

Supporting Document 4

Criteria for the establishment of maximum levels in food

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Contaminants in food are substances that serve no technological purpose and whose presence may lead to adverse health effects. Therefore, robust risk assessments and management options are used to reduce any risk from a contaminant to 'As Low As Reasonable Achievable' (ALARA) (ANZFA; 1998a; Abbott et al, 2003)).

There is currently no Australian or New Zealand definition of a contaminant and Australia and New Zealand defers to the following definition proposed by the Codex Alimentarius Commission (Codex, 1995).

- *'Any substance not intentionally added to food which is present in such food as a result of production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or hold of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matters.'*

FSANZ outlined criteria for setting maximum levels (MLs) for contaminants in the Inquiry Report for Proposal 157 Contaminants Review in 1999. These principles remain and are in line with the relevant Codex standard.

MLs are proposed only where they can be justified in terms of achieving public health and safety objectives, and are based on the following principles for setting MLs:

- only for those contaminants that present a significant risk to public health and safety
- only for those foods that significantly contribute to the dietary exposure of the contaminant; and
- to ensure that levels are as low as reasonably achievable.

Proposed MLs will be consistent with Codex levels, where possible. However, harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders (NFA 1999).

Codex criteria for the establishment of maximum levels in food

In the *Codex Standard for Contaminants and Toxins in Food and Feed* (FAO/WHO CAC, CODEX STAN 193-1995, last revised in 2015), criteria for the establishment of maximum levels in food and feed are outlined in Annex 1. In the case that, on the basis of the risk assessment, there is a need to establish a maximum level to protect public health, the following criteria are outlined to assist in maintaining a consistent policy in this matter:

- MLs should be set only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade.
- MLs should be set only for food that is significant for the total exposure of the consumer to the contaminant. When identifying the significance of certain foods in the total exposure to the contaminant, the criteria contained in Section 3 of the *Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* (Section IV of the Procedural Manual) should be consulted.
- MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable and necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake.

- Proposals for MLs in products should be based on data from various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.
- MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.
- Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.
- MLs should apply to representative samples per lot. If necessary, appropriate methods of sampling should be specified.
- MLs should not be lower than a level which can be analyzed with methods of analysis that can readily be set up and applied in food and feed control laboratories, unless public health considerations necessitate a lower ML which can only be controlled by means of a more elaborate and sensitive method of analysis with an adequate lower detection limit. In all cases, a validated method of analysis should be available with which a ML can be controlled.
- The contaminant as it should be analyzed and to which the ML applies should be clearly defined. The definition may include important metabolites when this is appropriate from an analytical or toxicological point of view. It may also be aimed at indicator substances which are chosen from a group of related contaminants.
- The product 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 in general preferably be expressed as a level of the contaminant related to the product as it is, on a fresh weight basis. In some cases, however, there may be valid arguments to prefer expression on a dry weight basis (this might be in particular the case for contaminants in feed) or on a fat weight basis (this might be in particular the case for fat soluble contaminants). Preferably the product should be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might interfere with the preparation and the analysis of the sample. The product definitions used by the CCPR and contained in the *Classification of Food and Feed* (CAC/MISC 4) may serve as guidance on this subject; other product definitions should only be used for specified reasons. For contaminant purposes, however, analysis and consequently MLs should preferably be on the basis of the edible part of the product.
- For fat-soluble contaminants, which may accumulate in animal products, provisions should be applied regarding the application of the ML to products with various fat content (comparable to the provisions for fat soluble pesticides).
- Guidance is desirable regarding the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgement of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food and feed can likewise be calculated from the composition of the food and feed. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance. When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general however, MLs should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient food and feed by using appropriate conversion factors. When these factors are sufficiently known, they should be mentioned in the suffix to the maximum level following the format of list of MLs as defined in Annex II.
- MLs should preferably not be set higher than is acceptable in a primary (theoretical maximum intake and risk estimation) approach of their acceptability from a public health point of view. When this poses problems in relation to other criteria for establishing MLs, further evaluations are necessary regarding the possibilities to reduce the contaminant levels, e.g. by improving GAP and/or GMP conditions. When this does not bring a satisfactory solution, further refined risk assessment and contaminant risk management evaluations will have to be made in order to try to reach agreement about an acceptable ML.

References

Abbott P, Baines J, Fox P, Graf L, Kelly L, Stanley G and Tomaska L (2003) Review of the regulations for contaminants and natural toxicants. *Food Control*, 14, 383-389. <http://www.ingentaconnect.com/content/els/09567135/2003/00000014/00000006/art00040>

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Relevant websites

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

http://files.foodmate.com/2013/files_1068.html

http://www.who.int/foodsafety/areas_work/chemical-risks/jecfa/en/

<http://www.foodstandards.gov.au/Pages/default.asp>