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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Sixth Session
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DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD (*LIQUID INFANT FORMULA*)

Comments at Step 6 (in reply to CL 2011/16-CF) submitted by Australia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, New Zealand, Sri Lanka and Uruguay.

AUSTRALIA

Australia supports the Proposed draft ML for melamine of 0.15 mg/kg.

The maximum level in liquid infant formula should be equivalent to that used for powdered infant formula. The proposed level of 0.15 mg/kg in liquid formula is equivalent to that permitted for powdered formula and is protective of the safety, based on the outcome of the risk assessment conducted by the CCCF electronic working group lead by Canada. Australia therefore supports this proposed level.

The levels of melamine which arise from food contact materials are expected to be considerably less than 0.5 mg/kg. Australian liquid formula manufacturers have indicated that the level of melamine in liquid formula is below a limit of detection (0.05 mg/kg). Whilst the removal of the exemption conditions would not cause problems for the Australian industry, we do not know whether there is a potential for different processing to result in levels exceeding 0.15 mg/kg. However, the proposed level, with an exemption where it arises as a result of migration from food contact materials, is still within safe levels given that the levels which would arise from migration are likely to be considerably less than 0.5 mg/kg.

The intention of developing this standard was to prevent the adulteration of foods with melamine. The proposed ML, together with an exemption in defined circumstances, achieves that intent.

BRAZIL

According to a WHO paper regarding Melamine and Cyanuric acid (http://www.who.int/foodsafety/fs_management/Melamine.pdf), the tolerable amount of melamine would be 2.5 mg per day for a 5 kg infant. This amount would be reached when consuming 750 mL liquid (or reconstituted) formula contaminated at a level around 3.3 mg/L (ppm).

The most packaging national legislation allows migration maximum limit of 30 mg/kg with no especial provisions to infants. It means that only the permitted migration from packaging material can exceed many times the tolerable intake. In this case, packaging material may contribute with the major part of melamine contamination; it is not only a dilution issue from the powder infant formula limit.

For this reason Brazil believes it is advisable establish a limit also taking into account the contribution of the melamine from the packaging material. If there are no data available to support a limit, Brazil also suggests that the producers of liquid infant formula could provide data on the occurrence level in this kind of products.

CHILE

1. Chile agreed with the proposed maximum level of 0.15 mg/kg for liquid infant formula (ready to consume), considering that for powered infant formula, Codex has already agreed to a maximum level of 1 mg/kg. In general these formulas are prepared by reconstituting the powder in water, using a reconstitution factor of 7 times, so you get a formula reconstituted limit of 0.142 mg/kg. This value is consistent with the limit being proposed for liquid infant formula (0.150 mg/kg). In addition, there are analytical methods to detect levels of 0.05 mg/kg, so the method of analysis does not limit the detection of the proposed value (0.150 mg/kg).

2. The Note is not supported since it does not apply in countries where migration of melamine from food contact materials is not regulated and only the total contact of melamine in the food is quantified, whichever its source.

COLOMBIA

Colombia supports the maximum level of 0.15 mg/kg of melamine in liquid infant formula. As for the note that allows exemptions to the established level due to migration from food contact materials, Colombia thinks that this note is not necessary for the following reasons:

The representatives of the pharmaceutical and food industries that import and sell liquid infant formula in Colombia support the elimination of this note of exemption, as in this country these products are distributed packed mainly in glass, which minimizes the risk of migration of melamine from the package to its liquid content, and the only contact remaining is between the formula and the polymer coated metal lids or seals of the jars. In turn, given the short time these products stay in the market before consumption, the risk of migration from the coating of the lids or seals to the content is minimized.

In addition, tests performed by some of the industries that sell liquid formulæ in the country to detect residues of melamine as part of their quality control processes did not find this substance in concentrations above 0.15 mg/kg.

Bradley *et al.*[1] evaluated the migration of melamine residues under conditions of sterilization and pasteurization in 13 cans with plastic coatings of different compositions (melamine-formaldehyde), as well as plasticized seals for glass jars used to pack food in ethanol (19%) and acetic acid (3%) based solutions, which simulate the food above mentioned.

In turn, in a second test, the migration of melamine from panels coated with two different types of resins, placed inside cans containing samples of acid or fatty foods, meat or fish, or a 10% ethanol base food-simulating solution, was evaluated. These samples were treated under pressure and temperature in an autoclave environment, under industrial processing conditions of sterilization and pasteurization for each type of food.

In the test of food-simulating solutions, the highest value of melamine migration in the studied cans was of 332 μg/kg, having received heat treatment at 130ºC for an hour, during which ammeline and ammelide migration in the analysis of that cover was also found. On the other hand, two of the lids studied were the same as the ones used in the metallic seals of the glass jars which are the baby foods packing, where a migration level was found of 2,5 μg/kg of melamine in the acetic acid solution at 3% simulating food with acid characteristics.

The evaluation of the migration of melamine in lined cans, containing samples of food or food-simulating solutions, the largest migration value found in food was 152 μg/kg, in one of the lids of fatty foods sterilized for a long time (90 minutes) over medium heat (121ºC). The highest migration of melamine in food-simulating solutions was also produced from the lid above, at 152 μg/kg, when processed at 134ºC for 60 minutes.

The study concludes that the release of melamine from the lids and seals of the cans is strongly influenced by the temperature used in applying heat treatment, and to a lesser degree by the heating time and the acidity of the food or simulating solution.

In another study by Lu J., Xiao T. and others[2] in China, 37 samples of packing where tested, including 15 packings of dairy products. The authors report that melamine was not detected in any of the 15 packages of dairy products analyzed.

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[1] Bradley El *et al*. Survey of the migration or melamine and formaldehyde from melamine food contact articles available in the UK market. *Food additives and contaminants*. June 2005: 22(6) 517-606.

[2] Lu, J; Xiao J., Study of migration of melamine from food packaging materials on markets. *Biomedical and Environmental Sciences*,2009 (22), 104-108.

To conclude, Colombia reiterates its position not supporting the exception included in the proposed maximum level (ML) for melamine in liquid infant formula, based on that, although experimental studies report that migration of melamine to food (2 µg/kg) can occur, from coated metal seals of the containers and after thermal processing of the product, sterilization or pasteurization, these quantities do not significantly increase the total concentration of melamine in dairy products, as to exceed the ML (0.15 mg/kg) for this food product.

No studies were found that support or demonstrate that the packages currently used for liquid infant formula consumed in Colombia can be a source of melamine, and justify the explanatory note concerning the maximum limit for this substance proposed by Codex.

Also, Colombia shares the position of other countries noting the need to avoid the use of melamine-based packaging or that may contain this material and/or similar compounds, to pack infant formulas, since this is a population particularly vulnerable to this contaminant. In this regard, keeping the note may favour the use of packages that contain melamine.

COSTA RICA

Costa Rica continues to support the maximum level of 0.15 mg/kg for the unintentional presence of melamine in liquid infant formula.

Costa Rica does not support the inclusion of the following Note: "The maximum level does not apply to liquid infant formula for which it can be proven that the level of melamine higher than 0.15 mg/kg is the consequence of migration from food contact materials taking into account any authorized migration limit."

Rationale

The spirit of international standard setting is precisely the standardization of the parameters to be defined in order to facilitate trade and protect the health of consumers. In this sense, including this note allows establishing exceptions according to the criteria of each country, and thus the effects of homologation are lost and the ML is left basically free. We maintain our position especially in this case concerning a food intended for vulnerable infants, where no exceptions should be allowed.

What sense does it make establishing a ML in an international standard if the Note will authorize other ML in the countries? Which is then the safe ML for infants that justifies allowing other values? For not establishing a ML means that it does not hold a risk for them, which we know isn't true.

DOMINICAN REPUBLIC

The Dominican Republic supports the implementation of the maximum level (ML) allowed for melamine contamination of 0.15 mg/kg in liquid infant formula (ready to consume)

But, suppressing the Note:

~~*Note*~~

~~*The maximum level does not apply to liquid infant formula for which it can be proven that the level of melamine higher than 0.15 mg/kg is the consequence of migration from food contact materials taking into account any nationally authorized migration limit.*~~

Therefore, Appendix III would say:

PROPOSED DRAFT MAXIMUM LEVEL FOR MELAMINE IN FOOD
(Liquid infant formula)
(FOR ADOPTION AT STEP 5/8)

Product	*ML (mg/kg)*
Liquid infant formula (as consumed)	*0.15*

NEW ZEALAND

In the light of the CAC's decision to adopt the proposed Draft Maximum Level for Melamine in Liquid Infant Formula at Step 5 and return it to the CCCF for further discussion, New Zealand offers the following comments on the issue:

1. New Zealand is of the view that some of the concerns expressed about the proposed draft limit for melamine in liquid infant formula are based on a misunderstanding of the Note that is included in the standard.

2. New Zealand would like to emphasise that the Note does not allow a full exemption from the proposed ML, but requires that any level above the level of 0.15 must, to be acceptable, be proven to result from the normal migration of melamine from food contact materials and also that any such migration be in conformity with each country's national legislation.

3. Any country that did not wish to accept the exemption would only need to ensure their national legislation did not allow it to apply. This could be achieved if their national legislation either did not allow for any contamination unless specified, or if it specifically did not allow the exemption to apply.

4. New Zealand would also draw the attention of the Committee statements in the discussion papers on melamine which made it very clear that the MLs being proposed for melamine in foods was to ensure that deliberate adulteration of foods was not allowed and they were being proposed at levels which did not pose any health risk. These same considerations also apply to the proposed ML because it is comparable with the level of melamine that could be present in infant milk that had been reconstituted from powdered infant formula that complied with the Codex ML that had already been established.

5. The reality is that migration of melamine is known to occur from some food contact materials, and the liquid infant formula is manufactured in a different process than simply reconstituting powdered infant formula, and hence the proposal to have the stated Note attached to the proposed ML for melamine in liquid infant formula.

6. On the basis of the above NZ supports the resubmission of the proposal as previously submitted.

SRI LANKA

Sri Lanka supports the proposed draft maximum level of 0.15 mg/kg for liquid infant formula, while disagreeing to the given note (REP11/CF, Appendix III) for the following reasons:

It will not be possible to demarcate the migrating from food contact material from adulteration if the note is approved for a country like Sri Lanka.

URUGUAY

The document of the 5th Session of the Codex Committee on Contaminants in Food, The Hague, The Netherlands, 21 - 25 March 2011 has been taken as a reference. The 34th Session of the Codex Alimentarius Commission (July 2011) adopted the Maximum Level at Step 5 and moved it up to Step 6. The 6th Session of the CCCF will analyse the exceptions to the draft maximum levels (REP11/CAC Para 62, Appendix IV). This due to the concerns expressed by a number of delegations.

As already expressed to the Codex Alimentarius Commission, Uruguay supported the Committee's decision of establishing a ML of 0.15 mg/kg for melamine in liquid infant formula since the technical rationale for establishing the maximum level was considered suitable, maintaining reservations for the additional note.

Nevertheless, the concern already expressed still exists since the ML which ought to be set should be as low as possible, considering that the product is intended for vulnerable infants and that no exceptions should be made. Furthermore, it is understood that the packaging materials from which melamine could migrate should be avoided, especially as these products are intended for infants.

If the note in which the exception is made for liquid infant formula, is left when it can be proved that a higher level of melamine would be higher than 0.15 mg/kg as a consequence of migration from food contact materials, the rules established by the Codex itself would not be complied with in the sense that the established maximum levels for contaminants must ensure that these levels in food products are as low as possible and never higher than the maximum levels considered admissible/tolerable from a health point of view.

Therefore Uruguay does not support the exception included in the Proposed Draft Maximum Levels for Melamine proposal of the JOINT FAO/WHO FOOD STANDARDS PROGRAMME, CODEX ALIMENTARIUS COMMISSION, Appendix III, considering that this proposal supports the use of materials with melamine content for the preparation of infant formula. We share the position already expressed by other delegations that infant formula must not be packed in melamine based packagings because children are vulnerable to the presence of this contaminant.

In short, it is requested that the remark "The maximum level does not apply to liquid infant formula for which it can be proven that the level of melamine higher than 0.15 mg/kg is the consequence of migration from food contact materials taking into account any nationally authorized migration limit" be deleted.