

FDA Economically Motivated Adulteration
Public Meeting; Request for Comment
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(Slide 1 – Title)

First, I'd like to thank the FDA for the opportunity to present today at this public meeting.

- I am John Spink from Michigan State University
- I have a PhD in packaging from MSU with my research focusing on Anti-Counterfeit Strategy and Counterfeit Risk Modeling
- I developed and teach the graduate course *Anti-Counterfeit Strategy and Product Protection*.
- I have been an Instructor in Food Safety, Packaging, and Criminal Justice, and as of June, I will be an Assistant Professor in the MSU School of ***Criminal Justice***.
- I co-created and am now the Associate Director of the Anti-Counterfeiting and Product Protection Program (A-CAPPP) at MSU.
- Our interdisciplinary approach includes a wide range of MSU programs including: Criminal Justice, Packaging, Supply Chain, Food Safety, Public Health, International Food Law, Intellectual Property Rights Law, Human/ Osteopathic/ and Veterinary Medicine, Nursing, Consumer Behavior, Retailing, Social Anthropology, Political Science, Forensic Science, Economics, and others.

One of my most valuable research engagements is as a Steering Committee Member on the Michigan Department of Agriculture's Ag & Food Protection Strategy Team, which is led by Brad Deacon, John Tilden, and Gerald Wojtala.

In addition, my relationship with the NCFPD has been especially important and I personally thank Dr. Kennedy and Dr. Busta for their personal and institutional encouragement.

(Slide 2 – The Matrix)

My presentation focuses on Food Fraud or Food Counterfeiting, but we have found that the concepts apply to all-products. Food is a good

case study for all counterfeiting since the consumer, regulators, and industries already have systems in place.

As a personal preference, rather than economically motivated adulteration, I favor the term **Food Fraud** since it is clear to the consumer and users, it ***is an action rather than a motivation***, and it fits in the Food Continuum. (For non-food products, it would be more generally called product fraud or fraud.) We also include Food Quality.

Actions that consider opportunities across the entire continuum can lead to more efficient and effective solutions.

(Click – box in)

This matrix defines the mutually exclusive categories by:

- Intentional and Unintentional, and
- Economic Threat and Public Health Threat

Any public health threat from Food Fraud is ***through negligence not intent***. If there was intent to harm, then this would be a Food Defense event.

Establishing these four autonomous concepts is critical in root cause analysis and prevention.

When there is a public health threat event, regardless of the root cause, the product is considered “adulterated.” This is an important concept in the detection and recovery, but does not shed light on the root cause.

From a corporate governance standpoint, incorporating Food Fraud responsibility in the current food infrastructure (such as food safety or quality assurance) is efficient for several reasons: it leverages current personnel and infrastructure, it can be incorporated into standard operating procedures, and there is already a management infrastructure and oversight in place.

(Slide 3 – Extremely Interdisciplinary)

I am frequently asked why there is not more research or refereed publications in the anti-counterfeit strategy area. After extensive review, it is really quite simple.

The concept of counterfeiting is very complex and extremely interdisciplinary. When considering anti-counterfeit **strategy** – the understanding of all aspects of the threat – no specific discipline contributes more than maybe 10% to the concept. It seems logical that this is an intellectual property rights discipline, but the laws and prosecution do not address the strategic understanding of, say, holograms or control of products within a free trade zone.

(Click 1 – 4 bubbles)

My research started in Packaging following the pleading of packaging managers for help in understanding the problem and in selecting technologies.

The research quickly incorporated Food Safety and Health Risk Communication, which is logical since these experts are accustomed to identifying and responding to public health risks.

The research then expanded to Supply Chain (since the product moves) and Criminal Justice (since we are dealing with the behavioral sciences and criminal-like behaviors).

A constraint of Supply Chain Management is that it mainly focuses on product moving within the legitimate supply chain – many of the counterfeit products move in-and-out, or are never in the legitimate supply chain.

As I kept discussing this topic, it seemed that more and more disciplines applied to a better understanding of the anti-counterfeit **strategy**.

(Click 2 – full Vin Diagram)

(Slide 3 – Types of Counterfeiting)

When we began our research we did not find a succinct summary of the types of counterfeiting. This could be called the “types of fraud” but using the term “**counterfeiting**” more precisely identifies the action.

This list was developed from the **risks** and the **motivations** of the fraudsters, **not** from current operating procedures, current job responsibilities, or regulatory responsibilities.

Through our research, we found that it was most appropriate to use the term “counterfeiting” in both a macro and a micro sense – to use the **macro** general term for this category of actions, as well as the **micro** pure counterfeiting where everything about the product, package, documentation and supply chain are fraudulent.

In each of these types, some component is fake – whether packaging, an additive, the product, the paperwork, or the statement of the source.

(Click in each)

As we reviewed events we expanded the list of the types of counterfeiting:

- Adulterator – this is where an entity has a legitimate right to produce a product, but some component of that finished product is fraudulent. When melamine in pet food is considered a **“counterfeit additive”** the action is considered in a new light.
- Tamperer – this could be where the product is used and returned, expired date codes “refreshed”, or product up-labeled to a higher priced product.
- Over-runs – this is where an entity has a legitimate right to produce product but violates the production agreement in some way.
- Theft – this stolen product is passed off as legitimately procured. Though this stretches the definition of counterfeiting, stolen product that is co-mingled back in the legitimate supply chain is such a high risk that it is important to include this concept in the types of counterfeiting.
- Diversion – (also referred to as parallel trade or gray markets) this is the sale or distribution of product outside of its intended market. It is not explicitly illegal, but in many cases violates a contractual distribution agreement or other labeling type regulations. As with theft, this is another type of counterfeiting that stretches the definition, but due to the high risks associated with co-mingling, it is an important concept to include here. Anytime products are loosely controlled in the supply chain, there is an opportunity for illegal product to be co-mingled with the legitimate product.
- Simulations – this is where a logo or product design is created to be like but not exact with a branded product.
- Counterfeiter – this is the **micro** term, where all aspects of the product and package are fraudulent.

(Slide 5 – Why Products are Counterfeited)

There is one reason why products are counterfeited: profit.

This is an economic crime at its heart. That being said, there are several components that lead to why products are counterfeited:

- Profit
- Cheap to Copy
- Easy to Copy
- Unsatisfied Market Demand
- Difficulties in Detection or Proof
- Non-Deterrent Laws or Enforcement

Laws and enforcement are common themes in my presentation and in the anti-counterfeit strategy. **It is important to not pawn off the responsibility to law enforcement and the courts too quickly because the solution is interdisciplinary and complex. The current legal and enforcement systems and institutions have made tremendous strides in all areas**, but the counterfeiters are ***extremely*** resilient, intelligent, resourceful, very well- funded, and well-motivated.

(Slide 6 – Reasons for Growth)

There are several reasons for the growth in counterfeiting.

- Availability and Growth of Technology
- Increased Globalization
- Low Legal Penalties
- Influence and Prevalence of Organized Crime

(Slide 7 – The Business Case for Anti-Counterfeit Research)

In 2007, my MSU colleague Dr. Robyn Mace and I conducted this research project, and to start, we did not find the statement, so we validated that “counterfeit food is a public health threat.”

(Slide 8 – The Chemistry of the Crime)

(Slide 9 – The Crime Triangle)

As my, and our, research continued, we kept searching for the bottom. I kept searching for a core, primary, basic concept that would anchor anti-counterfeit ***strategy***. I eventually came to “The Chemistry of the Crime.” This was a breakthrough because it led to the principle that the root of the problem was in behavioral sciences and the criminal justice discipline.

In the Chemistry of the Crime, or the Crime Triangle, the three components are:

- Likely Offender (Criminal)
- Suitable Target (Victim), and
- Opportunity

In our research, to be efficient and effective, we reviewed strategies and tactics and asked ***“are we disrupting the Chemistry of the Crime.”***

In many cases, seizures or prosecutions only temporarily disrupt cash-flow of an organization or an individual. **This is not to discount the critical role of seizures and prosecutions, but to *emphasize that they are only part of the solution.***

When considering the offenders, is it important to consider the worst-case scenario and to take empathy out of the equation. **We need to consider that these people are criminals and, in all seriousness, sociopaths.**

(Slide 10 – Define the Objectives)

A key to an effective and efficient solution, from both a regulatory and an industry standpoint, is to consider the objectives of the countermeasures.

Specifically, we’re dealing with three functions: Supply Chain Optimization, Traceability, and Authentication. It is important to understand the goal of the system, for example, authentication can be used to prove a product genuine or to prove a product fake. In addition, the ultimate use may be for intelligence gathering of the criminal network or for prosecution in court – two very different set of needs from a chain-of-custody standpoint.

There does seem to be logic to harmonizing data and systems across all consumer products, including *all* the products regulated by FDA and USDA.

(Slide 11 – A Strategic Solution)

There are a few concepts that I think are import to note:

- Monitoring ***all*** imported product is ***not*** practical.

- Monitoring ***all*** international food manufacturing is ***not*** practical.
- Focus on the root of the risk and actions...
 - *The chemistry of the crime: Criminal, Victim, and Opportunity*
- The Strategy should include:
 - Intelligence Gathering
 - Create a Public Forum
 - Create Awareness & Harmonization

(Slide 12 – Discussion)

It is our intent to continually expand our collaborative partnerships across other universities, to associations, to agencies, and around the globe.

I thank the FDA for scheduling this meeting and thank you for the opportunity to present to you today.

If you have any comments, clarifications, or suggestions about this presentation our courses and executive education... please feel free to contact me or us through our MSU.edu website.

This presentation and this script will be available by Monday at MSU.edu