Applying Risk Assessment Outcomes to Establish Food Standards

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The Safe Food Cycle

- Changing national food patterns
- Identifying potential food risks
- Undertaking risk assessment
- Introducing control measures

Safe nutritious food
<table>
<thead>
<tr>
<th>Food Additives, Processing aids, Herbicides, Pesticides</th>
<th>Nutritive Substances (\text{• Health promotion} ) (\text{• Performance enhancement} ) eg, creatine, CLA, glucosamine, choline, stevia extract, guarana extract, red clover extract, kava extract</th>
<th>Bioactive Substances or extracts</th>
<th>Contaminants or toxins</th>
<th>Other Foods (\text{• Novel foods} ) (\text{• GM foods} ) eg, herbs, native plants</th>
</tr>
</thead>
</table>
Identifying Potential Food Risks

Natural food components
Additives to food
Food contaminants
Application of new technologies
Novel ingredients

Minor change to food – risk assessment not warranted

Undertake risk assessment

No controls necessary

Some controls necessary
Risk Assessment Framework

1. **Hazard identification**
   What are the potential adverse health effects?

2. **Hazard characterisation**
   What adverse health effects occur at different dose levels?

3. **Dietary exposure**
   What is the level of dietary exposure?

4. **Risk characterisation**
   What is the likelihood of an adverse effect occurring for different population groups?
Inputs to Risk Assessment

**Toxicity data**
- Mainly international sources
- Interpretation of data varies
- Consensus through WHO committees (JECFA, JMPR, JEMRA)

**Exposure data**
- Local data most relevant
- Complex assessment often not necessary
- International data can also be used

Outputs:
1. Magnitude of the health risk
2. Risk control options
Specific Outcomes of Chemical Risk Assessment

- Nature of the hazards (if any) associated with the chemical
- Exposure level at which the various adverse effects might occur
- Identify ‘at risk’ population groups
- Likely short-term and long-term exposure levels

Likelihood of an adverse effect (comparison with safety benchmarks)

Options for risk management
Factors Influencing Acceptable Risk

- The ‘acceptability’ of a measurable food risk varies between individuals and between societies.
- Regulatory agencies need to recognise these differences in applying appropriate controls.

Measurable health risks:
- Minimise exposure to the risk factor in the food to a safe level.

Perceived health risks:
- Identify the presence of the risk factor to enable individual to make a choice.
Benchmarks to Identify Safe Exposure Levels

- **High** level of use + No evidence of potential harm
  - ‘GRAS’
  - ADI ‘not specified’
  - Margin of exposure
  - (novel foods; novel food ingredients; some food additives)

- **Variable** level of use + Measurable evidence of harm
  - ADI and TDI
  - Food additives; contaminants

- **Low** level of use + Little data to estimate potential harm
  - Threshold of toxicological concern (TTC)
  - (flavours, food contact materials)
Food Control Options Related to Food Safety

- Specifications for composition and purity
  - all substances added to food

- Maximum use levels
  - food additives (based on technical need / ADI)
  - contaminants (based on ALARA / TDI)

- Restricted or prohibited use
  - plants and fungi with natural toxins

- Approved (positive) list
  - processing aids
  - novel foods (+/- conditions of use)

- Maximum residue levels
  - pesticides and veterinary drugs

- Labelling
  - advise and warnings or preparation instructions
  - presence of allergens

- Production and manufacturing controls
Food Additives: Setting the ‘Safe’ or ‘Acceptable’ Level of Intake

- **Acceptable intake (ADI)**
- **Adverse response**
- **NOAEL**
- **LOAEL**
- **Safety factor**
- **Dose**

Safety factor as a multiplier to convert NOAEL to ADI:
Use Levels for Food Additives

1. Additives with a low ADI compared to the expected intake
   - Specify the maximum levels to avoid exceeding the ADI
   - Restrict the number of foods with the additive

2. Additives with ADI ‘not specified’ or high compared to the expected intake
   - Allow use in all foods according to GMP – very unlikely to exceed safe level
Control Options for Food Additives

<table>
<thead>
<tr>
<th>For the majority of the population</th>
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<tbody>
<tr>
<td>(including children and the elderly)</td>
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<tr>
<td>The potential health risks relate to possible exposure above the ADI</td>
</tr>
<tr>
<td>Establish maximum use levels or use according to GMP</td>
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<tr>
<td>Presence in food identified on label</td>
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<table>
<thead>
<tr>
<th>For a small percentage of the population</th>
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<tr>
<td>Additional risks relate to metabolism or sensitivity issues</td>
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<td>Managed by labelling (warning statements) and education programs</td>
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<td>(eg, Individuals with intolerance to phenylalanine)</td>
</tr>
<tr>
<td>(eg, Individuals with hypersensitivity to sulphites)</td>
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Standard Setting for Processing Aids

Food Additive  v  Processing Aid

- Used during food preparation or added to the final food product
  - Present in the final food – variable levels
  - Has a technological function in the final food

- Used during food preparation only
  - Generally not present in the final food or very low residues
  - No technological function in the final food
Control Options for Processing Aids

• Positive approval list
  - generally grouped according to functional class

• Use levels controlled by GMP
  - majority of processing aids

• Establish MLs, if necessary, for small number still present in final food

• Use is not identified on food labels
Standard Setting for Contaminants

Food Additive v Contaminant

- Specifically added to food
- Levels in food controlled
- Standard set on technological level and ADI
- Standards always set for food additives

- Present normally or inadvertently added
- Levels highly variable
- Standards only set for some contaminants – other effective control options are available
- Standard set on lowest reasonably achievable level / GMP and TDI
What factors influence contaminants levels?

**Physical and climatic conditions**
Cadmium in vegetables; aflatoxin in peanuts; ochratoxins in grains and coffee

**Cooking and processing**
Acrylamide in starchy foods; chloropropanols in soy sauce

**Environmental levels**
Dioxins, lead, PCBs, arsenic in foods

**Manufacturing controls and specifications**
Vinyl chloride monomers, heavy metals, solvents in packaging

**Adulteration**
Melamine in infant formula, borate in noodles, rhodamine in confectionery
Control Options for Contaminants

At primary production level:
- waste management / disposal programs
- water quality control programs
- industrial zoning regulations
- MLs / guidelines for primary produce

At food manufacturing level:
- quality assurance programs
- good manufacturing practices

At retail and consumer level
- food preparation and storage advice
When are food standards necessary for contaminants?

Other control measures not fully effective leading to:

• High potential risk from food consumption
  - could be to a susceptible sub-population

• On-going food contamination in important food commodity
  - evidence from total diet surveys
Use of Guideline Levels rather than Standards

• Useful where health risk is low, but still potential for some contamination

• Benchmark for both manufacturers and enforcement agencies regarding ‘normal’ levels

• Can act as a trigger for remedial action

• Does not automatically remove food from market
How are standards for chemical contaminants established?

Collection of available data on toxicity and levels in foods

- Evaluate toxicity data or use TDI established by JECFA
- Evaluate data on local contaminant levels and food consumption or use WHO regional data

Determine the total dietary intake and compare with the tolerable intake level

Establish MLs for individual foods using ALARA approach
Setting MLs for Cadmium

Tolerable daily/weekly intake

Exposure

Various Foods

MLs established

MLs not established
Setting a Contaminant Standard

ML established at the upper end or just above the normal concentration range
- ALARA (‘as low as reasonably achievable’)
National Contaminant Standards

1. The health risk may be assessed differently in some countries (e.g., mercury, aflatoxin):
   - different TDI determination (based on toxicology data)
   - different dietary intake determination (different foods and/or consumption rates)

2. The achievable level of contamination may vary between countries (e.g., aflatoxin, ochratoxin):
   - Climatic differences
   - Economic factors
Standard Setting for Novel Food Ingredients

Definition of novel food vary between countries, but essentially:

Non-traditional foods or food ingredients where the safety is uncertain.

Examples
Phytosterol, phytostanols and their esters
Alpha-cyclodextrin
Gamma-cyclodextrin
Dried marine micro-algae (Schizochytrium sp.) - rich in docosahexaenoic acid (DHA)
Oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexaenoic acid (DHA)
D-Tagatose
Trehalose
Conjugated linoleic acid
Benchmarks for Safety of Novel Food Ingredients

1. No evidence of harm at the anticipated levels of exposure
2. Large margin of safety between use level and NOAEL

- No restriction on use
- Maximum use levels for novel ingredient in food
- Restrict use to certain food types

Approved list of novel foods (+/- conditions of use)
Use Levels for Novel Ingredients

1. Set MLs - toxicity is observed at achievable intake levels
   - Specify maximum levels in foods
   - or
   - Restrict the number of foods with ingredient

2. No MLs necessary – no toxicity at well above the expected levels of intake
   - Allow use in all foods according to GMP
Standards for Very Low Intake Chemicals

- Packaging materials
- Flavours

- Generally little or no toxicity data
- Can use metabolism data and structural class data to predict toxicity
- Threshold of Toxicological Concern (TTC) used as benchmark of safety

Positive Approval List