

Tamper-Evident Packaging in Brand Protection

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Tamper-evident (TE) and tamper-resistant (TR) packaging provide an opportunity for incremental actions which can provide a means to combat counterfeit products, product diversion, shoplifting, cargo theft, return and warranty fraud, and unauthorized refills. This backgrounder provides information on TE and TR packaging including their regulatory definitions, the current and likely future extent of their use, and their applications for brand protection.

The main body of Packaging Science effort to combat intentional adulteration is focused on tamper-evident (TE) and tamper-resistant (TR). The primary regulatory definition of TE and TR packaging is in the US Food, Drug, and Cosmetic Act (FD&C, 21 CFR 211.132.b [2001] and 21 CFR 211.132 [1992], respectively). The laws focus on malicious tampering intended to cause harm. In 1992, the US Food and Drug Administration (FDA) implemented regulatory change in terminology from TR to TE, but TR is still considered as a separate concept by packaging developers. **Tamper-evident** packaging is designed to show a trace, or evidence, such as a torn label or lid, when a product has been tampered. **Tamper-resistant** packaging is designed to resist tampering by including hurdles or barriers that challenge a would-be perpetrator to breach and repair. The concept of “tamper-proof” is not used since no package is considered impenetrable. In the Federal Register final notice, FDA stated “Labeling is unacceptable if it implies that the product is tamper resistant or tamper proof.” In 1999, Lockhart stated “Tamper evident researchers believe that when a [intelligent and motivated] malicious tamperer is operating, the probability that someone will fall victim is [100%].”

Current State

TE packaging features have been used for some products such as plastic milk bottles since the mid-

1960’s, but widespread adoption occurred after the Tylenol poisonings of the early 1980’s. In 1983, the Federal Anti-Tampering Act (FATA, 18 USC 1365) was enacted. FATA classified tampering in *Crimes and Criminal Procedures* and Chapter 65 on *Malicious Mischief*. In *Tampering with Consumer Products*, an adulteration attempt is a felony punishable by fine and imprisonment for not more than ten years—and with a possible life sentence if death results. Tampering of a label—defined as misbranding in the FD&C—is also a felony punishable by imprisonment for three years. FATA specifically focuses on intent to harm “with reckless disregard for the risk that another person will be placed in danger.” This burden of proof is challenging to prosecute but consistent with the placement of the act under a criminal code where the act is defined as malicious.

TE packaging is a regulatory requirement for over-the-counter drugs (21 CFR 211.132.b), specific cosmetics (21 CFR 700.25.b), contact-lens solutions and tablets (21 CFR 800.12.b), and no mandatory action but a reference to the concept in pesticide containers (40 CFR 165.65.f.1). The laws have evolved from a prescriptive requirement (e.g., selecting suggested components to meet the regulation) to a performance requirement (e.g., deemed effective or can “reasonably be expected to provide visible evidence to consumers that tampering has occurred”).

FDA considered developing more direct regulations for packaging performance standards as implemented for child resistant packaging by the Consumer Product Safety Commission (CPSC) for poison prevention packaging (16 CFR 1700), but ultimately decided against doing so, finding its Compliance Guide on TE for over-the-counter (OTC) medicines (CPG 7132.a.17 Section 450.500) to be sufficient. It specifically opted against “a rigid checklist of criteria to determine whether a package meets the tamper-evident requirement,” instead favoring a performance policy that “allows for flexibility in packaging technology and encourages technical innovation to improve tamper-evidence and enhance packaging security.”

FDA also expressed concerns that the use of a measurable performance standard might result in generic rankings of TE technologies that do not consider unique aspects of the overall systems. “The agency deems a technology to be in compliance with the regulation if the feature provides visible evidence to consumers that tampering has occurred, as required by the tamper-evident packaging regulation,” other industries have implemented voluntary practices and most products have some form of TE packaging. Such efforts stem in part from the benefits TE packaging can offer in carrying features for combating shoplifting, organized retail theft (boosting), cargo theft, return-fraud, unauthorized repackaging of new or used components, threats to brand authentication, and even curious consumer sampling of products in stores.

Future State

Two key issues that are driving future TE packaging efforts are the intentional adulteration focus in the January 2011 US Food Safety Modernization Act (FSMA) and the economically motivated adulteration (EMA) focus in the November 2011 Government Accountability Office (GAO) report “Better Coordination Could Enhance Efforts to Address *Economic Adulteration* and Protect the Public Health.” Although these efforts focus on FDA regulated products, they will affect all products and geographies because these regulations and practices will become common in food and drugs, drive innovation and

implementation for TE components, and become so familiar that consumers will expect them in more products.

FSMA is considered the next major evolution of the laws pertaining to food, food safety, and food defense, including food adulteration and food misbranding. The act includes eleven mentions of “intentional adulteration” but the term is not explicitly defined. It currently includes traditional food adulteration as defined in the FD&C but it is anticipated to expand to include concepts such as tampering, food fraud, theft, and smuggling. Misbranding is a separate regulatory concept but FSMA includes seven mentions of “misbranding,” specifically regarding provision of “assurances that such food is not adulterated under section 402 or misbranded under section 403(w).”

FDA is engaging many groups—such as the Institute of Food Technologists (IFT), the Grocery Manufacturers Association (GMA) and the Global Food Safety Initiative (GFSI)—to create public-private partnerships to address key issues or to conduct pilot tests required by FSMA. An example is a December 2011 IFT food traceability pilot project. These projects will be critical in defining the interpretation of the act and FDA Guidance Documents which are *de facto* regulations. These pilot projects will help define FDA interpretation of FSMA. The pilot projects are scheduled for early 2012 for products such as “...tomatoes and a ready to eat or non ready to eat complex food product containing meat, spices, and peanut containing ingredients.”

Other organizations such as the U.S. Pharmacopeia (USP) for drug ingredients and the Food Chemicals Codex (FCC) for food ingredients also have TE packaging guidelines or recommendations. The USP and FCC Non-US Monographs and General Notice Requirements address TE but include references that declare compliance with meeting the FDA regulations. USP has been active in combating counterfeiting through USAID grants as well as workshops and expert panels focusing on intentional adulteration. Packaging components will surely have a continued key role in a holistic, all-encompassing approach to detect and deter fraud.

Malicious tampering—an intentional act with the intent to cause harm—is classified as a food defense incident. Food Defense encompasses preventing and recovering from an intentional and deliberate contamination or tampering of food motivated by desire for economic gain or to harm public health. Food fraud differs in that the motivation is only for the perpetrator’s economic gain. For most U.S. regulatory activities, food defense is defined by Homeland Security Presidential Directive-7 and -9 (HSPD-7 and -9) to encompass prevention of many acts defined as terrorism (though the term, itself, is not a clearly defined).

Other groups such as US Customs and Border Protection (CBP) are reviewing a wide range of anti-tamper features for documents such as passports and shipping manifests. The CBP Intellectual Property Rights Five-Year Strategy includes an initiative for Self-Authenticating Imports. Its intent is to expedite genuine products while efficiently, and automatically, identifying suspicious products. This type of initiative demonstrates the opportunity for collaboration and underscores the importance of Interoperability and harmonization.

Applications for Brand Protection

TE packaging can offer brand protection for all products that are—or are not—regulated by the FDA. A key to its fulfilling the TE role will be optimizing how it addresses direct regulatory and product-protection needs, and how it can contribute to product and supply chain transparency. Products have increased brand protection value when they or their packaging is

under greater scrutiny by consumers. Such protection, as noted, includes combating intellectual property infringement and counterfeiting but also to assist in fighting diversion, shoplifting, cargo theft, return fraud, warranty fraud, unauthorized refill, and TE.

For brand protection countermeasures including authentication, traceability, and for child-resistant packaging, it is logical for agencies to adopt performance standards rather than to define specific technologies or procedures, as it has done for child-resistant packaging.

Defining the optimal role and opportunity of TE packaging in overt, cover, or forensic brand protection is complex and depends on many factors. Anti-tamper systems can fulfill many functions and be valuable across the supply chain. Continuing efforts for TE packaging for brand protection should consider such issues as:

- the role of consumers in authentication
- consumer awareness of tampering (or the absence of a TE feature)
- consumer reaction to increased consumer confidence where counterfeit products actually incorporate higher-quality components than the genuine product to avoid scrutiny
- aligning countermeasures with specific types of fraud and risks
- current TE and package component features
- regulatory trends
- consumer expectations for a safe product
- how countermeasures may work in combination to disrupt the chemistry of the crime



The Michigan State University Anti-Counterfeiting and Product Protection Program (A-CAPPP) is the first and preeminent academic body focusing on the complex global issues of anti-counterfeiting and protection of all products, across all industries, and in all markets, and on strategies to effectively detect, deter, and respond to the crime. Linking industry, government, academic, and other stakeholders through interdisciplinary and translational research, education, and outreach, the A-CAPPP serves as an international hub for evidence-based anti-counterfeit strategy. For more information and for opportunities to partner, contact Dr. Jeremy Wilson, Director of A-CAPPP at (517) 353-9474 or JWILSON@msu.edu. Additional information can also be found at <http://www.acappp.msu.edu>. For further information related to this topic, contact Dr. John Spink at (517) 381-4491 or SPINKJ@msu.edu.

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