Criteria for the Establishment of Maximum Levels

MAFF

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What is JECFA?

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Joint FAO/WHO Expert Committee on Food Additives (JECFA)

1. International expert scientific committee that is administered jointly by FAO and WHO
2. JECFA is independent from the Codex system
3. Provides scientific advice to Codex and any other interested parties
4. It has been meeting since 1956, initially to evaluate the safety of food additives.

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Areas of work of JECFA

1. Risk assessment/safety evaluation of:
   a. Food additives and processing aids (>2500)
   b. Flavouring agents (by functional groups)
   c. Residues of veterinary drugs in animal products (ca. 90)
   d. Contaminants and natural toxins (ca. 40)
2. Exposure assessment
3. Specifications and analytical methods for food additives; and residue definition and MRL proposals for veterinary drugs
4. Development of general principles

   Consistent with current thinking on risk assessment and taking account of developments in toxicology and other relevant sciences

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Evaluation of contaminants by JECFA

1. Hazard characterization (WHO)
2. Exposure assessment (FAO & WHO)
   a. Dietary exposure to contaminants and toxins
   b. Effect of different ML proposals on exposure, upon request by the CCCF
3. Guiding document
   a. *Principles and Methods for the Risk Assessment of Chemicals in Food* (EHC 240, WHO 2009)
      (Chapter by chapter)

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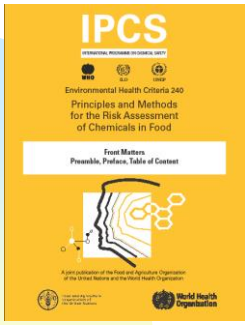

- **Basis for evaluation by JECFA (and JMPR)**
- **For:**
  - **toxicological evaluation**
  - **exposure assessment**
- **Under revision now**

Available on the WHO website:
http://www.who.int/foodsafety/publications/chemical-food/en

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JECFA recommendations for contaminants and natural toxins

1. Health-based toxicological guidance values
   a. Provisional tolerable daily intake (PTDI), Provisional tolerable weekly intake (PTWI), Provisional tolerable monthly intake (PTMI)
   or
   b. Benchmark dose (BMD) Benchmark dose lower limit (BMDL)
2. Dietary exposure assessment, and/or
3. Assessment of the effect of different ML proposals on dietary exposure

A PTWI or PTMI: When a contaminant accumulates in the body or when it takes long time for a contaminant to show health effect(s)

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How can we use the JECFA recommendations?

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JECFA Recommendations on Contaminants

1. Toxicological endpoints
   a. If the same data set is used, usually universal
   b. There may be some room for different interpretation
   c. Normally they can be used in individual countries if there is no time for detailed risk assessment
2. Exposure assessments
   a. The result may be different from country to country
      1) Different concentrations in foods
      2) Different consumption of foods
   b. Need to be done by countries

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Maximum Levels (MLs) for Contaminants

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Codex Definition of Contaminant

1. Any substance not intentionally added to food or feed for food producing animals;
2. Present in such food or feed as a result of the production (incl. operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed; or
3. Present as a result of environmental contamination.
4. Does not include insect fragments, rodent hairs and other extraneous matter.

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"Contaminant" includes

1. Mycotoxins / Bacterial toxins
2. Phytotoxins
3. Phycotoxins (incl. marine toxins)
4. Heavy metals
5. Organic substances
   a. Occurring during processing, etc.
   b. Migrating from packaging materials to foods
6. Radionuclides
7. Also pesticide & veterinary residues and processing aids

Note: Substances used in adulteration are not contaminants (intentionally added)

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Codex definition of maximum level for contaminant

1. Maximum concentration (in mg/kg) of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity (food or feed)

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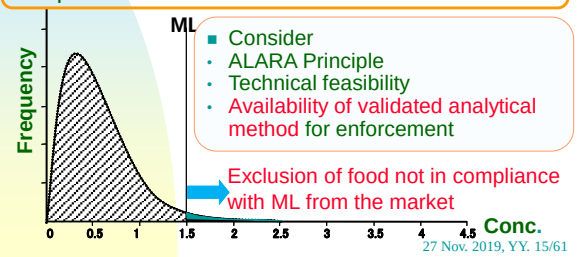
Effect of MLs on Reduction of Concentrations

- MLs are based on occurrence data
- Low MLs would exclude large amount of food from market
- Impossible to examine all foods in the market



- Consider
  - ALARA Principle
  - Technical feasibility
  - Availability of validated analytical method for enforcement

Exclusion of food not in compliance with ML from the market

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Maximum Levels should be:

1. Sufficiently low to
   – Protect the health of consumers; and
   – Prevent "bad practice", such as mixing the non-compliant food with the compliant food for selling (ethical problem)
2. Sufficiently high to
   – Protect honest farmers/manufacturers following the "good practice"
   – Be able to be analyzed (MLs must be higher than the LOQ of the method)

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Codex General Standard on Contaminants and Toxins in Food and Feed

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General Standard on Contaminants and Toxins in Food and Feed

1. First adopted in 1995
   a. There was no mentioning of "feed"
2. Revised in 1997, 2006, 2008, 2009 (Inclusion of MLs)
3. Amended in 2010, 2012, 2013, 2014, 2015, 2017 and 2018 to include or delete MLs
4. Main text
   a. Scope
   b. Definition of terms, in particular, for "contaminants" and "maximum level"
   c. Principles regarding contaminants in food and feed
   d. Format of the GSCTFF

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5. Annex I: Criteria for the Establishment of Maximum Levels in Food and Feed
6. Annex II
   a. Format of the GSCTFF
   b. Schedule = list of MLs and COPs

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Scope

1. Contains
   a. Main principles in dealing with contaminants and toxins in food and feed
   b. Lists of Codex MLs and associated sampling plans of contaminants and natural toxicants in food and feed to be applied to commodities moving in international trade
2. Includes only MLs of contaminants and natural toxicants in feed only where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health.

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Principles

1. General

- Contaminant levels in food and feed shall be as low as reasonably achievable through best practice such as GAP and GMP following appropriate risk assessment.
- Actions to prevent or reduce contamination:
  - Preventing contamination at the source (e.g., reducing environmental pollution);
  - Applying appropriate technology control measure(s) in the process;
  - Applying measures aimed to decontamination

⇒Elaboration of COP (source related measures, GMP, GAP)

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- Contamination levels and the effect of actions shall be assessed by monitoring, survey or research programs.
- Risk assessment should be conducted if consumption of contaminated food may involve health problem
- Risk management measures shall be applied if heath concern is substantiated.
  - ML, other measures, or dietary advice
- Creation of unnecessary barriers to trade of food/feed should be avoided.
- For contaminants present in multiple commodities, a broad approach shall be applied.

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2. Principles for establishing maximum levels in food and feed

- MLs shall only be set for food in which the contaminant may be found in amounts that are significant for the total exposure for consumers (explained later)
- MLs shall be set a such a way that the consumer is adequately protected. The other legitimate factors need to be considered.
- The principles of GMP and GAP as defined by Codex shall be used. MLs shall be based on sound scientific principles leading to MLs acceptable worldwide.

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3. Specific criteria
   Details are included in Annex I

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Annex I: Criteria for the Establishment of Maximum Levels in Food and Feed

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Toxicological Information

For proposing MLs, information the following aspects is desirable:

a. Identification of the toxic substance(s)
b. Metabolism in humans and animals,
c. Toxicokinetics and toxicodynamics including information on possible carry-over from feed to foods of animal origin
d. Information about acute and long term toxicity in animals and humans and other relevant toxicity data
e. Integrated toxicological expert advice regarding the acceptability and safety of intake levels
   1) Recommendation of JECFA can be used

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Analytical data

1. Validated qualitative and quantitative analytical data on representative samples
   a. Portions of commodity analyzed
   b. Validation of analytical method
2. Information on appropriate sampling procedures
   a. Homogeneously distributed or not homogeneously distributed (mycotoxins in some commodities)

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Intake data

1. Presence in food of dietary significance
   a. Desirable to have information about the contaminant concentrations in foods or food groups that together are responsible for ≥50% and preferably ≥80% of the total dietary intake of the contaminant, both for consumers with average and high consumption patterns.
2. Presence in food that are widely consumed
3. Presence in feed and feed components ⇒presence in foods of animal origin

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5. Food consumption data for average, high consumers and susceptible consumer groups
6. Results from total diet studies
7. Calculated contaminant intake data from food consumption models
8. Data on intake by food producing animals

Dietary intake of contaminants:
Reference is available from the WHO websiste.

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Technological considerations

1. Information on:
   a. Contamination processes
   b. Technological possibilities
   c. Production and manufacturing practices
   d. Economic aspects related to contaminant level management and control
2. Adapt
   a. Source-related measures
   b. Good manufacturing practice (GMP)
   c. Good agriculture practice (GAP)

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Risk assessment and risk management considerations

1. Follow the Working Principles for Risk Analysis for Food Safety for Application by Governments
   a. Risk management options and considerations
   b. Consideration of possible MLs based on the criteria mentioned above
   c. Consideration of alternative solutions

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Establishment of MLs Criteria

1. MLs should be set:
   a. Only for contaminants presenting a significant risk to public health
   b. Only for food that is significant for the total exposure of the consumer to the contaminant (explained later)
   c. As low as reasonably achievable and at levels necessary to protect the consumer (next slide)
   d. On a basis of data from various countries and sources, encompassing the main production areas/processes of these products.

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Application of the ALARA Principle

- As Low as Reasonably Achievable
- MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods which are produced with current adequate technological methods to avoid undue disruptions of food production
- Precondition:
  - Protection of the health of consumers
  - Appropriate production/manufacturing to avoid contamination

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Establishment of MLs Criteria (2)

2. MLs may be set for food groups when sufficient information is available for the whole group, or extrapolation is appropriate.
3. MLs should apply to representative samples per lot.
4. MLs should not be lower than a level which can be analyzed with analytical methods that can readily be set up and applied in control laboratories, unless health concern necessitates a lower ML.
5. The contaminant as it should be analyzed and to which the ML applies should be clearly defined.

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Establishment of MLs Criteria (3)

6. The food as it should be analyzed and to which the ML applies should be clearly defined. In general, MLs are set on primary products. MLs should preferably be expressed as a level in the product as it is, on a fresh weight basis.

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Identification of foods/food groups that contribute significantly to total dietary exposure

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Policy of the CCCF for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups

1. Contained in the Procedural Manual as guidance to CCCF
2. Section 3 contains, "Identification of Foods/Food Groups that Contribute Significantly to Total Dietary Exposure of the Contaminant or Toxin"

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Identification of Foods/Food Groups that Contribute Significantly to Total Dietary Exposure of the Contaminant or Toxin: Criteria

Foods or food groups for which exposure to the contaminant or toxin contributes approximately:

1. 10% or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Cluster Diets;
2. 5% or more in two or more of the GEMS/Food Cluster Diets; or
3. Less than 5% but foods/food groups have significant impact on exposure for specific groups

Can be modified for uses in a country.

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Checking the safety and validity of MLs - Importance of Dietary Exposure Assessment

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Why Assess Dietary Exposure?

1. In order to check the validity and safety of MLs.
2. Until the estimated dietary exposure is sufficiently lower than the health-based guidance value, it is not possible to decide on the ML(s).
3. Food consumption may be different from country to country.
4. In the following slides, the importance of dietary exposure assessment is explained

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Need for Exposure Assessment

1. Presence of a toxic hazard does not necessarily pose significant risk
2. Even if a hazard is highly toxic, if it is contained only in foods not consumed frequently in significant amount, risk from this hazard may be negligible.
3. In order to know the level of risk, need to know:
   a. Concentration of the hazard in foods
   b. Consumption of these foods
   c. Toxicity of the hazard

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Need for Exposure Assessment

1. Risk estimate is obtained by comparing:
   a. Toxicological endpoint obtained from hazard characterization
      1) International recommendations (JECFA's or JMPR's) can be used universally
   b. Exposure estimate obtained from exposure assessment
      1) Different from country to country due to differences in occurrence and consumption of foods

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Health Based Guidance Value

1. Chronic toxicity
   a. ADI for intentionally used chemicals
      1) Pesticides, Veterinary Drugs, Food Additives
   b. PTDI/PTWI/PTMI for unintentional presence
      1) Contaminants
2. Acute toxicity
   a. Acute Reference Dose (ARfD)
      1) Pesticides, Veterinary drugs, contaminant (so far for Deoxy nivalenol)

Elements in Exposure Assessment

1. Levels of chemicals of concern in specific foods
   a. Analytical data (or theoretical values)
2. Food intakes/day/person
3. Additional factors, such as
   a. Distribution of the chemical in edible/inedible portions
   b. Processing factors
   c. Percentage of use on crops or in foods

Estimation of intake

1. Surveillance or monitoring data
2. Food consumption data

↓

1. Distribution curve
2. Intake estimates
   a. Deterministic approach (mean or median)
   b. Probabilistic approach/Semi-probabilistic approach

Deterministic Approach (Point estimation)

- Can be used for both long-term and short-term exposure estimation
- Refined methods are available
- Easy, not expensive, not time consuming
- Many data points are not necessary
- Assuming the worst-case scenario
- Some limitations: no information on the high-end intakes, distribution or uncertainty; eaters vs whole population

Probabilistic Approach

- Can be used for both long-term and short-term exposure estimation
- Need for extensive data (occurrence and food consumption) and PC
- Not as easy as deterministic approach
- Gives much more information including
  - Distribution
  - High percentile values depending on the number of data points
  - Uncertainty

Dietary Exposure Assessment in Codex

1. Dietary Exposure Assessments of:
   a. Pesticide Residues
   b. Veterinary Drug Residues
   c. Contaminants
      1) Heavy Metals,
      2) Mycotoxins
      3) Other contaminants
   d. Food Additives

Exposure Estimates

1. Compared with Toxicological Endpoints
   a. Acceptable Daily Intakes (ADIs)
      1) For intentionally used chemicals
         Pesticides, Veterinary Drugs, Food Additives
   b. Provisional Tolerable Intakes (PTDI, PTWI, PTMI)
      1) For unintentional presence
         Contaminants, Natural Toxins

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Total Diet Studies

1. Effects of cooking can be observed
2. Less analysis necessary
3. Faster and easier
4. Information is obtained on food(s) or group(s) of foods for which more detailed surveillance is necessary, i.e., can be used for screening/prioritization
5. Information on the distribution of intake cannot be obtained
6. Reference books published by WHO

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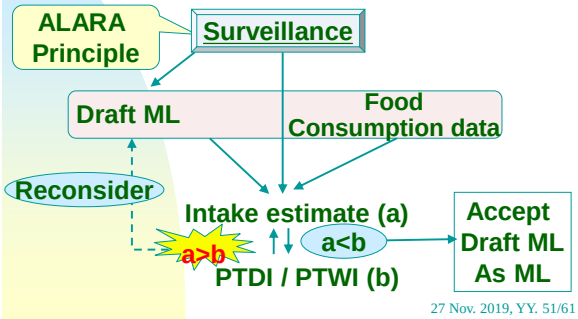
Establishment of Maximum Levels Summary



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ML Setting

1. When there are many different data sets:
   a. Different year
   b. Different methods of analysis with different LOQ
   c. Different regions
2. Need to know if these data sets can be combined or not
   a. 2 data sets: Mann-Whitney U test
   b. 3 or more data sets: Kruskal-Wallis H test
   c. Most of the cases, data from regions are combined: to look at the whole nation
3. However, information on pollution must be collected and remove any data from the polluted areas

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ML Setting

3. Draw the cumulative distribution curve
4. Use of distribution model (@Risk or other software)
   a. Capable of recommending an ML higher than the highest analytical result (depending on the model)

Or

2. Use the distribution of real values (Excel can work for this)
   a. Always percentile values are lower than the highest analytical result
   b. Not suitable for insufficient data set

The quality of data determines the quality of MLs

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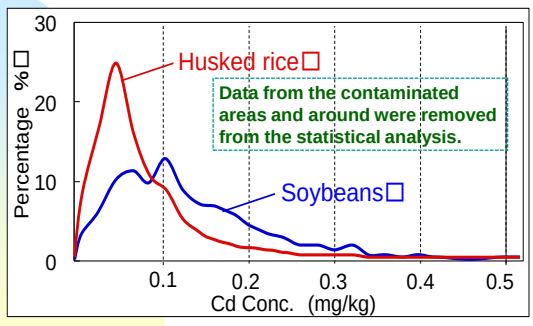
Distribution of concentrations



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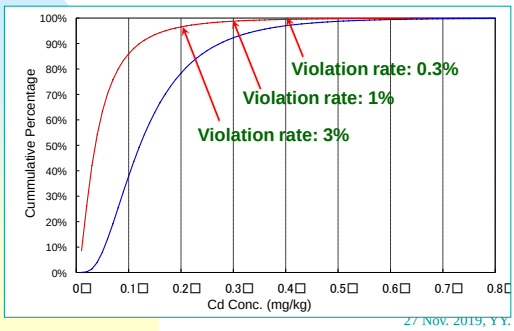
Cumulative Distribution (Assuming log normal distribution)



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Example: iAs in polished rice

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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Agenda Item 6 CX/CF 14/8/6

February 2014

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Eighth Session

The Hague, The Netherlands, 31 March – 4 April 2014

PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE (RAW AND POLISHED RICE)

(Prepared by the Electronic Working Group chaired by China and co-chaired by Japan)

BACKGROUND

1. The 5th session of the Committee on Contaminants in Foods (CCCF) (March 2011) agreed to initiate new work on maximum levels for arsenic in rice based on a discussion paper prepared by China.[1] The proposal was approved by the 34th session of the Codex Alimentarius Commission (July 2011).[2]

2. The 6th session of the CCCF (March 2012) agreed to retain the proposed draft maximum levels (MLs) for inorganic or total arsenic in rice at Step 4 until the Committee resumed the consideration of the MLs at its 8th session based on the outcome of proposals to be prepared by China following identification of additional relevant data and information provided by member countries, especially rice-producing countries, to GEMS/Food.[3]

3. The 7th session of the CCCF (April 2013) agreed that the Electronic Working Group (EWG) led by China and co-chaired by Japan would prepare a discussion paper on proposals for draft MLs for arsenic in rice and rice products for consideration at the next session. The Committee encouraged members to submit relevant data to the EWG, especially those from rice-producing

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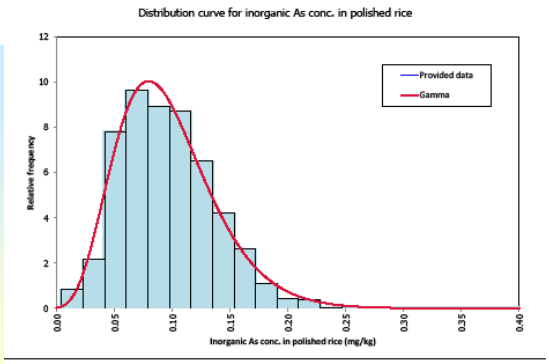

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When there is no toxicological endpoint, what can we do?

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Surveillance/Monitoring Data

1. Can be used to know the background levels (range)
2. Any analytical result significantly higher than the background range indicates that there is something wrong
3. Can be used to develop MLs
4. Estimated intake can be compared with the NOAEL or benchmark dose to get the margin of exposure

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Codes of Practice

1. Developing codes of practice does not require the toxicological endpoint
2. Efforts to decrease the concentrations of contaminants

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Thank you for your attention!

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