

Global Food Regulatory Landscape 2020

Martin Slayne, PhD

President, SlayneConsulting LLC

Regulatory - Risk - Science - Advocacy - Consumers

martin@slayneconsulting.com

www.slayneconsulting.com

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



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

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.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"



EPA

United States
Environmental Protection
Agency

Risk Agencies disagree with IARC – low risk

CONFLICT ON RISK!



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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

EFSA evaluated Southampton 2007 study on food additives and child behavior



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

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

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

CONFLICT ON RISK!



OEHHHA Risk review

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



Approved



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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



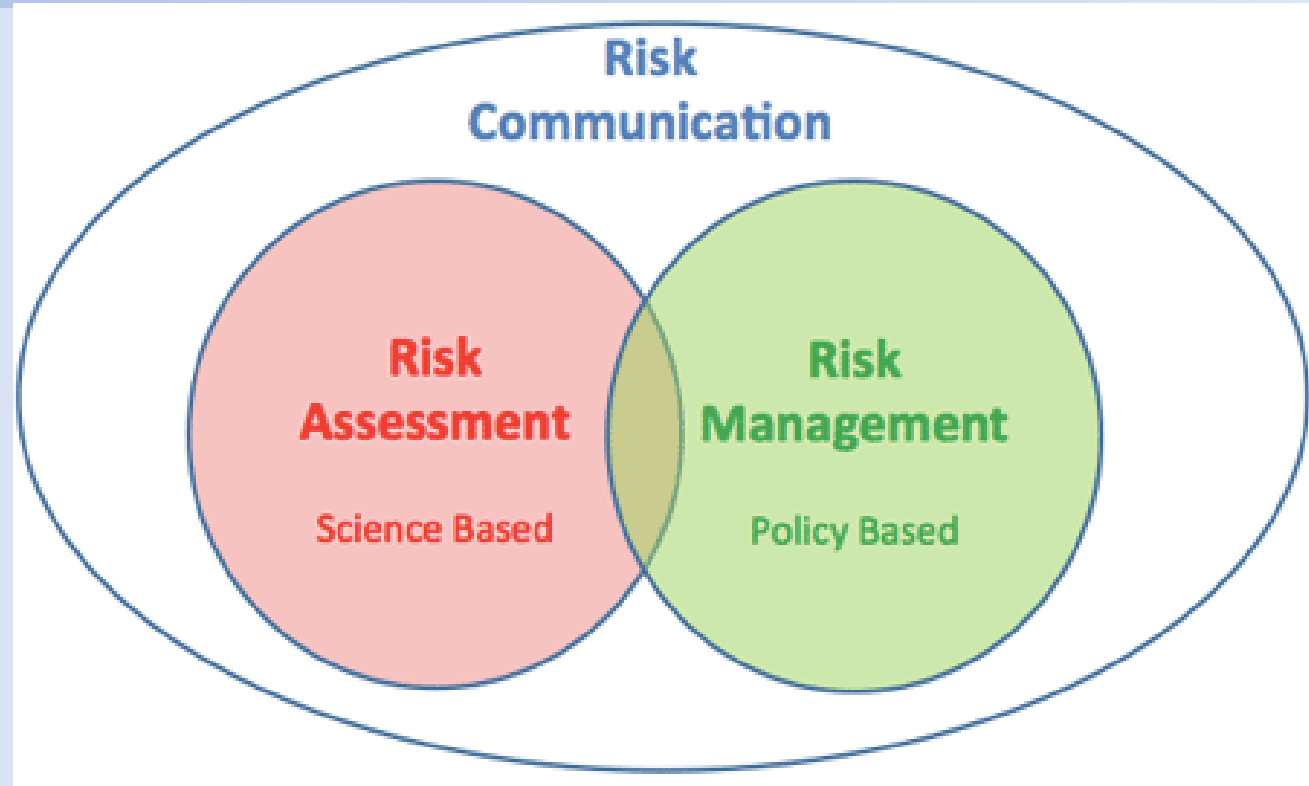
<https://slayneconsulting.com/blog/f/food-risk-communication---action>

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.**

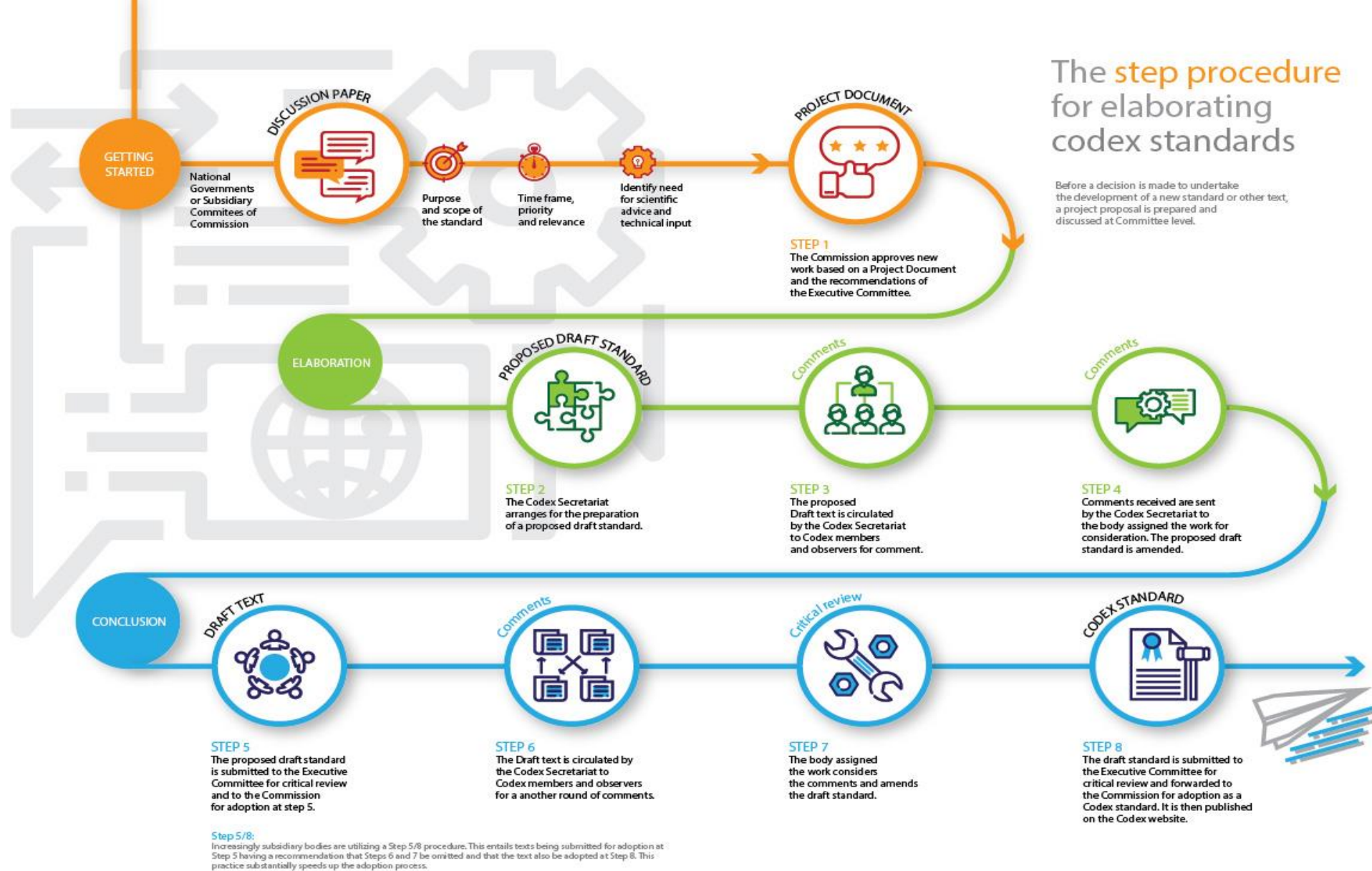


JECFA

JOINT FAO/WHO
EXPERT COMMITTEE
ON FOOD ADDITIVES

JMPR

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES



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)

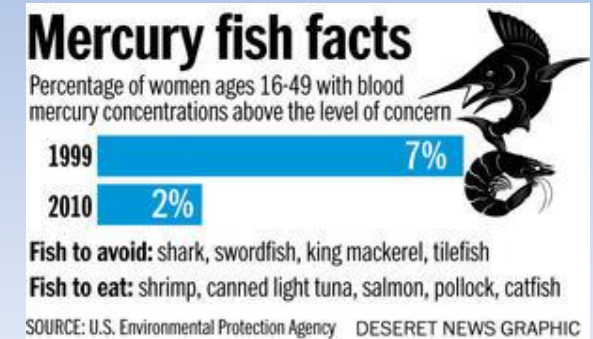
Process

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

Natural Toxicants

Economic Adulteration (illegal)

- **Dyes in spices (sudan red)**
- Melamine



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.

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”

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 $\mu\text{g/kg}$ for AFT and 20 $\mu\text{g/kg}$ 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:

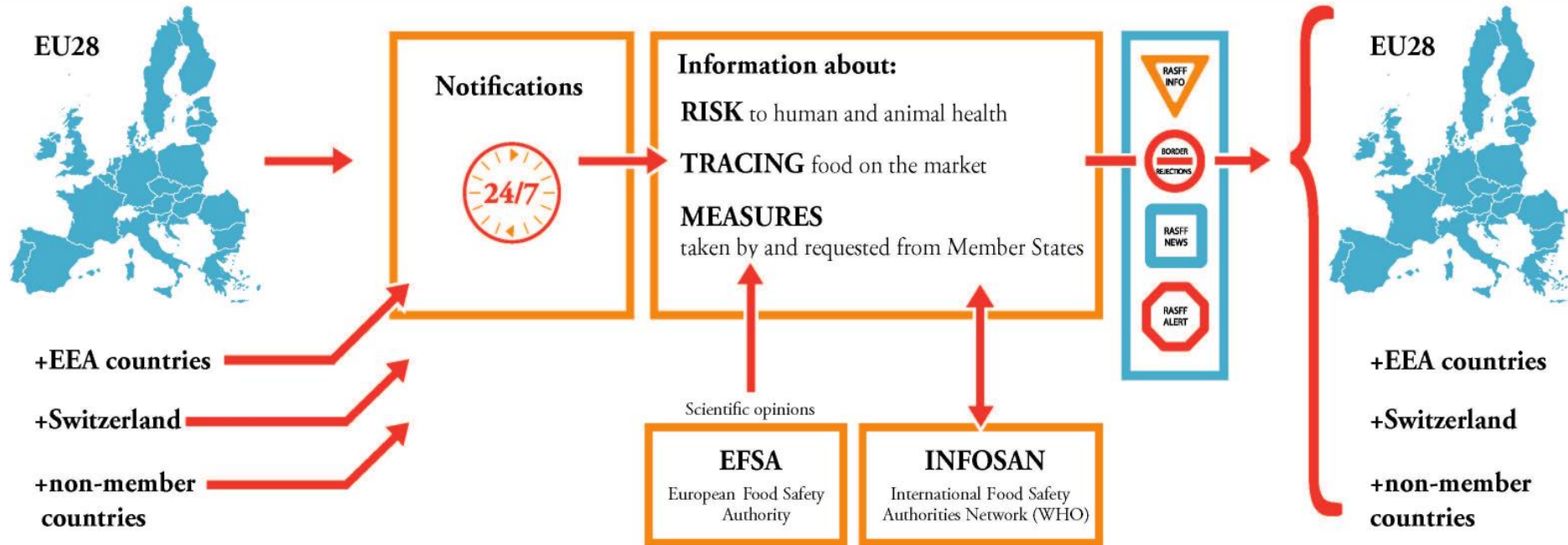
- MRLs based on functional use levels. Environ impact.

Opportunity to Engage with CODEX: Achievable Risk Management

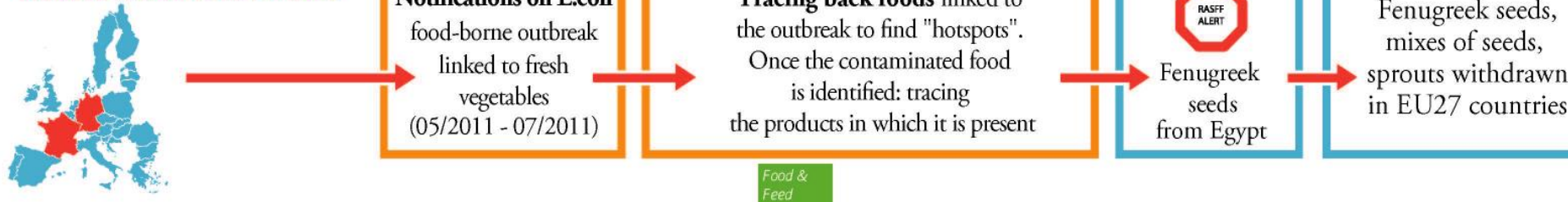
- ✓ **Consistent, Common Global Standards (vs regional default)**
- ✓ **Based on Risk, Science, Global Achievability**
- ✓ **Simpler: Compliance, Execution, Trade, Education**
- ✓ **Share: Data, Perspectives, Feasibility
Have a Voice, Influence**



How does RASFF work

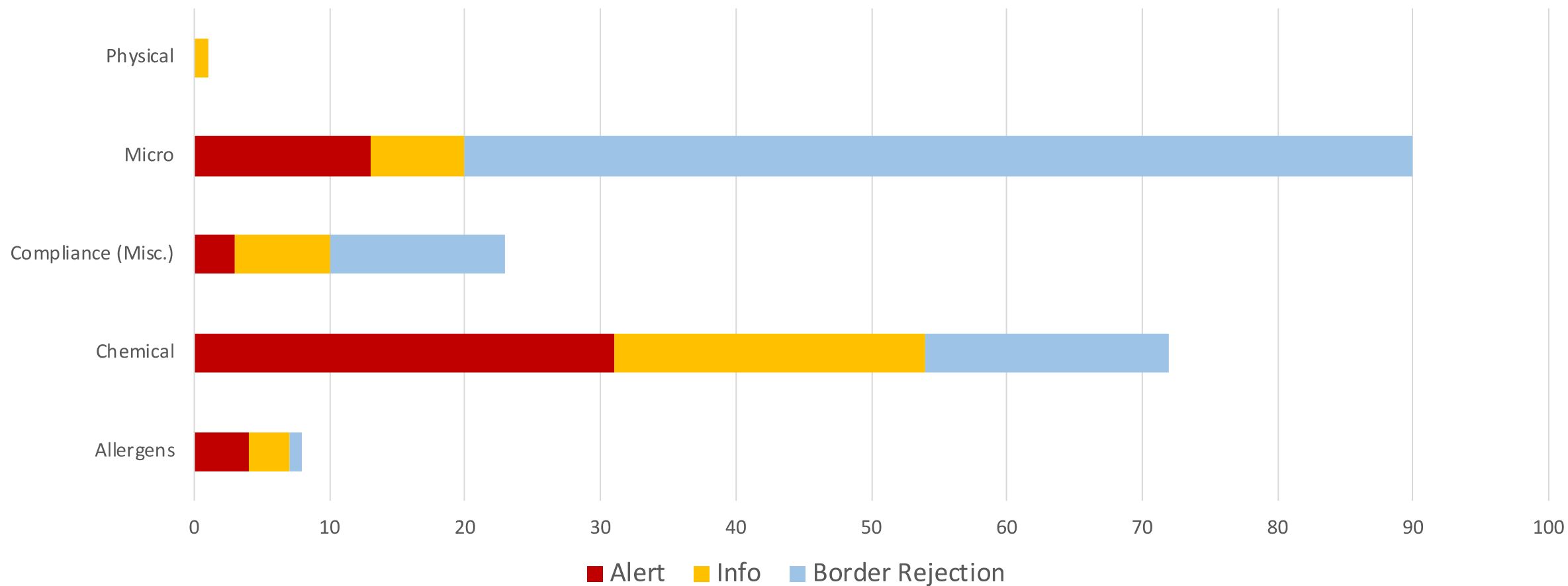


CASE STUDY: E.coli



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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