

Managing Chemical Hazards in a Food Safety Modernization Act (FSMA) World



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Elemental Impurities in Food Ingredients: Pathways
to Reducing Levels

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At It's Core, Toxicology is Straight Forward



“All things are poison, and nothing is without poison, only the dose permits something not to be poisonous”

-Paracelsus

“Dose Makes the Poison”

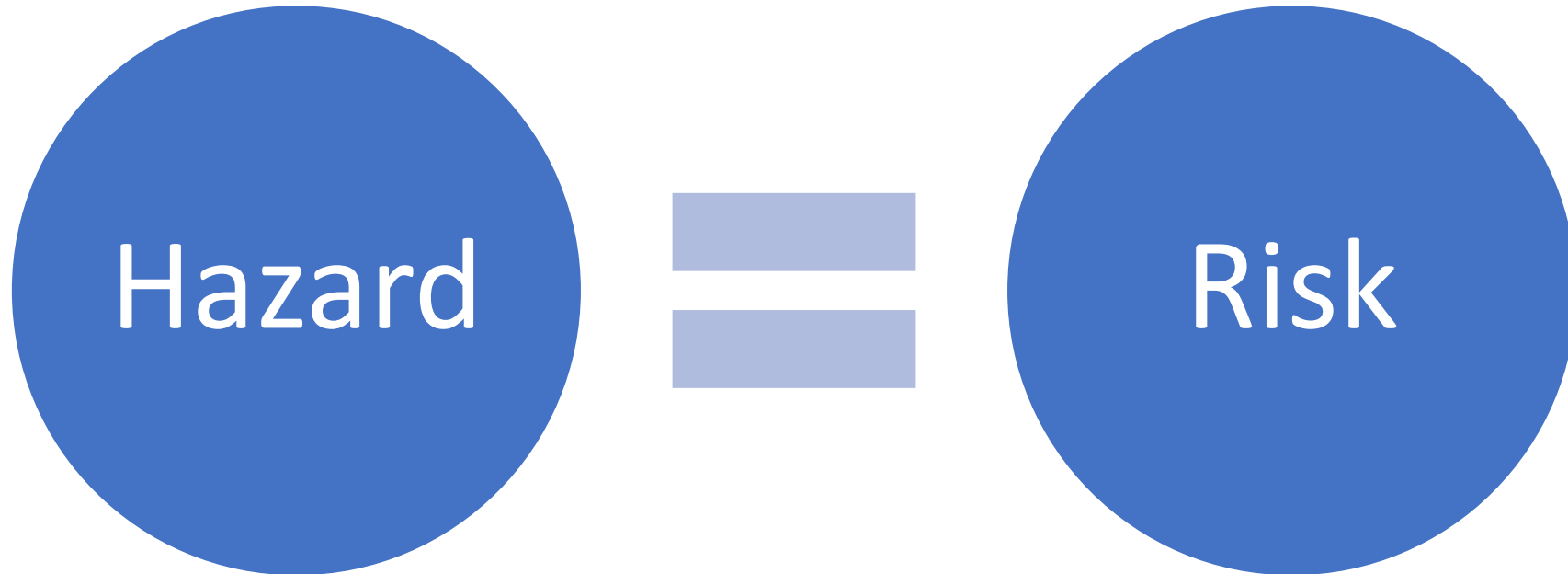
Hazard Assessment is Easy – Risk? Not So Much

- World is full of hazard assessors and very few risk assessors
- Inherent limits to determining risk
 - Uncertainty
 - Limited analytical resources
 - Complexity (e.g. mixtures, exposures, food matrix, etc.)
- External pressures
 - Public health protection
 - Special interest groups
 - Politics
 - Perception

Risk is a function of Hazard and Exposure



Perceptually, There is No Difference



The Risk Paradigm Takes a Tripartite Approach

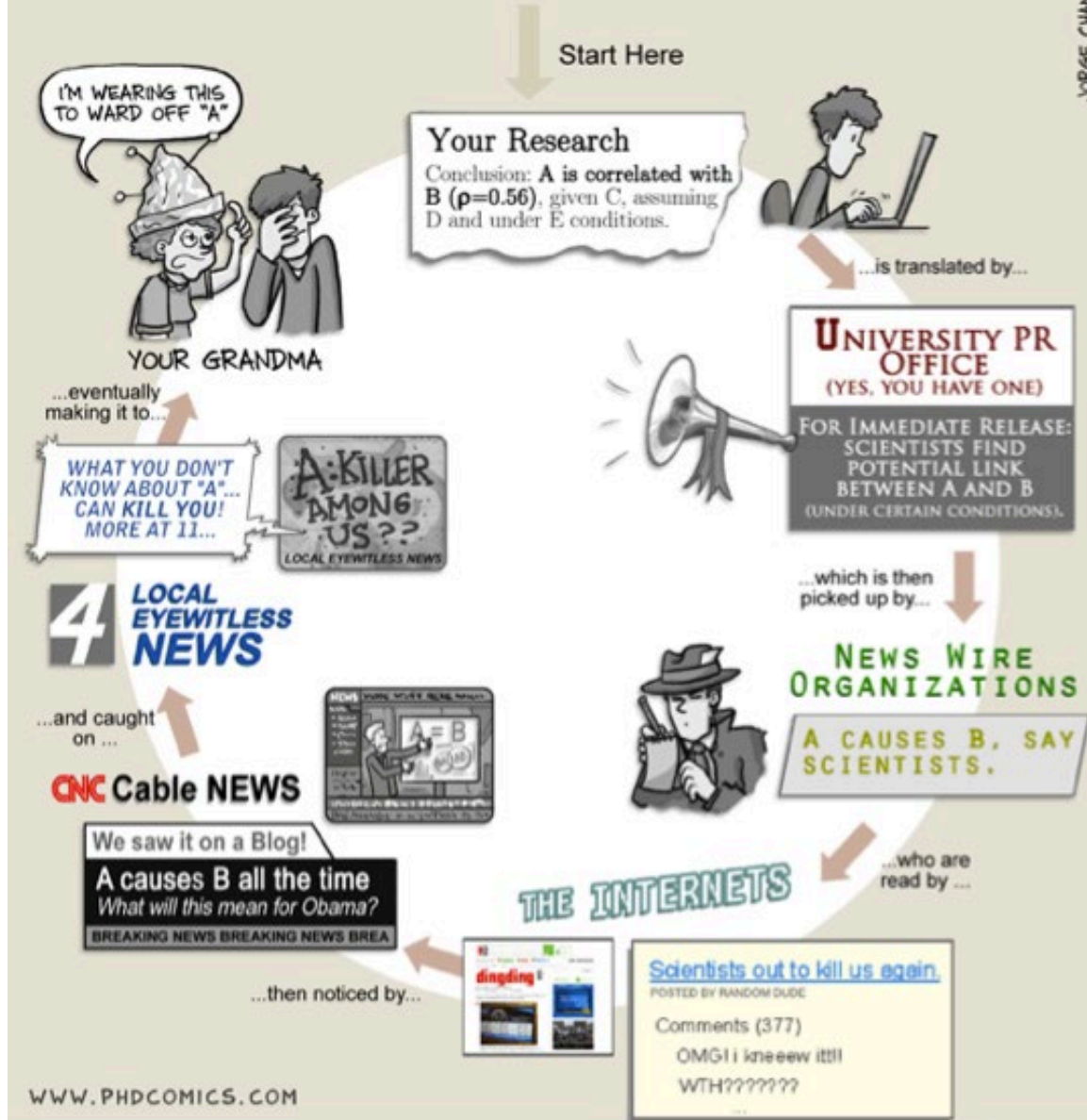
Assessment

Management

Communication

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How Does FSMA Play Into Risk and Chemical Management?

“Risk-Based Preventive Controls” is the Backbone of FSMA

- Chemical hazards are ubiquitous up and down the supply chain
 - Some are natural
 - Some are used in formulation
 - Some are unintentionally present
 - Some are incidentally present

Health Effects from Chemicals Must be Assessed

- Depend on the chemical and level in food
- Some may cause immediate or near-term illness
 - Undeclared food allergens may lead to anaphylaxis
 - Caustic cleaning compounds may lead to acute tissue injury
- Some may cause long-term effects
 - Lead in candy may lead to impaired cognitive development in children
 - Chronic aflatoxin exposure may lead to liver cancer
- FDA evaluates long-term and short-term exposure risks to establish specific food chemical use policy

Adapted from FSPCA



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Chemicals are Ubiquitous

Naturally Occurring

- Allergens
- Mycotoxins
- By-Products
- Heavy metals

Formulated

- Food additives
- Colors
- Preservatives

Unintentional/Incidental

- Cleaning compounds
- Pesticides
- Heavy metals
- Radiological

Adapted from FSPCA



Outside of Food Allergens, the Vast Majority of Chemical Management Revolves Around Mycotoxins and Heavy Metals

- Mycotoxins – chemical hazards produced by certain molds
- Factors that influence formation – weather, damage, storage, etc.

Aflatoxins	Ochratoxin A	Fumonisin	Deoxynivalenol (DON)	Zearalenone	Patulin
<ul style="list-style-type: none">• Peanuts• Corn• Tree nuts• Spices• Rice	<ul style="list-style-type: none">• Coffee• Cocoa• Raisins• Cereal grains• Spices	<ul style="list-style-type: none">• Corn	<ul style="list-style-type: none">• Wheat• Barley• Oats	<ul style="list-style-type: none">• Wheat• Barley• Oats• Corn	<ul style="list-style-type: none">• Fruit (e.g. apples)

Adapted from FSPCA



Outside of Food Allergens, the Vast Majority of Chemical Management Revolves Around Mycotoxins and Heavy Metals

- Heavy metal contamination is, for the most part, naturally occurring
 - Arsenic – organic vs. inorganic arsenic
 - Lead
 - Mercury – specifically methyl-mercury
 - Cadmium
- Bioaccumulation – “farm to fork” approach
- Risk assessment – risk management – risk communication
 - “Zero” is infinite and unattainable
- Susceptible sub-population focus
- Regional differences

Adapted from FSPCA



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Controls for Mycotoxins and Heavy Metals is Dynamic, Complex, but Necessary

Spec
Management

Use of
Ingredient
and/or Food

Changing
Scientific and
Regulatory
Landscape

Routine
Monitoring

Sample
Identification

Costly

Overall Approach to Compliance Falls Into Three Buckets



Ultimately, FSMA Levelled the Playing Field

- Proactive vs. Reactive
- Large, medium, small firms – equal “playing field” from a compliance standpoint
- Safety is not competitive – shared learnings and knowledge is important

Questions?

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