

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON CONTAMINANTS IN FOODS 5th Session

The Hague, The Netherlands, 21 – 25 March 2011

PROPOSED DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD (LIQUID INFANT FORMULA) (N13-2009)

Comments at Step 3 submitted by Brazil, Canada, New Zealand, Peru and IDF

BRAZIL

Brazil supports the Proposed Draft Maximum Level for Melamine in Food as proposed.

CANADA

BACKGROUND

At the Fourth Session of the Codex Committee on Contaminants in Food (CCCCF), the Committee agreed to forward the *Proposed Draft Maximum Levels for Melamine in Food (powdered infant formula and foods other than infant formula) and Animal Feed* to the 33rd Session of the Codex Alimentarius Commission (Geneva, Switzerland, 5-9 July 2010) for adoption at Step 5/8 (with omission of Steps 6 and 7), and the *Proposed Draft Maximum Level for Melamine in Food (liquid infant formula)* to Step 3 for comments and consideration by the next session.

POSITION

Canada supports the proposed draft maximum level of 0.5 mg/kg for liquid infant formula.

REASON

Information provided in the document, CX/CF 10/4/5, *Proposed Draft Maximum Levels for Melamine in Food and Feed*, prepared by an electronic working group led by Canada, supports the need for a maximum limit (ML) of 0.5 mg/kg melamine in liquid infant formula. Specifically, paragraphs 59 and 61, in which the latter paragraph, Table 2, contains a theoretical exposure estimate for melamine resulting from the consumption of liquid ready-to-consume infant formula, either describe or demonstrate the need for a lower ML in liquid infant formula than 1 mg/kg.

As a result of Canada adopting the WHO recommended Tolerable Daily Intake (TDI) for melamine of 0.2 mg/kg body weight per day in December 2008, and in consideration of the various types of infant formula that are available on the Canadian market (i.e., liquid ready-to-consume, liquid concentrated and powdered products), the maximum level (ML), in the form of an interim standard, for melamine* in infant formula and sole source nutrition products, including meal replacement products, was lowered from the initial 1 mg/kg ML to a 0.5 mg/kg ML in Canada. The lowering of the ML for infant formula and sole source nutrition products from 1 mg/kg to 0.5 mg/kg was supported by a dietary exposure and risk assessment that was undertaken in consideration of the WHO recommended TDI, in order to ensure that any exposures resulting from these types of products remain below the WHO TDI. All infant formula products tested from the Canadian retail market have been well below the 0.5 mg/kg maximum limit.

In Canada, all infant formulas and sole source nutrition products are subject to a 0.5 mg/kg melamine* ML, regardless of whether they are powdered, liquid concentrated or liquid ready-to-consume products.

**These levels will apply to a combined concentration of melamine and cyanuric acid (a chemical analogue that may be found with melamine).*

NEW ZEALAND

1. In accordance with circular letter CL 2010/13-CF of 10 May 2010, New Zealand wishes to submit the following comments on the Proposed Draft Maximum Level for Melamine in Food (liquid infant formula).
2. While not seeking to formally oppose the adoption of the proposed limit of 0.5 mg/kg for melamine in liquid ready-to-consume infant formula, New Zealand does query whether there is an actual need to adopt such a limit, or if there is another way of achieving the same outcome.

Comment on the proposed ML of 0.5 mg/kg in liquid ready-to-consume infant formula

3. The 33rd Session of the Codex Alimentarius Commission formally adopted MLs for melamine in 2010 and the relevant ML for infant formula that was adopted is 1 mg/kg for powdered infant formula. We understand that to reconstitute liquid infant formula from the powder, the powder is diluted 7 times, and so if the infant formula powder met the current Codex limit, that liquid formula would have less than 0.15 mg/kg melamine in it (rounded from 0.14 mg/kg).
4. New Zealand accepts that melamine can leach into liquid ready-to-consume infant formula if it is packed and stored in melaware containers and understands that for that reason, the ML for this food is being proposed at a level higher than would be expected if the liquid ready-to-consume formula was reconstituted from powdered infant formula that complied with the current Codex ML.
5. The current Codex MLs are set to ensure that the deliberate adulteration of foods and feeds with melamine would lead to a non-compliance with those Codex limits. New Zealand agrees that the proposed ML of 0.5 mg/kg for liquid ready-to-consume infant formula would be consistent with this goal and believes that it does not pose a food safety risk.
6. However, we are aware that the rate of leaching of melamine from packaging into foods contained in that packaging is time dependent. Is the shelf-life of the liquid ready-to-consume infant formula long enough for any potential leaching to increase the level of melamine in that formula from 0.15 mg/kg to 0.5 mg/kg? If this is unlikely, the number being proposed for this product does not need to be as high as 0.5 mg/kg. And, in this case, it would appear that the proposed limit could (in effect) allow the use of potentially non-compliant powdered infant formula to be used in the manufacture of liquid ready-to-consume formula.

Comment on whether there is a need for a specific Codex limit

7. New Zealand queries whether there is an actual need for the proposed extra ML for liquid ready-to-consume infant formula.
8. The General Standard for Contaminants and Toxins in Foods and Feed (CODEX STAN 193-1995), Annex 1, Criteria for the Establishment of Maximum Levels in Food and Feed gives the following guidance:

“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.”

9. In effect, this indicates that if the powdered infant formula is considered to be the primary agricultural product, then without specifying a level for liquid ready-to-consume infant formula, the appropriate conversion factor would already allow for a melamine residue of up to 0.15 mg/kg.
10. Further, there is an exemption from the current Codex ML applying to foods other than powdered infant formula if it can be proven that the excess melamine is a consequence of migration from food contact materials taking into account of any nationally authorised migration limit. If a similar exemption was applied to the limit for powdered infant formula, and the principle stated above is applied to residues of melamine in liquid ready-to-consume infant formula, then there would appear to be no reason to adopt a specific limit for liquid ready-to-consume infant formula.

On the basis of above comments New Zealand questions whether there is a need to adopt a specific ML for Melamine in Food (liquid infant formula). We would suggest that the desired outcome be achieved by adopting an exemption similar to that applying to food other than infant formula.

PERU

General comments

The maximum level allowed for melamine in powder formula for infants is 1mg/kg, and in other foods and feeds this substance shall not exceed 2.5 mg/kg, according to the new provisions of the ruling body of the United Nations for food, the Codex Alimentarius Commission.

Melamine is a chemical used in various industrial processes, as well as for producing plastics for tableware and kitchen utensils. It is also used for can lining, and the presence of traces in food conveyed through contact is unavoidable, and these do not pose a health problem. "Establishing maximum levels will help governments to distinguish between the presence of inevitable low levels of melamine, which pose no health risks, and intentional adulteration, which will in turn protect public health without raising unnecessary trade barriers." These new levels, though not legally binding, will allow countries to reject the imports of foods with melamine excessive levels.

IDF

The last Codex Alimentarius Commission adopted the following levels for melamine: 1 mg/kg in powdered infant formula and 2.5 mg/kg in foods (other than infant formula) and animal feeds. In addition, the Codex Committee on Contaminants in Foods agreed to circulate for comment an additional level of 0.5 mg/kg in liquid infant formula (for comments at step 3) for discussion at the next CCCF session in April 2011.

Because IDF supports the limit of 1 mg/kg in powdered infant formula (PIF), IDF does not agree with the proposed maximum level (ML) of 0.5 mg/kg of melamine in liquid infant formula (LIF) for the following reasons.

The CAC has recently adopted a ML of 1 mg/kg in PIF based on the outcome of appropriate risk assessment. Therefore, the proposed level for melamine in LIF (0.5 mg/kg) would create an inconsistency; it appears to be inexplicably on the higher side when compared with the ML for PIF on total solids basis and may not be safe for infants.

With regards to LIF, we question if a limit is required at all, given PIF is the primary product. In this case, the maximum level of '1 mg/kg on dry matter basis' for melamine in LIF could be applied.

If a limit is to be adopted, we support a limit that is 1/8th that for PIF, e.g. 0.125 mg/kg, to take account of the eventually varying dilution factor when reconstituting. The proposed limit of 0.5 mg/kg for LIF has no sound scientific basis and is not appropriate.