Importance of International Standards and MRLs and MLs for Accurate Data Analysis

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International Agreement: WTO-SPS Agreement

Agreement on the Application of Sanitary and PhytoSanitary Measure

Protecting life or health of

• human
• animals
• plants
SPS Agreement

Article 2

(1) Member have the right to take *sanitary and phytosanitary measures (SPS)* necessary for the *protection of human, animal or plant life or health*...

(2) SPS Measures applied only to the extent necessary *based on scientific principles*...
SPS Agreement

Article 3

(2) SPS Measures which conform to international standard, shall be deemed to be necessary to protect human, life or health

(3) Members may introduce or maintain SPS measures which result in a higher level or SPS protection than measures based on the relevant international standards, if there is a scientific justification...
SPS Agreement

Article 3

(1) Members shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human…life of health, taking into account risk assessment techniques developed by the relevant international organizations.
International Standards

**CODEX >>> human health**
(Joint FAO/WHO Food Standards Programme)

**IPPC >>> plant health**
(International Plant Protection Convention)

**OIE >>> animal health**
(The Office International des izooties, World Organization for Animal Health)
WTO/SPS Trade Concerns/Disputes

- Specific trade concern – raised by Member(s) to other Member(s) under WTO/SPS Committee
- 312 STCs in 16 years, of which 28% are on food safety
- 22 food standard related STCs raised in 2010-11 SPS Committee on:
  - Chemical (MRLs MLsd) (9), Specific foods (6), Labelling (2)
- 40 SPS trade disputes are in WTO process, of which 15 cases the Dispute Settlement Bodies have been established – only 3 cases related to food safety
Objectives

- Protecting health of consumers
- Ensuring fair practices in international food trade

by Elaboration of international standards & related texts
Established 1961/1962
Member (2011) 184 countries + EU
Codex Bodies

- Codex Alimentarius Commission (CAC)
- Codex Executive Committee
- Codex Subsidiary bodies - Committee
  - ad hoc Task force
- FAO/WHO Secretariat

🔗 Expert bodies
Expert Bodies (under FAO/WHO)

- Joint FAO/WHO Meetings on Pesticide Residues (JMPR)
- Joint FAO/WHO Expert Committee on Food Additives (JECFA) – food additives, contaminants, vet drugs
- Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA)
- Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) (on process of establishment)
- FAO/WHO Expert Consultation on specific issue e.g. Nanotechnology
Codex Standards relating to Food Safety

1. Food safety limits
   - MRLs (Maximum Residue Limits) – Pesticide residue, Vet drug residue
   - MLs (Maximum Levels) - Contaminants
   - MLs (Maximum Use Levels) - Food additives
   - Microbiological criteria (MC) – Pathogenic microorganisms

2. Code of Hygienic Practices

3. Others e.g. Labelling, Methods of analysis & sampling
MRLs: Pesticide & Veterinary Drug

Residues from the uses of

1. Pesticide including:
   - Insecticide, Acaricide, Rodenticide
   - Fungicide
   - Herbicide
   - Plant growth regulator

2. Veterinary drug including:
   - Substances applied to food producing animal for therapeutic, prophylactic or diagnostic or for modification of physiological functions/behaviour
Codex Standards on Pesticide Residues

- Pesticides in the system ~ 240
- Pesticides with limits ~ 175
  - MRL 170 pesticides >3000
  - EMRL 5 pesticides ~ 50
- MRL on step process ~ 30
Codex Standards on Residues of Veterinary Drugs

- Veterinary drug residues with limits ~ 50
- Total MRL already established > 500
- Commodities e.g. muscle, fat, milk, egg, liver, kidney including fish & crustaceans
**MLs : Contaminants**

**Contaminant** means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination.

The term does not include insect fragments, rodent hairs and other extraneous matter.  
*(Codex Procedural Manual)*
Contaminants

- Environmental contaminants: heavy metals, POPs, PCBs, dioxin
- Industrial contaminants: 3-MCPD, PAH
- Mycotoxins: aflatoxin, ochratoxin A, fumonisn, DON
- Prohibited/Banned substances: melamine
- Codex Maximum Level (ML) = maximum permissible/tolerable level
Food Additives

- intentional added to food for a technological (including organoleptic) purpose
- Codex Maximum Use Level (ML) = maximum level added into food  not  maximum detectable level
- Codex General Standard on Food Additives (GSFA)
- Not include food ingredients, processing aids, contaminants, pesticides, vet drugs, nutrients,
Pathogens in Foods : MC

- Microbiological Criterion (MC) :
  - A criterion that defines the acceptability of a food lot, based on the absence or presence, or number of microorganisms including parasites and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot. (CAC/GL 21-1997)
  - A metric which can indicate the acceptability of a food, a food lot, a process or a food process environment at a specific point in the food chain following the outcome of sampling and testing for microorganisms, parasites and/or their toxins/metabolites
  (draft revised CAC/GL 21-1997)
Codex : MC

MC already established by CCFH

- *Enterobacter (Cronobacter) Sakazakii* and *Salmonella* spp. in powdered infant formula (PIF) and *Salmonella* spp. in powdered follow up formula (FUF)
- *Listeria monocytogenes* in ready-to-eat (RTE) food
- MC in Codex standard for natural mineral water
Codex Risk Analysis

Risk Assessment
FAO/WHO Expert Bodies

Risk Management
CAC, Committees

Risk Communication
Risk Assessment & Management

Risk assessment policy

Risk Assessment

Scientific data & information

Risk assessment result

Risk management

Other legitimate factors
- benefits, economic
- social, cultures
- stakeholders

RM measures e.g. standards
Codex: Standard Setting

Various Comments

Government, Consumer, Private sectors, Experts...
risk

benefit
Codex Pesticide MRL Establishment

- Foods/Feeds
- Mainly on raw agricultural commodity (RAC)
- Only on some specific cases that MRL established for processes food commodity
- MRL as a trading limit *not* actually safety limit
Principle for MRL establishment

- Complete data evaluation and MRL recommended by JMPR
- Highest residue from supervised residue trial according to highest/critical GAP
- Provide adequate safety to consumer according to dietary exposure assessment
JMPR Work Process

WHO Panel

Toxicological + others

ADI

Exposure assessment

Codex MRL

FAO Panel

Use Patterns = GAP

&

Supervised Trial

Draft MRL

Codex MRL
Risk assessor:
- Toxico evaluation
- Risk assessment
- MRL recommendation / propose for withdrawal

Risk Manager:
- Priority list for pesticide evaluation by JMPR
- Establish risk assessment policy
- Consider MRL establishment / withdrawal
Key Issues on the Use of Food Safety Limits at National Level

• The basis/portions of food the limit applied to e.g. fresh wt, dry wt, whole commodity, edible portion, raw commodity, processed food

• Level of the limit vs LOQ/detection limit of the method of analysis used

• Default/Uniform limits where no specific limit for a specific chemical/food e.g. refer to Codex standards, LOQ, 0.01 mg/kg or a specific permission/acceptance

• Decision making when found violation of the limit
Conclusions

- National food safety limits should be comparable to Codex standards unless there are reasons based on risk assessment.

- Codex standards do not cover all limits needed by all countries so standard harmonization among countries is important.

- Violation of food safety limits is not always implied as unsafe food.
For more information

www.codexalimentarius.net

Thank you

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