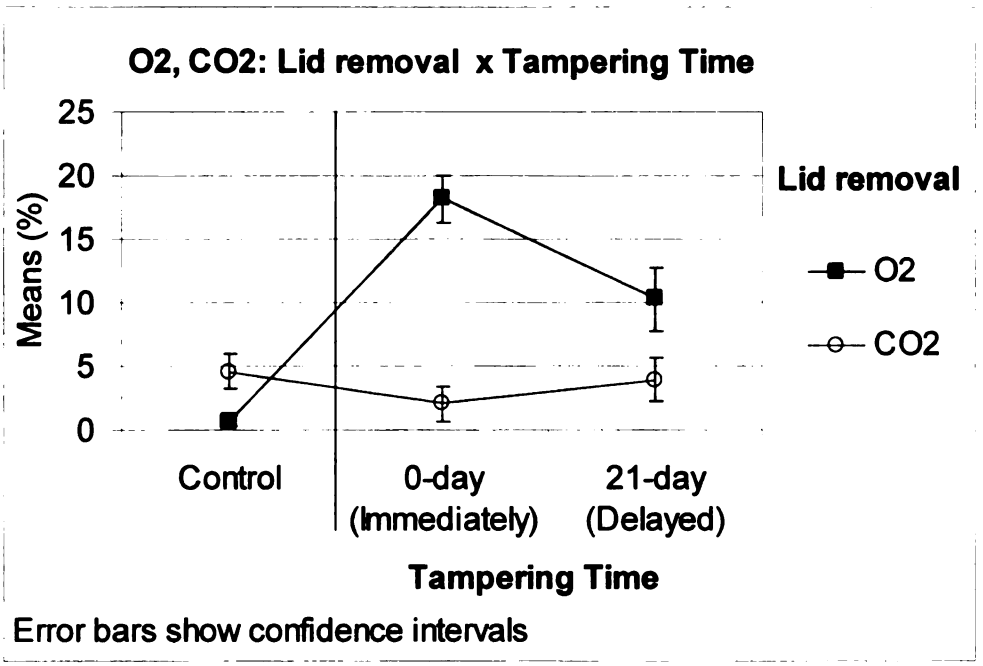

Figure 15. Changes in O_2 and CO_2 concentrations for 'Lid removal' tampered samples

The likely reason for the consumption of oxygen and evolution of carbon dioxide in 'Lid removal' tampered samples after three weeks (see Figure 15) is most likely due to aerobic microorganisms particularly molds. They consume

available oxygen and convert it into carbon dioxide. After three weeks, the oxygen concentration is almost half of what was measured right after tampering and the carbon dioxide concentration approximately doubled.

The carbon dioxide content found in the control group samples is probably related to the pH and the chemistry of the puree. The concentration in carbon dioxide is higher for the vegetable puree (Green Beans) than for the fruit purees at the 'Beginning of shelf life' stage. Thus, it is likely that the production of carbon dioxide is related to the pH of the food, because the vegetable puree (higher pH, see Table 7) shows a higher concentration of carbon dioxide than the fruit purees. The low acidity and the lower content of glucose (reducing sugars) in green bean puree likely inhibit the increase of carbon dioxide over time.

Table 7. Acidity and pH for the tested purees

Puree Type	**Acidity**	**pH**
Green Beans	Low acid	5.6 - 6
Bananas	Medium acid	4.5 – 5.2
Prunes	Acid	3.6 – 4.3
Applesauce	High acid	3.1 - 3.6

Fruit purees (Applesauce, Prunes, Bananas), however, have a higher carbon dioxide concentration at the 'End of shelf life' stage (see also Figure 14). Visual assessment also showed that browning occurred in the fruit purees, which was especially noticeable in 'Applesauce' and 'Banana' samples. This could be related to a chemical reaction such as the Maillard reaction (non-enzymatic browning). The Maillard reaction is a complex set of reactions initiated between carbonyl (e.g. reducing sugar, ascorbic acid) and amino compounds (e.g.

proteins, amino acids). Carbonyl derivates of the non-enzymatic browning sequence react with free amino acids resulting in the degradation of the amino acid to carbon dioxide, also known as the 'Strecker degradation' [99]. The observed browning confirms to some extent that the food product degraded. The observation of accumulating carbon dioxide in the fruit purees seems right, because the amount of glucose is probably higher than for the vegetable puree. Higher acidity, provided by the fruit purees, is with a higher glucose content a better starting point for the Maillard reaction.

5.7 Conclusions

Results suggest that the development of a gas sensor intended to detect tampering in a nitrogen gas-flushed aseptic puree packaged in plastic would be, to some extent, reliable for oxygen and carbon dioxide. A carbon dioxide sensor, however, would not be as practical, due to a higher variability in the initial carbon dioxide content for different puree types. An oxygen sensor would be more efficient due to the less variability in the concentration and the low initial concentration. However, a needle prick through the plastic package did not indicate an increase in oxygen. Thus, tampering with a needle cannot be reliably be detected with an oxygen sensor. Tampering via 'Lid removal', on the other hand, shows a great difference in the oxygen content after tampering. Therefore, tampering that involves the opening of the lid, or that has a similar amount of gas exchange could be discerned from packages that maintained their integrity (for these four products) by an oxygen sensor if it was designed properly.

6 Recommendations for future research

The evaluation of tamper evident packaging demonstrates that research in this area stagnated in the last twenty-five years. To ensure state-of-the-art technology, new innovations of tamper evident features are important. Tamper evident features are required for OTC drugs. his review, however, suggests that those in use commercially haven't changed tremendously since the implementation of the law (1982). Solutions of future tamper evident features that don't rely on the consumer are beneficial and recommended. The retailer as control point should also be considered.

The headspace gas data (oxygen and carbon dioxide) obtained for fruit and vegetable purees and visual assessment of the color of the purees illustrates that scientific color measurement can give more insights regarding the fruit and vegetable puree behavior. Color measurement is recommended, when analyzing headspace data of fruit and vegetable purees.

The headspace analysis of an aseptic puree packaged in plastic indicates that future research should focus on the detection of minimal invasive tampering.

Appendices

Appendix A. History of Tampering

Table 8. Tampering incidents of food and pharmaceutical products

Year	Product	Country	How tampering occurred	Type of Incident	Level of Packaging
1982	Extra Strength Tylenol	USA	Extra Strength Tylenol capsules were tainted with cyanide; 7 people died in the Chicago area. [100]	Random attack: Initial incident	Consumer unit: tampering
1982	Cheese snack	USA	Student swallows pin in a cheese snack. Two straight pins were later found in the remaining snack in the bag. Product is removed from the store where it was bought. [101]	Random attack: Initial incident	Consumer unit: tampering
1986/ 02	Tylenol	USA	Tylenol again laced with cyanide, 23-year old woman dies. [12]	Random attack: Initial incident	Consumer unit: tampering
1986/ 03	Contac, Dietac, Teldrin	USA	Products are immediately recalled after traces of rat poison warfarin was detected in nine capsules. [16]	Random attack: Initial incident	Consumer unit: tampering
1986/ 06	Extra strength Excedrin	USA	Stella Nickell placed cyanide is placed in capsules, repackaged them and placed three of the bottles in area stores and kept two bottles to use to kill her husband; another person died, too. [102]	Random attack: Initial incident	Consumer unit: tampering

Table 8. cont.

1986/09	Lipton Cup-A-Soup	USA	Soup powder was tainted with cyanide, a 27-year-old New Jersey man died. [17]	Random attack: Initial incident	Consumer unit: tampering
1989	Dairy Crest Butter	UK	All Cornish butter is taken off the shelves after traces of mercury were discovered in one pack. [18]	Random attack: Initial incident	Consumer unit: tampering
1989	Heinz Baby food	UK	Jar of baby food contained caustic soda and two large metal drawing pins; others contained slivers of glass. [19]	Random attack: Initial incident	Consumer unit: tampering
1989	Chilean fruits	Chile	2 Chilean grapes were poisoned with cyanide; non-lethal dose; no death or illness occurred. [20]	Terrorism: Initial incident	Consumer unit: tampering and extortion
1991	Sudafed 12-Hour	USA	At least six packages of "Sudafed 12-Hour" capsules were laced with cyanide; resulted in two deaths and a national recall. The foil on the internal blister pack had been "cut and pulled back, and then pushed back into place. [22]	Random attack: Initial incident	Consumer unit: tampering
1991	Gerber Baby food	USA	Woman put more than 460 pieces of glass in a jar of baby food and then fed several spoonfuls to her 13-month-old son. [103]	Random attack: Initial incident	Consumer unit: tampering

Table 8. cont.

1992	Heinz Baby food	Australia	Baby food jar laced with cyanide has been sent to Perth police in a sequel to the Rodney King bashing case in Los Angeles. Heinz removed all glass baby food jars in Western Australia from super market shelves. [104]	Random attack: Initial incident	Consumer unit: extortion
1992	Goody's Headache Powder (OTC headache remedy)	USA	The headache powder was replaced with sodium cyanide; 51-year old man died; product is recalled. [23]	Random attack: Initial incident	Consumer unit: tampering
1993	Pepsi	USA	Started with a report of the Tripletts, who claimed to find a syringe in their Pepsi can; more than 60 cases had been reported where people claimed to find objects like needles in their Pepsi cans. [24]	Copycat incident	Consumer unit: extortion
1994	Safeway Tonic Water	UK	Safeway's (UK) labeled tonic water was contaminated with deadly nightshade; Eight people fell ill, four of them seriously. [4]	Random attack: Initial incident	Consumer unit: tampering
1997	Arnott biscuits	Australia	Extortionists threatened to poison the product with a pesticide; Arnott recalled biscuits. [27]	Terrorism: Threats of tampering	Consumer unit: extortion
1997	Thomy (Nestlé)	Germany	Thomy mustard and mayonnaise laced with cyanide; Thomy has been targeted by an extortionist since early 1996; no one injured. [14]	Terrorism: Copycat incident	Consumer unit: extortion

Table 8. cont.

1998	Nestle Iced Tea	Germany	30-year-old Turkish-born man sent contaminated iced tea to the company; also telephoned the concern threatening to place poisoned iced tea on shelves unless the company met his demands. [105]	Terrorism: Threats of tampering	Consumer unit: extortion
1998/ 99	Alete Baby food (Nestlé)	Germany	Jars of baby food laced with pesticide and placed in several grocery stores; also a sticker with a warning for customers that the goods had been poisoned was put on; all questioned products had been removed from shelves. [26]	Random attack: Initial incident	Consumer unit: tampering and extortion
2000	Herron	Australia	Herron pharmaceutical capsules, produced in TE packaging, had been laced with strychnine, a highly toxic poison used to kill rats; product is recalled, after 2 people were poisoned. [28]	Terrorism: Initial incident	Consumer unit: tampering and extortion
2003	Safeway	Canada	Safeway received threatening letters from an animal rights group, claiming to have thawed several frozen turkeys and injected them with arsenic. Safeway asked customers to look for tears or punctures in the packaging. In all cases, no evidence was ever found. [106]	Terrorism: Threats of tampering	Consumer unit: extortion
2004	Gerber Baby food	USA	Jars contained poison ricin and similar notes inside warning that the jars were contaminated; no one is harmed. [25]	Random attack: Initial incident	Consumer unit: tampering and extortion

Table 8. cont.

2005	Snickers, Masterfoods	Australia	Snickers bar had been laced with a substance similar to pest poison and was sent to the company along with extortion threats. [29]	Terrorism: Threats of tampering	Consumer unit: extortion
2008	Gerber Baby food	USA	Harlem man falsely claimed to have poisoned 5,000 bottles of baby food with cyanide that has killed babies. There was no evidence baby bottles were tampered with and there have been no reports of injury or death reported to the FDA. [107]	Terrorism: Threats of tampering	
2009	Earth's Best	USA	A woman tampered Earth Best banana baby food jars inside a Florida's Publix store without concealing it. She was using a plastic syringe to transfer an unknown dye from a Victoria's Secret body splash container to various jars. She was caught before leaving the store. No one was injured. [108]	Random attack: Initial incident	Consumer unit: tampering
2009	Gerber Baby food	USA	A man admitted tampering with a jar of baby food at a CVS in San Jose. He was crushing up Aspirin tablets and putting them in baby food. Another tampering incident at another local store occurred two weeks ago, where he crushed between 7-8 tablets of Aspirin and put them in a jar of oatmeal apple flavored Gerber baby food. Officers went to the CVS store and found a jar that had been tampered with and had white powder inside. The other jar hasn't been located yet. [109]	Random attack: Initial incident	Consumer unit: tampering

Appendix B. Field Study on Baby Food Packaging

To compare the safety features of baby food packages from a survey conducted in 1984 (see 2.2 Research on Tampering) with currently available commercial packages, the same study was performed on a single category, prepared baby food for a single store, Meijer, Lansing (see Table 10). I repeated the work of Hotchkiss and Gravani, but felt that the use of a single store was justified in the repeat study, because the food category tends to be dominated by national brands, which do not tend to vary packaging formats widely in different stores. The degree of protection against tampering is ranked with safety categories, defined by Hotchkiss and Gravani defined in the following:

Table 9. Safety categories for protection against tampering

Category I	TE container would likely meet current FDA regulations for OTC drugs and has a label statement describing the TE feature
Category II	TE container would likely meet current FDA regulations for OTC drugs, but there is no label statement describing the TE feature
Category III	TE container would likely not meet current FDA regulations for OTC drugs, but the inherent nature of the package gives some degree of tamper evidency.
Category IV	Containers have no tamper evident feature and can be easily reclosed without detection.

The 1984 field survey was done on many more categories than just baby food, but our repeat comparison was limited to baby food, especially baby puree. Package surveys were conducted at the store. In Table 10, the current baby puree packages are evaluated with the same methodology as in 1984. In total, five different brands offered baby puree at the store surveyed. It should be noted

that brands sometime offer the puree in different package forms. Therefore, the number of brands per container type is mentioned separately (see column "Container Types"). The five brands offer their puree in three different container types (glass jars, plastic tubs and plastic pouches) and used different closures and tamper evident features. These are enumerated in the column entitled "Closure types/TE feature". Some tamper evident features, however, are the same (e.g. sealed thermoform), but they incorporate a different closure type or material (see row entitled "plastic tub"). The number preceding the closure material doesn't represent the amount of puree packages, but the amount of this type of closure and TE feature for a given brand. For purees packed in glass jars, there was one brand that had a TE feature in addition to the vacuum button; a shrink band was incorporated around the closure, for some, but not all packages. The column entitled safety category aggregates the information presented in columns 1-3 and uses the system established by Hotchkiss and Gravani to evaluate the containers that were surveyed. (Purees packages in plastic tubs, for instance, are offered by two brands. One brand offers it in two different closure types, but integrates the same TE feature. The puree closed with a heat sealed closure, however, has a label statement that describes the TE feature leading to safety category I.

Table 10. Current baby puree packages evaluated with method used in the 1984 field survey [34]

Brand Types	Container Types	Closure Types/ TE feature	Safety category	% in each category			
				I	II	III	IV
5	glass jars (4 brands)	4 Lug thread-Metal/ TE: Vacuum button	III	-	-	80	-
		1 Continuous Thread, TE: Plastic- Shrink band	II	-	20	-	-
	plastic tub (2 brands)	1 Heat Sealed-Composite/ TE: Sealed Thermoform	I	33.3		-	-
		2 Induction sealed-Metal/ TE: Sealed Thermoform	II	-	66.7	-	-
	plastic pouch (1 brand)	1 Heat Sealed-Composite/ TE: Sealed bag/pouch	II	-	100	-	-

Glass jars fared poorly in the safety ratings (Safety category III – see Table 10), largely due to the fact that the vacuum button in closure is not considered as TE feature for OTC drugs (see 2.3.2 Drugs). On the other hand, a sealed plastic tub or pouch is considered having TE features and therefore listed under safety category II.

Table 11. Summary: Average % per safety categories

Product Group	Average # Brand types	Average % in each Category			
		I	II	III	IV
Baby Food (prepared, dry), 1984	5	-	61	39	-
Baby Food (prepared), 2009	5	11	62	27	-

Table 3 compares the results of the original study conducted by Hotchkiss and Gravani (1984) when their results for the baby food category was compared to our brief survey of this category in a single grocery store. Above findings suggest that the use of tamper evident packaging has somewhat increased over the last 15 years, however, most of current the packages surveyed do not include a labeling statement on the existent TE feature.

Appendix C. Rosette Protocol

The effectiveness of the employed tamper evident feature of our test packages (aseptic puree in a plastic container) was determined by the use of the Rosette protocol (see 2.2 Research on Tampering and 2.5 Evaluation Methods). For this purpose, three single aseptic puree packages were violated with usual household tools. Each violated package and two control packages (i.e., unviolated) were presented to a panel that consisted of company executives. The inspector had to detect evidence of tampering within five minutes, without using special devices of any sort.

The accuracy of the rating (established by use of the test) is dependent on reliable and objective answers to all questions. Any violated package, where violation was obvious to inspectors under the previous instructions, cannot be used for obtaining a rating for the tamper evident feature [37].

For the rating of the TE features (see Figure 16), the factors of violation time, degree of knowledge of packaging, utilized equipment, material of TE feature and TE feature visibility are considered. For a successfully violated test package, the required time to tamper was 10-15 minutes, which earns points according to the factor values (see Table 12, p. 91) a 2.0. The person, who violated the package successfully, was highly specialized in packaging or research training which resulted in the value 10.0. The utilized equipment was defined as "required small hand tools", where no special equipment purchase was required, which resulted in a 2.0. The TE feature could be reproduced by using locally available materials

and therefore resulted in a 4.0. The visibility of the feature (blister) is in widespread use and associated with consumer awareness (C), which resulted in the value 4.0. This value is in this case multiplied with factor E or every other visibility factor that accounts. E asks for "Destroys package upon opening", which in this case is applicable, because tampering with the blister pack causes destruction of the TE feature (value 10.0).

Tamper-Evident Feature Rating Index-1989 Revision

Product _____ Date 6/30/09
Test Code #2/#3/#6 Feature Sealed container (Blisters)

	Index
Time Required (lowest level) – 10 min / 15 min	2.0
Knowledge Level (lowest level)	10.0
Equipment Used (highest level)	2.0
Feature Material (all that apply)	
0.0 + 4.0 + ___ + ___ = _____	4.0

Feature Visibility (all that apply)
(1) Blister pack
(2) _____
(3) _____

A__ x B__ x C4.0 x D__ x E10.0 =	40.0
Index Rating	58

Supervisor Jules Breitinger Date 7/6/09
Approved: _____
Date _____

Figure 16. Tamper-Evident Feature Rating Index for a sealed plastic tub

As result, all three tampered packages successfully passed the inspection. The "Rating Index" (according to the Rosette Protocol) for determining the effectiveness of the TE features ended in the value 58. This method, however, has to be repeated with any new implemented TE feature for comparison.

Table 12. TE Testing Procedure: Values accorded for Factors [37]

Degree of Knowledge of Packaging Required	
No special knowledge or ability required	2.0
Basic knowledge of manufacturing process	3.0
Less than six months experience in packaging	5.0
More than six months experience in packaging	6.0
Specialized training in packaging field	9.0
Highly specialized in packaging or research training	10.0
Feature Material	
Feature can be reused	0.0
Replaceable by material normally found in homes	2.0
Feature reproduced using locally available materials	4.0
Generic feature, not available from most outlets	6.0
Printed feature, limited distribution	6.0
Printed feature, local source, small quantity	7.0
Feature not available locally, in small quantity	8.0
Printed feature, large order quantity required	9.0
Proprietary feature, available without order	9.0
Proprietary feature not available	10.0
Time Required to Violate Successfully	
Under five minutes	1.0
Five to thirty minutes	2.0
Thirty minutes to one hour	3.0
One to three hours	4.0
Three to six hours	5.0
Six to twenty-four hours	6.0
One to seven days	7.0
Seven to fifteen days	8.0
Fifteen to sixty days	9.0
Over sixty days	10.0

Table 12. cont.	
Equipment Utilized	
No special equipment needed	0.0
Requires small hand tools	2.0
Requires household appliances	4.0
Requires special tools not found above	6.0
Special Equipment Purchase Required	
Under$50	6.0
$51-100	7.0
$101-500	8.0
$501-800	9.0
Over $800	10.0
Feature Visibility	
A. Not visible if package is sealed	1.5
B. Requires close inspection	2.0
C. Widespread use with consumer awareness	4.0
D. Prominent feature, high visibility	7.0
E. Destroys package upon opening	10.0

Appendix D. IRB Approval and IRB approved Moderator Guide

MICHIGAN STATE
UNIVERSITY

Initial IRB Application Approval

March 30, 2009

To: Laura BIX
153 Packaging Building

Re: **IRB# 09-225** Category: EXPEDITED 2-7
Approval Date: March 30, 2009
Expiration Date: March 29, 2010

Title: Tampering in aseptic purees packaged in plastic

The Institutional Review Board has completed their review of your project. I am pleased to advise you that **your project has been approved.**

The committee has found that your research project is appropriate in design, protects the rights and welfare of human subjects, and meets the requirements of MSU's Federal Wide Assurance and the Federal Guidelines (45 CFR 46 and 21 CFR Part 50). The protection of human subjects in research is a partnership between the IRB and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: IRB approval is valid until the expiration date listed above. If you are continuing your project, you must submit an ***Application for Renewal*** application at least one month before expiration. If the project is completed, please submit an ***Application for Permanent Closure***.

Revisions: The IRB must review any changes in the project, prior to initiation of the change. Please submit an ***Application for Revision*** to have your changes reviewed. If changes are made at the time of renewal, please include an ***Application for Revision*** with the renewal application.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects, notify the IRB office promptly. Forms are available to report these issues.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

Good luck in your research. If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

Sincerely,

Dan Ilgen, Ph.D.
SIRB Chair

Figure 17. Initial IRB Application Approval

Focus group moderator guide

GOALS

We are trying

1. To gather information about the various forms of tampering for an aseptic puree packaged in plastic
2. To gather information about the different mechanisms by which tampering can be effectively detected
3. To generate ideas for tamper evident features and sensors

Note

We will provide a liquid, solid and powder to expert teams, and ask that they get them into the packages without being detected. We will also challenge teams to come up with as many different ways in as they possibly can. Goals are only for the moderator, they are not intended to be told to the participants

Time allotted for each section is as follows:

Section	Minut
Intro	5
Warm up	10
Baseline	20
Tampering	60
Group Debrief	20
Tamper Evident	20
Total	**135**

INTRODUCTION (5 minutes)

Hello everyone. My name is Julia. Welcome to our focus group discussion. A focus group is just a group of people who get together to a talk about a specific topic. For a portion of the focus group, you will be divided into subgroups, and asked to tamper these packages (show the aseptic puree). Your teams have two challenges:

1. To get the three materials we are giving you (bbs, Gatorade and crystal light) into the packages in a way that cannot be detected
2. To come up with as many different ways as you possibly can to get each of the materials into the packages

To do this, we have provided some common household tools, but please feel free to use your imagination; you may use anything in the building to accomplish your task. One group can use this room; another can use 167, and the third can use room 173.

I'll be your moderator today and with me are other members of the team, Cindee Wilcox, Evangelyn Alocilja and Yun Wang and Laura Bix; we will be taking notes as your teams start to do your work. After one hour, we will call you all back in here to see what you have come up with, and to discuss a few questions about product tampering. I have to confess that I am not expert in this topic. During the focus group portion of the day, my job will be to lead the discussion and make sure that everybody gets a chance to talk. Basically, the

research team is here to find out what you think, to listen to your opinions and to gather insights from your actions.

We want everyone to feel comfortable talking about their ideas and opinions so here are some typical rules for focus group discussion:

1. There are no right or wrong answers here.
2. Everything you have to say is very important for us.
3. Feel free to disagree or agree with other's opinions. We expect people to have different opinions
4. Please try not to interrupt each other.
5. I might skip over you if have talked a lot or I might call on you if you haven't talked at all. My goal is to try to get everyone to talk.

Ok. Whatever is said in this room will only be used for research purposes and presentations in conferences. We will be transcribing our discussion today and some of the dialogue that occurs during the tampering session today. Please be aware that specific thoughts and discussion will not be attributed to individuals.

Any questions? All right, let's get started!

<u>WARM-UP (10 minutes)</u>

I'd like to begin by having each of you tell us your name, and a bit about your background regarding tamper-evident packaging.

BASELINE (20 minutes)

1. What comes to your mind when you hear the phrase "tamper evident" packaging? PROBES
    a. Are you familiar with the terms "tamper evident" and "tamper resistant"?
    b. What do each of these terms mean to you?
    c. Do you investigate packages for tamper evident features or potential tampering prior to using products?
    d. Do you know that what products require tamper evident features?
2. How would a consumer know if a product has been tampered? PROBES
    a. What types of tamper evident features are you aware of?
        - Shrink bands
        - Printed foil over seals
        - Tear tapes
    b. How do you feel about these technologies and the current approach to tamper evidence?

TAMPERING (60 minutes)

(Break participants into groups and dismiss them to the other 2 rooms)

ACTIVITY: Please try to tamper these packages with the following objectives

1. Find the least detectable way to introduce the bbs you have been provided

2. Find the least detectable way to introduce the powder

3. Find the least detectable way to introduce the liquid

4. Find the most ways into these packages (detectable or undetectable)

RECONVENE GROUP to room 159 with tampered examples

GROUP "DEBRIEF" (20 minutes)

(Set the powder, liquid and solids onto the table for participants to view)

1. Please comment on the experience that your group had trying to get the liquid into the products provided. PROBES

   a. Each team briefly present your "best work" that involved getting the liquid into the package.

   b. Were there any challenges that were unique to the liquid?

   c. Was there anything about the liquid that made it easier?

   d. What were the varying ways that you were able to put the liquid into the package?

2. Please comment on the experience that your group had trying to get the bbs into the products provided. PROBES

   a. Each team briefly present your "best work" that involved getting the bbs into the package.

   b. Were there any challenges that were unique to the solid?

   c. Was there anything about the solid that made it easier?

d. What were the varying ways that you were able to put the solid into the package?

3. Please comment on the experience that your group had trying to get the powder into the products provided. PROBES

   a. Each team briefly present your "best work" that involved getting the powder into the package.

   b. Were there any challenges that were unique to the powder?

   c. Was there anything about the powder that made it easier?

   d. What were the varying ways that you were able to put the powder into the package?

TAMPER EVIDENT FEATURES (20 minutes)

(Set some samples of the aseptic puree on the table)

1. What features of the packaging would you consider to be tamper evident? PROBES

   a. What approach did your team use to defeat the features that you felt were tamper evident?

2. How do you feel about these features? PROBES

   a. Are the features effective?

   b. Would you notice the tampering that was shown by the teams?

   c. Do you think that the average consumer would notice the tampering that was done by these teams?

3. What suggestions do you have for tamper evident features? PROBES

    a. Should the tamper evident features rely on consumers?

    b. What approaches would you take with design?

Thank you very much for participating in our focus groups! Your input will help us to improve the tamper evidence of package design. Have a good day!

Appendix E. Consent Form

Research Study Consent Form

Tampering and Aseptic Puree

You are being asked to participate in a research study. We are conducting a study that investigates the different ways that product packaging can be tampered. Ultimately, this study attempts to:

- Gather information about the different mechanisms of tampering
- Gather information about the different mechanisms by which tampering can be effectively detected
- Generate ideas for tamper evident features

To participate you must:

- Be willing to try to tamper packages
- Be willing to share your thoughts regarding the best way to tamper the packages (provided by the research team)
- Be 18 years of age or older

You will be assigned to a team with other participants (teams will consist of 3-4 people). Your team will be provided with some basic household items, a case of aseptic puree product and a liquid, powder and solid. We ask that your team find a way to insert the liquid, powder and solid into the puree product (to tamper

them). In addition, we are curious about the number of ways into the package; we are looking not only for the most difficult to detect methods of tampering, but also the largest variety of techniques.

You are free to withdraw from the study at any time for any reason.

The "tampering" session will be followed by a focus group that is meant to synthesize the insights that you have garnered during the course of the tampering session. During the course of both the tampering session and the focus group meeting, members of the research team will transcribe thoughts around this issue in an attempt to gather insights for the research team that can be used to develop and refine future tamper evident designs. All information provided in the transcripts will not be tied to your name, and only members of the research team will have access to them.

You will not directly benefit from your participation in this study, although your participation in this study may contribute to an understanding of the mechanisms of tampering, serving to inform designers about this issue.

Possible risks include the chance that you could injure yourself as you try to open packages. (This will be particularly true if you choose to use tools to try to open or close any of the packages). The research team will have first aid supplies on hand should you need them.

If you are injured as a result of your participation in this research project, researchers from Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have

insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have.

You may contact Laura Bix at 517-355-4556 with any questions or to report an injury. If you have any questions or comments regarding this study, please contact Dr. Laura Bix, Assistant Professor of Packaging, at 153 Packaging Building Michigan State University 48823, 517-355-4556 or bixlaura@msu.edu

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 202 Olds Hall, MSU, East Lansing, MI 48824.

I voluntarily agree to

Participate in this study:_____

Date:_____

You will be provided with a copy of this form.

Appendix F. Data Collection Sheet and Results

Data Collection Sheet - Focus Group

"Tamper Evidence in the Plastic Packaging of an Aseptic Puree"

Female Male Other

Age_____

Race_____

Profession_____

Results of Data Collection Sheet

Table 13. Data Collection of participants in focus group

Gender	Age	Race	Profession
Male	80	Caucasian	Packaging Professor Emeritus
Male	22	Caucasian	Packaging Student
Male	43	Caucasian	Packaging Educator
Male	23	Caucasian	Packaging Student
Female	42	Caucasian	Packaging Manager
Female	24	Asian	Biosystems Engineering Student
Male	21	Caucasian	Packaging Student
Female	-	-	Biosystems Engineering faculty
Male	-	-	Biosystems Engineering faculty

Appendix G. Matrix Development

Based on the different TE categories, evaluated through literature search, patent review and brainstorming, a Matrix with tamper evident solutions (x-axis) versus tampering methods (y-axis) was developed. The tampering methods were identified with help of the focus group (see 4 Focus group). The table includes the rating of technologies identified to be the most promising solutions for the aseptic puree packaging. The rating of the incremental solutions, however, is based on the existing technologies and not based on the assumption of turning them into a TE solution. The many unknowns regarding the leap solutions made a clear rating impossible and therefore the rating was left blank. To find out the security level the current TE feature bears, the effectiveness of the TE feature is determined (see Appendix C: Rosette Protocol). But "the best feature for a product is the one that provides the greatest resistance to violation for the product in its current form and size" [31].

Tampering Methods	Damage of pkg components	Microbial growth	"Poisoning" of bulk container	Puncturing with needle	Cutting package with knife	Removing lid and regluing it	Delamination of plastic layers	Cutting lid and resealing with another	Cutting out bottom and regluing	Remanufacturing of container	RATING
Prod	0	0	0	0	2	2	2	2	2	1	10
Consumer+Distrl	1	0	0	1	1	1	0	1	1	1	7
Commercially available: 1. Film Wrappers	1	0	0	1	1	1	0	1	1	1	7
2. Blister/ Strip packs	1	0	0	0	1	2	1	2	1	0	6
3. Carded Display Packaging- Rigid Blister	1	0	0	0	1	1	1	2	1	0	3
4. Carded Display Packaging- Skin*	1	0	0	0	1	0	0	1	0	0	2
5. (Printed) Heat shrink bands/ wrappers	0	0	0	0	1	1	0	0	0	0	2
6. Foil, Paper or Plastic Pouches	0	0	0	0	0	0	0	0	0	0	0
7. Container mouth inner seal	0	0	0	0	0	0	0	0	0	0	0
8. Tape seals	0	0	0	0	0	0	0	0	0	0	0
9. Tamper-Evident Closure (Tear Away Bands)	0	0	0	0	0	1	0	0	0	0	1
10. Breakable Caps	0	0	0	0	0	1	1	0	0	0	2
11. Sealed metal or plastic heat sealed tubes	0	0	0	0	0	2	1	2	2	1	6
12. Aerosol containers	0	0	0	0	0	2	0	2	2	1	7
13. Metal and Composite Cans	0	0	0	0	0	2	0	2	2	0	6
14. Sealed paperboard packages	0	0	0	0	0	2	0	2	2	0	6
15. TE labels (e.g. with Holograms, 3M)	0	0	0	0	0	1	0	1	1	0	3
16. Acrylic-based multipolymer compound	0	0	0	0	0	1	0	1	1	0	3
17. Tamper-Evident RFID tag (e.g. MIKOH)	0	0	0	0	0	1	0	1	1	0	3
18. Tamper-Evident RFID film/ wrapper/ tape	0	0	0	0	0	1	0	1	1	0	3
19. Synthetic TE security substrate (STES)	0	0	0	0	0	1	0	1	1	0	3
20. Fluorescence changing film	0	0	0	0	0	1	0	1	1	0	3
21. Pathogen detector (e.g Toxin Guard)	0	0	0	0	0	1	0	1	1	0	3
22. Thermochromic ink	0	0	0	0	0	1	0	1	1	0	3
Incremental: 23. Gas indicators (e.g. Ageless Eye)	0	0	0	0	0	1	0	1	1	0	3
Leap: 24. Color changing film (photochem oxidation)	0	0	0	0	0	1	0	1	1	0	3
25. Color changing film (photonic crystals)	0	0	0	0	0	1	0	1	1	0	3
26. Nanomarker/ Nanotechnology "fingerprints"	0	0	0	0	0	1	0	1	1	0	3
27. RFID based gas or pressure sensors	0	0	0	0	0	1	0	1	1	0	3
0 No Detection / 1 Maybe detectable / 2 Detection	7	0	0	1	1	2	1	2	2	1	7
Primary Pkg / Secondary Pkg	6	0	0	1	1	2	0	2	2	0	5
* Not suitable for liquid products	3	0	0	1	1	2	0	1	1	0	3
	13	0	0	1	1	2	0	1	1	0	5
	9	0	0	1	1	2	0	1	1	0	5
	7	0	0	1	1	1	0	1	1	0	4
	3	0	0	0	1	1	0	1	1	0	3
	5	2	0	1	1	1	0	1	0	1	7
	7	0	0	1	1	1	0	1	1	0	5
	8	1	0	1	1	1	0	1	1	0	6
	7	1	0	1	1	1	0	1	1	0	6

Figure 18. Matrix: Tampering Methods vs. Technologies

Appendix H. Details of tested product, Raw Data

Table 14. Expiration dates of tested product

Type	Sample #	Expiration Date	Exp. Date
Applesauce	1-15	4-Oct-10	Beg.
Applesauce	16-30	16-Nov-09	End
Green Beans	31-45	18-Sep-10	Beg.
Green Beans	46-60	12-Feb-10	End
Prunes	61-75	11-Oct-10	Beg.
Prunes	76-90	9-Jul-09	End
Bananas	91-105	26-Nov-10	Beg.
Bananas	106-117	14-Jun-09	End
Bananas	118	10-Mar-09	Beg.
Bananas	119, 120	29-Aug-09	End

Table 15. Legend for raw data tables and graphs

Exp. Date:	Expiration Date	**Beg:**	Beginning of shelf life
		End:	End of shelf life
T:	Tampered	**NT:**	Not tampered
LR:	Lid removal	**Syr:**	Syringe
Delay:	Tested after 3 weeks	**Imm:**	Immediate testing

Table 16. Raw Data for Puree 1: Applesauce

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
1	14	1	1	1	1	1	1	6.30		3.80	
2	59	5	1	1	1	1	1	2.78	5.12	5.41	1.11
3	86	8	1	1	1	1	1	12.86		3.29	
4	3	1	2	1	1	1	2	21.21		0.98	
5	85	7	2	1	1	1	2	20.21	11.31	0.76	1.75
6	92	7	2	1	1	1	2	1.14		3.89	
7	94	7	1	1	1	2	1	0.00		4.39	
8	37	4	1	1	1	2	1	1.03	0.60	3.78	0.35
9	76	6	1	1	1	2	1	0.00		4.38	
10	31	2	2	1	1	2	2	1.19		3.95	
11	73	6	2	1	1	2	2	0.47	0.39	4.23	0.15
12	58	5	2	1	1	2	2	0.58		4.17	
13	60	5	3	1	2	3	3	0.39		3.78	
14	98	7	3	1	2	3	3	0.00	0.81	4.39	0.35
15	11	1	3	1	2	3	3	1.56		3.78	
16	47	5	1	2	1	1	1	3.17		6.39	
17	87	8	1	2	1	1	1	18.11	8.03	0.65	3.44
18	89	7	1	2	1	1	1	5.53		6.82	
19	27	2	2	2	1	1	2	19.12		2.33	
20	9	1	2	2	1	1	2	20.80	0.97	1.87	0.25
21	15	1	2	2	1	1	2	19.12		2.28	

Table 16. cont.

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
22	51	5	1	2	1	2	1	0.48	0.25	6.76	
23	110	8	1	2	1	2	1	0.00		7.34	0.32
24	70	6	1	2	1	2	1	0.35		7.27	
25	90	7	2	2	1	2	2	0.00		7.33	
26	54	5	2	2	1	2	2	0.37	0.21	6.88	0.26
27	81	6	2	2	1	2	2	0.00		7.34	
28	6	1	3	2	2	3	3	1.71		6.55	
29	2	1	3	2	2	3	3	1.14	0.57	6.97	0.22
30	113	8	3	2	2	3	3	0.57		6.89	

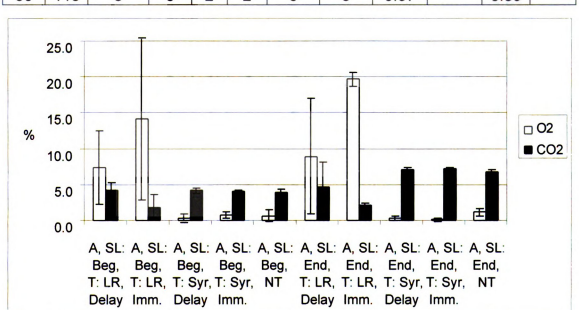

Figure 19. Headspace Variation: Applesauce

Table 17. Raw Data for Puree 2: Green Beans

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
31	80	6	1	1	1	1	1	5.89		5.57	
32	62	6	1	1	1	1	1	6.46	1.01	4.80	0.59
33	104	8	1	1	1	1	1	4.50		5.97	
34	52	5	2	1	1	1	2	14.46		3.89	
35	26	2	2	1	1	1	2	18.07	2.28	1.96	1.04
36	40	4	2	1	1	1	2	13.86		3.59	
37	29	2	1	1	1	2	1	1.24		4.38	
38	72	6	1	1	1	2	1	0.00	0.77	4.84	0.28
39	8	1	1	1	1	2	1	1.40		4.34	
40	4	1	2	1	1	2	2	1.88		4.29	
41	57	5	2	1	1	2	2	0.37	0.76	4.60	0.44
42	45	5	2	1	1	2	2	1.31		3.72	
43	25	2	3	1	2	3	3	1.18		4.04	
44	10	1	3	1	2	3	3	0.73	0.59	4.47	0.27
45	109	8	3	1	2	3	3	0.00		4.54	
46	67	6	1	2	1	1	1	20.51		0.30	
47	105	8	1	2	1	1	1	18.96	2.50	0.50	0.45
48	117	8	1	2	1	1	1	15.62		1.16	
49	21	2	2	2	1	1	2	21.66		3.14	
50	111	8	2	2	1	1	2	20.44	0.64	1.16	1.12
51	56	5	2	2	1	1	2	21.38		1.26	

Table 17. cont.

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
52	78	6	1	2	1	2	1	0.00		4.91	
53	30	2	1	2	1	2	1	0.32	0.19	4.80	0.07
54	65	6	1	2	1	2	1	0.00		4.92	
55	13	1	2	2	1	2	2	1.39		4.45	
56	101	8	2	2	1	2	2	0.00	0.80	5.05	0.31
57	118	8	2	2	1	2	2	0.00		4.88	
58	48	5	3	2	2	3	3	0.71		4.43	
59	68	6	3	2	2	3	3	0.00	0.36	4.88	0.24
60	83	7	3	2	2	3	3	0.48		4.80	

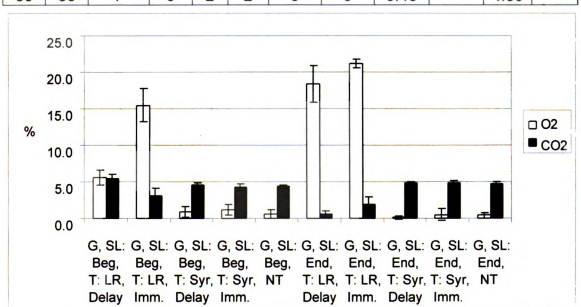

Figure 20. Headspace Variation: Green Beans

Table 18. Raw Data for Puree 3: Prunes

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
61	5	1	1	1	1	1	1	10.18		2.30	
62	35	2	1	1	1	1	1	9.88	2.07	2.38	0.23
63	103	8	1	1	1	1	1	6.46		2.74	
64	17	1	2	1	1	1	2	21.29		0.75	
65	91	7	2	1	1	1	2	19.57	1.37	0.67	0.06
66	112	8	2	1	1	1	2	18.59		0.63	
67	43	4	1	1	1	2	1	10.35		1.74	
68	79	6	1	1	1	2	1	0.00	5.83	2.22	0.25
69	49	5	1	1	1	2	1	0.53		2.13	
70	116	8	2	1	1	2	2	0.00		2.31	
71	108	8	2	1	1	2	2	0.00	0.99	2.26	0.07
72	12	1	2	1	1	2	2	1.71		2.17	
73	44	4	3	1	2	3	3	1.12		2.11	
74	100	8	3	1	2	3	3	0.00	0.59	2.36	0.13
75	75	6	3	1	2	3	3	0.26		2.23	
76	38	4	1	2	1	1	1	8.98		3.01	
77	84	7	1	2	1	1	1	15.86	4.52	1.74	0.85
78	77	6	1	2	1	1	1	7.33		3.34	
79	19	1	2	2	1	1	2	20.75		1.05	
80	102	8	2	2	1	1	2	20.51	0.51	0.77	0.27
81	55	5	2	2	1	1	2	19.78		1.31	

Table 18. cont.

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
82	114	8	1	2	1	2	1	0.00	0.76	3.59	
83	42	4	1	2	1	2	1	1.32		3.11	0.35
84	96	7	1	2	1	2	1	0.00		3.80	
85	61	5	2	2	1	2	2	0.00		3.56	
86	46	5	2	2	1	2	2	0.00	0.00	3.43	0.09
87	107	8	2	2	1	2	2	0.00		3.61	
88	39	4	3	2	2	3	3	1.19		3.43	
89	115	8	3	2	2	3	3	0.00	0.68	3.84	0.25
90	82	7	3	2	2	3	3	0.00		3.88	

Figure 21. Headspace Variation: Prunes

Table 19. Raw Data for Puree 4: Bananas

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
91	50	5	1	1	1	1	1	18.43		3.63	
92	63	6	1	1	1	1	1	1.71	9.82	8.40	2.91
93	120	8	1	1	1	1	1	1.16		8.89	
94	28	2	2	1	1	1	2	18.57		1.03	
95	32	2	2	1	1	1	2	18.24	1.76	1.56	0.27
96	18	1	2	1	1	1	2	21.44		1.15	
97	33	2	1	1	1	2	1	0.57		3.57	
98	74	6	1	1	1	2	1	0.00	0.33	3.65	0.07
99	66	6	1	1	1	2	1	0.00		3.51	
100	119	8	2	1	1	2	2	0.00		3.50	
101	95	7	2	1	1	2	2	0.00	0.00	4.23	0.41
102	97	7	2	1	1	2	2	0.00		3.57	
103	1	1	3	1	2	3	3	1.15		3.24	
104	36	3	3	1	2	3	3	1.59	0.50	2.76	0.50
105	88	7	3	1	2	3	3	0.60		3.75	
106	53	5	1	2	1	1	1	1.86		10.2	
107	106	8	1	2	1	1	1	16.44	9.61	4.65	4.86
108	22	2	1	2	1	1	1	19.98		0.48	
109	69	6	2	2	1	1	2	18.28		2.96	
110	41	4	2	2	1	1	2	11.15	4.14	6.11	1.75
111	16	1	2	2	1	1	2	18.37		3.22	

Table 19. cont.

Sample #	Random #	Test date, 2/15/10 =1, 2/16/10 =2, 2/18/10 =3, 2/23/10 =4, 2/24/10 =5, 2/25/10 =6, 2/26/10 =7, 2/27/10 =8	Tampering Date, 2/1/10 =1, On Test Day = 2, None =3	Exp. Date, Beg. =1, End =2	T =1, NT =2	Tampering Method: LR =1, Syr =2, None =3	Test time after tampering: Delay = 1, Imm =2, None =3	Amount of O2 (%)	Std. dev O2	Amount of CO2 (%)	Std. dev CO2
112	64	6	1	2	1	2	1	0.00	0.86	9.24	
113	24	2	1	2	1	2	1	1.51		8.58	0.68
114	23	2	1	2	1	2	1	1.47		7.89	
115	34	2	2	2	1	2	2	0.56		9.37	
116	93	7	2	2	1	2	2	0.00	0.69	8.95	0.45
117	20	1	2	2	1	2	2	1.37		8.48	
118	99	7	3	2	2	3	3	0.00		8.52	
119	7	1	3	2	2	3	3	1.01	0.58	7.54	0.54
120	71	6	3	2	2	3	3	0.00		8.41	

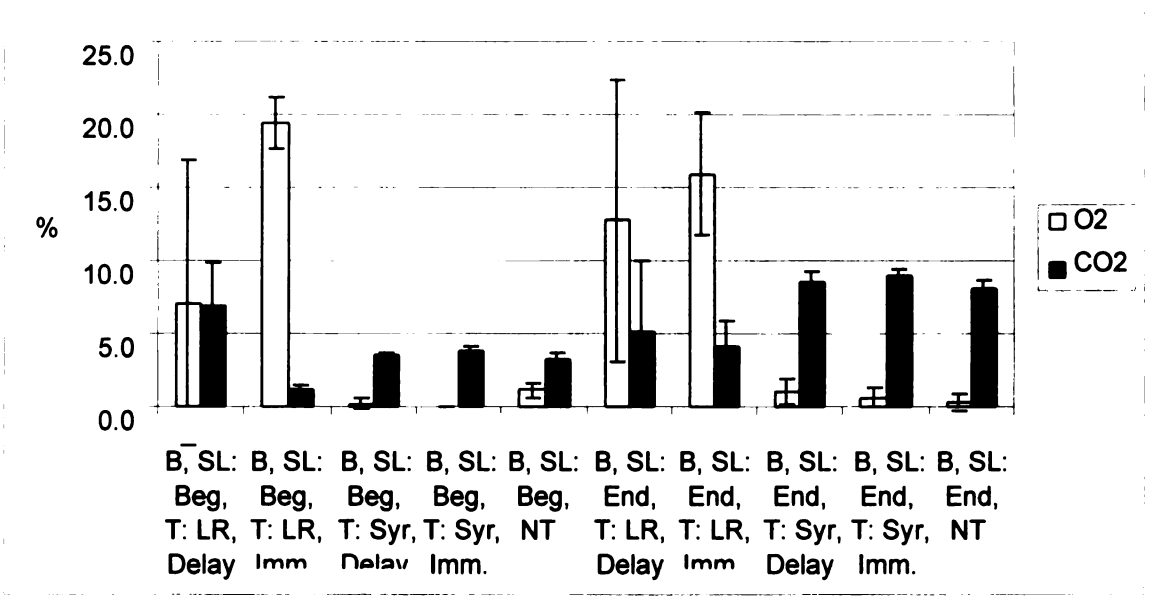

Figure 22. Headspace Variation: Bananas

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