

# Global Food Regulatory Landscape 2020

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*American Spice Trade Association (ASTA)*  
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# What's the Story on Spices?

- ❖ Flavor, nutritional support, novel innovations, health and well-being
  - **consumer values**
- ❖ Claims and messaging
  - **science-based**
- ❖ Quality and safety, micro, chemical, allergens, adulteration
  - **risks**
- ❖ Supply chain, management and traceability
  - **integrated**
- ❖ Regulatory requirements, best practices
  - **proactive compliance**



# COMPLEX REGULATORY LANDSCAPE



<b>Common Aims</b>	<b>Simplicity</b>
<ul style="list-style-type: none"><li>▪ <b>Protect Consumers</b></li><li>▪ <b>Best Practices</b></li><li>▪ <b>Enable Trade</b></li><li>▪ <b>Consumer Information &amp; Choice</b></li></ul>	<ul style="list-style-type: none"><li>▪ <b>Common Global Standards</b><ul style="list-style-type: none"><li>✓ Science-based</li><li>✓ Simpler compliance</li><li>✓ Import/ export</li><li>✓ Easier to educate</li></ul></li></ul>

## **COMPLICATIONS...**

- **Cultural**
- **Political**
- **Competitive industry**
- **Interpretation of science**
- **Distorted Information**
- **Consumers**

# Historical Factors... (lost consumer trust)

BSE (Bovine Spongiform Encephalopathy/ 'Mad Cow Disease' - neurodegenerative)  
late 1980s, 90s...



1990 UK Agriculture minister Gummer: "There is no need to be worried"

1996 BSE – CJD link, EU bans UK beef

**Consumer Confidence** ↓

## GMO (Genetically Modified Organisms)

1996 GM tomato paste approved in UK. Public skeptical.

1997 EC Novel Foods Regulation (258/97) comes into effect, requiring a safety assessment for novel and GM foods

1998 April, UK supermarket chains begin to ban use of GMOs in products

❖ 2000 MAFF splits, UK Food Standards Agency formed: 'farm to fork'



# Key Risk Assessors



**Established under EU Food Law 2002**

**“Trusted Science for Safe Food”**

[www.efsa.europa.eu](http://www.efsa.europa.eu)



[http://www.fda.gov/Food/FoodScienceResearch/  
RiskSafetyAssessment/](http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/)



Global Risk Assessment committees for CODEX ALIMENTARIUS e.g. JECFA

[http://www.fao.org/food/food-safety-quality/scientific-  
advice/jecfa/en/](http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/)



# Jury awards couple \$2 billion in Monsanto Roundup cancer lawsuit trial

BY APRIL SIESE  
MAY 13, 2019 / 7:38 PM / CBS NEWS



WHO IARC: 'Probably carcinogenic to humans' (despite limited evidence)



Joint FAO/WHO Meeting on Pesticide Residues: (JMPR) "unlikely to present a public health concern"



Risk Agencies disagree with IARC – low risk

**CONFLICT ON RISK!**

# IARC Monographs on the Identification of Carcinogenic Hazards to Humans

International Agency for Research on Cancer



‘National health agencies can use this information as scientific support for their actions to prevent exposure to potential carcinogens.’

Group 1	Carcinogenic to humans
Group 2A	Probably carcinogenic to humans
Group 2B	Possibly carcinogenic to humans
Group 3	Not classifiable as to its carcinogenicity to humans

**‘The *Monographs* identify cancer hazards even when risks appear to be low’**

**CONCERN: Hazard assessments alone can be taken out of context**  
?Alarmist, misinterpreted, intentionally to support an agenda...

# Approved Chemicals

## 'Southampton Six' food colors



### Artificial Food Colors and Hyperactivity

University of Southampton, UK (2007), research into possible links between food colors and hyperactivity in children.

- Mixtures tested
- No concrete findings
- Limited data



2008 EU precautionary Label required:  
E number + 'May have an adverse effect on activity and attention in children'

**EFSA evaluated Southampton 2007 study on food additives and child behavior**



EFSA + experts in behaviour, child psychiatry, allergy and statistics, concluded limited evidence

2016 EFSA completed review of individual colors. Found no exposure concerns and supported existing Acceptable Daily Intakes

**CONFLICT ON RISK!**



**OEHHA** Risk review

<https://www.linkedin.com/pulse/oehha-synthetic-food-dyes-symposium-sept-19-20-objective-slayne/>



U.S. Food and Drug Administration  
Protecting and Promoting Your Health

Approved



Slayne Consulting

# THE BALANCE ON CHEMICALS IN FOOD: RISK vs HAZARD

## **Hazard:**

- entity with potential to cause harm

## **Risk:**

- the likelihood that a hazard would cause harm
- dependent on dose and how consumed

***The World is made of chemicals!***

***Zero tolerance not possible***



AP Associated Press

SACRAMENTO, Calif. — 2007

A woman who competed in a radio station's contest to see how much water she could drink without going to the bathroom

**died of water intoxication**

Oct 2015

Daily Mail  
.com

A 47-year-old British woman is the first hiker to have **died from drinking too much water**, doctors have reported. The high volumes of water and exercise caused levels of salt in her blood to plummet

# Risk Communication - Dubai Nov 2019

## **COMMON GLOBAL PATTERN**

- Conflicting messaging on science, benefits, relative risk, approved uses vs hazardous potential, single chemicals vs complete foods, and poor public understanding of actuality.
- Consistent, best science-based regulation can help reduce conflicts, building public confidence.
- Key opportunity: **Risk Perception** strategy.
- Saudi FDA – model ‘Risk Communication Department’, Dr. Hamoud Alnughaymishi



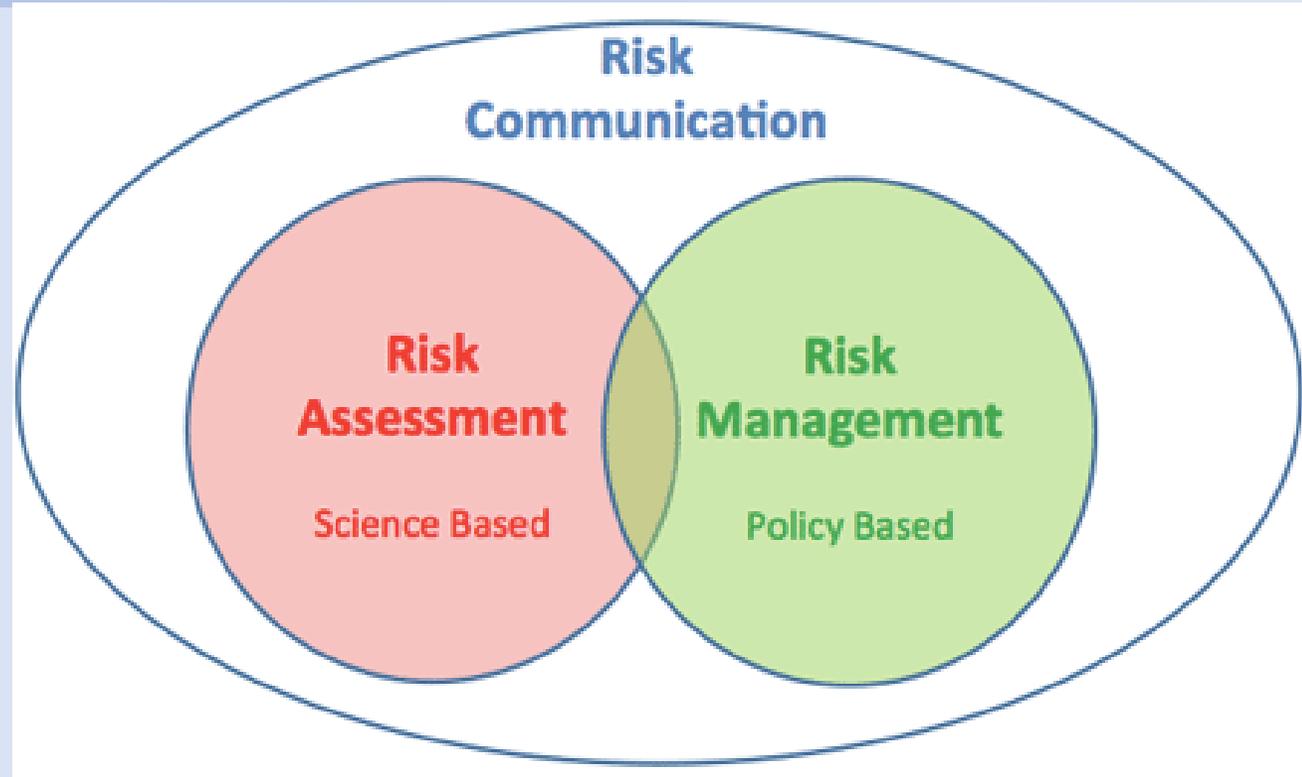
<https://slayneconsulting.com/blog/f/food-risk-communication---action>

# The Risk Analysis paradigm

**Risk Assessment:** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and, (iv) risk characterization.

**Risk Management:** The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

**Risk Communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.



Provides National Food Safety Authorities a systematic and disciplined approach for making evidence-based food safety decisions

# CODEX ALIMENTARIUS

(<http://www.codexalimentarius.org/>)

- Created in 1963 by the **Food & Agriculture Organization (FAO)** and the **World Health Organization (WHO)**
- Protect **consumer health**  
Ensure **fair trade**
- Food standards, guidelines, codes of practice...
- 25 Committees: Contaminants, Additives, Food Labeling, Nutrition, Food Hygiene, Pesticides...
- Expert Risk Assessments...e.g.**

**C O D E X**  
A L I M E N T A R I U S  
International Food Standards



World Health Organization



Food and Agriculture Organization of the United Nations

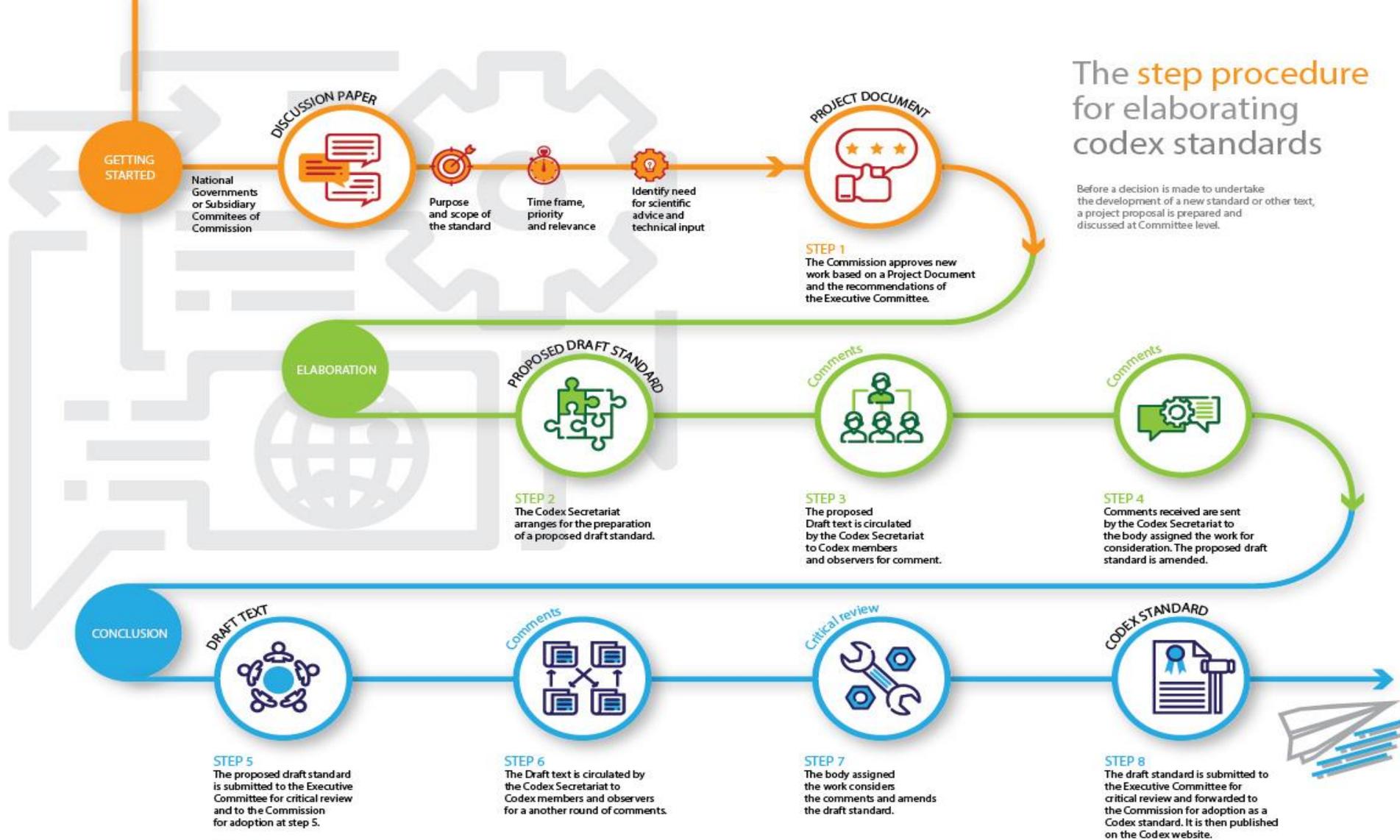


**JECFA**

JOINT FAO/WHO  
EXPERT COMMITTEE  
ON FOOD ADDITIVES

**JMPR**

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES



# The step procedure for elaborating codex standards

Before a decision is made to undertake the development of a new standard or other text, a project proposal is prepared and discussed at Committee level.

**Step 5/8:** Increasingly subsidiary bodies are utilizing a Step 5/8 procedure. This entails texts being submitted for adoption at Step 5 having a recommendation that Steps 6 and 7 be omitted and that the text also be adopted at Step 8. This practice substantially speeds up the adoption process.

# Chemical Contaminants in Food:

*Manage based on Achievability/ Good Practices, Scientific Risk, & Legality*

## Agricultural

- Mycotoxins – aflatoxin, ochratoxin A, *Fusarium* toxins, patulin... (Code of Practice 2017, Spices)



## Industrial & Environmental

- Metals – Arsenic, Cadmium, Lead, Mercury, Tin
- Dioxins & Polychlorinated Biphenyls (PCBs)

## Process

- Acrylamide, Polycyclic Aromatic Hydrocarbons (PAH), 3-MCPD

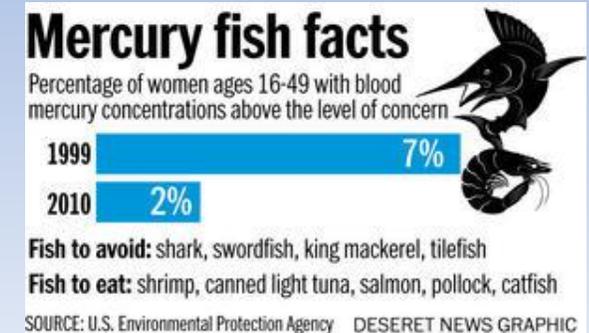


## Natural Toxicants

## Economic Adulteration (illegal)

- Dyes in spices (sudan red)
- Melamine

**European Commission 2005**  
“all food ingredients or foods prepared from spices containing illegal dye(s) above the relevant LOD using HPLC should be withdrawn from the market”



**The Times, November 25, 2009**  
Two men have been executed in China for selling hundreds of tonnes of contaminated milk that killed six babies and made 300,000 ill.

# Codex Committee on Contaminants in Food

## PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD

Codex members and observers invited to consider the following proposals:

- Establish a ML of 0.2 mg/kg for fresh culinary herbs;
- Establish a ML of 2.0 mg/kg for dried culinary herbs;
- Establish the following MLs for spices:
  - Fruits and berries: 0.6 mg/kg
  - Rhizomes, bulbs and roots (dried): 2.5 mg/kg
  - Rhizomes, bulbs and roots (fresh): 0.8 mg/kg
  - Bark: 3.0 mg/kg
  - Floral parts: 1.0 mg/kg
  - Seed: 0.9 mg/kg
- Postpone to next year the establishment of MLs for lead in food for infant and young children and sugar and confectionery...



# Codex Committee on Contaminants in Food

## MYCOTOXINS: AFLATOXINS AND OCHRATOXIN A

### 2019 Conclusion

- hold ML 20/30  $\mu\text{g}/\text{kg}$  for AFT and 20  $\mu\text{g}/\text{kg}$  for OTA in nutmeg, chili and paprika, ginger, pepper and turmeric, at Step 4 to give time to *implement the Code of Practice for the prevention and reduction of mycotoxins in spices* (CXC 78- 2017)
- JECFA would issue a call for data in three-years' time (2022)
- an EWG would be re-established when data submitted



# ALARA Principle

## What is 'As Low As Reasonably Achievable'?

- Follow Good Practices + ...?  
Depends on dietary exposure risk assessment...
- Commercial feasibility:  
Regional data might not reflect Global feasibility  
e.g. raw materials, climate, soil types... Cadmium in volcanic regions...
- ALARA levels based on available data:  
**share data to ensure commercial feasibility**

# The Precautionary Principle

<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:l32042&from=EN>

Designed to assist with decision-making under uncertainty.

*"... lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures..." (UNEP 1992).*

## **CRITICISMS**

- Interpretations, strong
- everything a risk, need pragmatism
- overly-strict stifles innovation
- rejections/ food waste without benefit

## **EU Common Guidelines**

The precautionary principle shall be informed by **three specific principles**:

- the fullest possible **scientific evaluation**, the determination, as far as possible, of the degree of scientific uncertainty;
- a risk evaluation and an evaluation of the potential **consequences of inaction**;
- the **participation of all interested parties** in the study of precautionary measures, once the results of the scientific evaluation and/or the risk evaluation are available.

# Impact for Risk Management?

## Contaminants:

- Maximum Levels for highest contributing foods
- >5% dietary exposure = trigger to set an ML
- What if several foods contribute low amounts?

## *SCENARIO*

1. Three food ingredients = 80% total dietary exposure
2. Several other food ingredients, each lower than 5%, make remaining 20% exposure
3. Set MLs just for the main three, or for the small contributors too?
4. What's achievable?

## Additives:

- Levels approved based on amounts for desired functional effects, vs safety thresholds.
- Less flexible for innovation
- Keeps check on use levels

## Agri Residues:

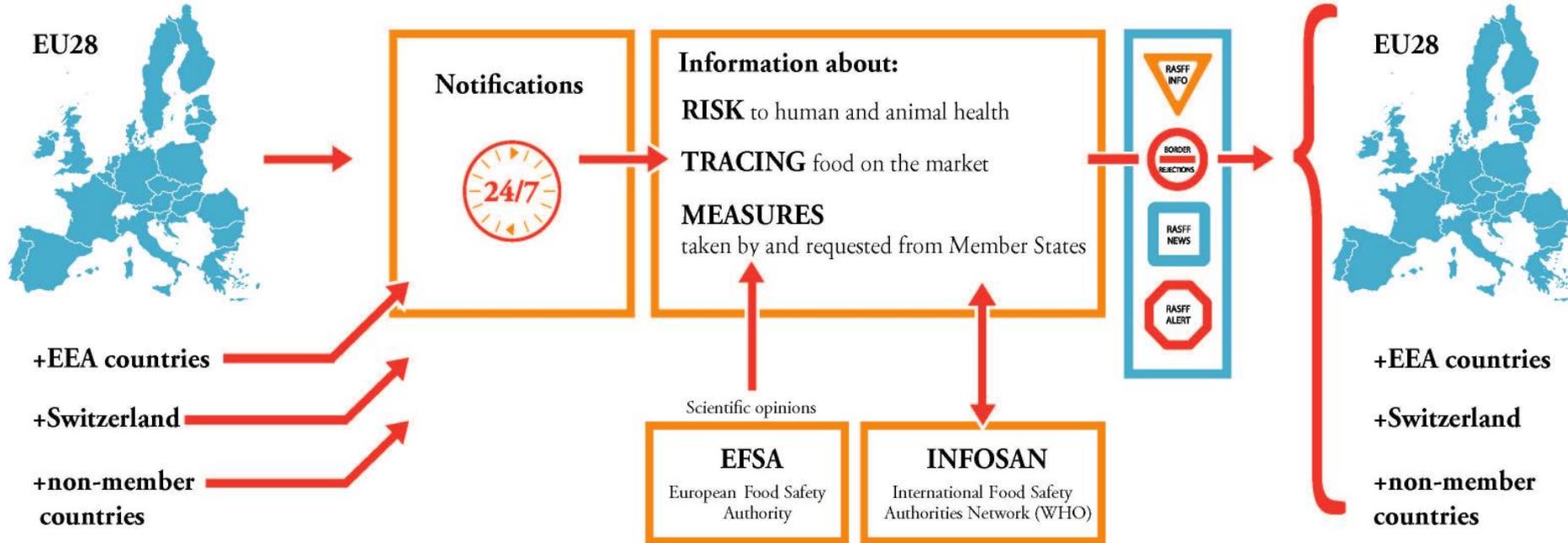
- MRLs based on functional use levels. Environ impact.

## **Opportunity to Engage with CODEX: Achievable Risk Management**

- ✓ **Consistent, Common Global Standards (vs regional default)**
- ✓ **Based on Risk, Science, Global Achievability**
- ✓ **Simpler: Compliance, Execution, Trade, Education**
- ✓ **Share: Data, Perspectives, Feasibility  
Have a Voice, Influence**

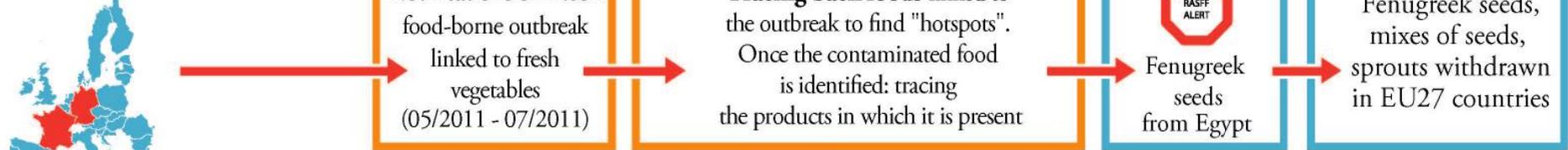


# How does RASFF work



## ORIGIN      PROCESS      MEASURES

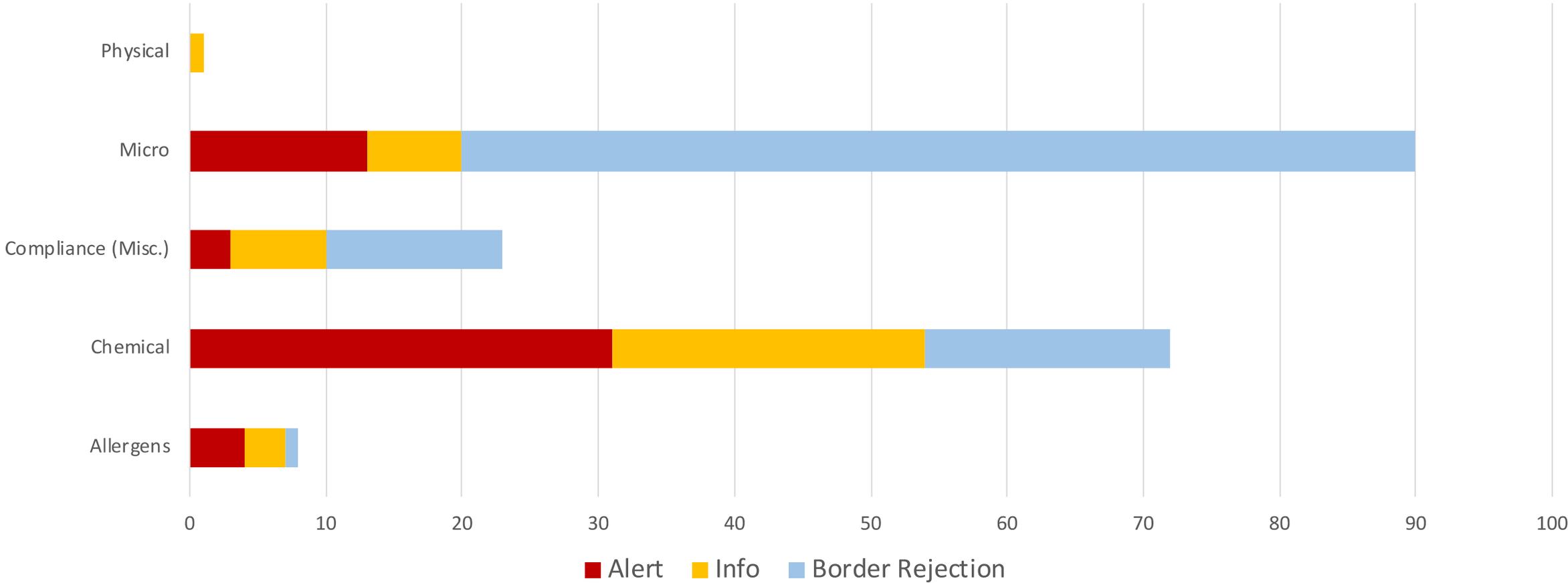
### CASE STUDY: E.coli



Food & Feed

# EU RASFF - Rapid Alerts for Herbs & Spices

Herbs & Spices: 194 Reports, EU RASFF, April 16, 2019 - April 15, 2020



# UNACCEPTABLE RISK – PROACTIVE EDUCATION

## ❖ Business Risk-taking Trend

- Liability, Knowledge & Insights
- Educate to separate UNACCEPTABLE RISKS
- Scenarios Planned - Supply Chain and Senior Leadership
- Action on food safety culture commitments

## ❖ Culture & Proactive Approach Established

- Shift risk-taking to risk scenario mitigation
- Informed Supply Chain practice, quick, effective risk decision-making
- Avoids reactive internal conflict and delays

# IMPLICATIONS OF COVID-19?

## ❖ Shopping On-line/ eCommerce

## ❖ Grocery Categories vs Unavailable Brands

## ❖ Innovation, Value, Trust

## ❖ Nutritional Ingredients

- deliver nutritional promise
- recipe consistent
- healthful convenience foods/ home preparation

## ❖ Messaging & Claims

- science-based; don't over-promise on health and immunity!
- supplements: scrutiny for solid science
- authentic, trust

## ❖ Strong on Sustainability & Fairness

- workers, environment, global awareness/ social responsibility

# Business Value: Science and Regulatory - Issues & Trends

- Food Safety Laws + Execution
- Chemicals – Contaminants, Toxicants, Residues, Additives (Prop 65, Codex, WHO, Scientific Risk)
- Ingredients - Approvals, Supply, Authenticity, Adulteration
- Healthy & Sustainable Food
  - Lowering Sugar, Fats, Sodium
  - Positive Health & Nutrition, Fair, Environment & Workers
- Labels, Claims, Consumer messaging – transparency and trust
- GMO/ Bioengineering/ Technology – Labels, Claims, Acceptance
- Organic, Natural, Healthy/ Artificial
- Allergens - Labeling laws
- Halal, Kosher - Certifications
- Date Coding - 'Use By', 'Best By/ Before'
- Packaging - Chemical migration/ quality, sustainable
- E-Commerce - compliance
- Innovation, M & A



# Simply Communicating Business Value

## Issue Title

### Issue

- Describe challenge impacting the business...

### Action

- What we will do/ did about it...

### Impact

- Avoided \$ fees?
- Saved \$ costs?
- Enabled \$ business?
- Deliverable that adds value to your organization



# Thank You!

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