

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 6

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

Tenth Session
Rotterdam, The Netherlands, 4-8 April 2016

(Comments submitted on by Japan, Senegal, Thailand and USA)

Proposed draft maximum levels for lead in selected fruits and vegetables (fresh and processed) in the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995) (at Step 4)

JAPAN

Japan appreciates the great efforts of the United States of America in leading the EWG.

Japan supports the recommendations of the EWG on the proposed revised MLs of selected commodities in general and on further collection of occurrence data on those commodities with insufficient number of samples to date.

Acceptable minimum number of samples for MLs

As already mentioned in paragraph 53 of CX/CF 16/10/7, the number of samples of 20 is too few for proposing an ML with a high level of statistical confidence. Codex MLs should be based on the analysis of statistically sufficient number of samples in order to minimize potential negative impacts on the health of consumers and international trade.

The existing Codex Guidelines¹² developed by CCPR and CCRVDF provide useful information on the minimum number of samples for specific violation rates and confidence levels. A probability (confidence level) (p) to detect at least one non-compliance sample from a certain number of samples (n) for a different violation rate (i) is calculated from the following equation in the Guidelines.

$$p=1-(1-i)^n$$

Table: Probability (%) of success to detect a non-compliance sample for a different violation rate.

Violation rate \ Number of samples (n)	10% ($i=0.1$)	5% ($i=0.05$)	2.5% ($i=0.025$)	1% ($i=0.01$)
10	65%	40%	22%	10%
20	88%	64%	40%	18%
30	96%	79%	53%	26%
40	99%	87%	64%	33%
50	99%	92%	72%	39%
60	100%	95%	78%	45%
70	100%	97%	83%	51%
80	100%	98%	87%	55%
90	100%	99%	90%	60%
100	100%	99%	92%	63%

The above table indicates that if 20 samples are taken, the probabilities (confidence level) that at least one sample contains lead (Pb) higher than the 95th or 97.5th population percentile values are 64% or 40%, respectively. If 60 samples are taken, the probabilities increase to 95% or 78%, respectively.

From the statistical view point, 60 or 50 rather than 20 would be an appropriate minimum number of samples to derive an achievable ML based on occurrence data.

¹ Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs (CAC/GL 33-1999)

² Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009)

An availability of occurrence data on some minor commodities may be very limited. If there seems impossible to collect further data on such commodities in the near future, the Committee should consider, on a case by case basis, the use of limited data of small number of samples below a specified minimum number of samples, or merging these data with other data on similar commodities in order to ensure a sufficient number of samples for ML setting.

SENEGAL

Position 1: Nous n'appuyons pas la décision d'abaisser les LM de plomb dans certains fruits et légumes sans données en provenance des différentes zones agro-écologiques d'Afrique.

Justification: Les LM sont établies afin de protéger la santé du consommateur dans le monde entier; mais si les données relatives à la concentration de plomb qui sont utilisées ne portent que sur une zone géographique restreinte, alors l'objectif de fixer des normes internationales ne sera pas atteint. Ces limites ont été proposées sans les données africaines.

Position 2: Nous encourageons également la poursuite des discussions pour identifier un nombre minimum acceptable d'échantillons pour revoir les LM.

Nous proposons d'avoir 20 échantillons par point de données. En veillant à ce que chaque continent ait au moins deux points de données.

Justification: nous pensons que le grand total de 20 échantillons proposé par le GTE est faible et non représentatif. Et comme chaque continent est constitué au minimum de deux zones géographiques de pratiques alimentaires distinctes. Un minimum de deux (2) points de données par continent serait plus approprié.

THAILAND

Thailand would like to submit comments to the proposed draft of MLs for lead in selected fruits and vegetables as follows:

We agree with the EWG recommendation on the draft MLs for lead in commodities as followed:

- Juices and nectars from berries and other small fruits: Postpone the decision pending new submission data in 2017.
- Canned berries and other small fruits: Include in the canned fruits category with an ML of 0.1 mg/kg
- Canned leafy vegetables: Include in the canned vegetables category with an ML of 0.1 mg/kg.
- Canned legume vegetables: Include in the canned vegetables category with an ML of 0.1 mg/kg.
- Canned brassica vegetables: Maintain the note in the GSCTFF to exclude canned brassica vegetables from the ML for canned vegetables.
- Jams (fruit preserves) and jellies: Lower the ML to 0.1 mg/kg.
- Mango chutney: Postpone the decision pending new submission data in 2017.
- Canned chestnuts and chestnut puree: Postpone the decision pending new submission data in 2017.
- Pickled cucumbers (cucumber pickles): Lower the ML to 0.1 mg/kg.
- Preserved tomatoes: Lower the ML to 0.05 mg/kg.
- Table olives: Lower the ML to 0.4 mg/kg.
- Fresh fungi and mushrooms: Establish an ML of 0.3 mg/kg.

On the other hand, we propose to postpone the decision to include passion fruit juices and nectars in the fruit juices category with an ML of 0.03 mg/kg. Generally, the ML is only reduced when the percentage of excluded samples was less than 5%. Table PF-3 shown that only 91% of samples of passion fruits and nectars may meet a hypothetical ML of 0.03 mg/kg. This ML would eliminate 9% of samples in international trade. Moreover, almost occurrence data were contributed from only one countries. More data should be collected in order to support decision made by the Committee.

Besides, we propose to postpone the recommendation for lowering the ML in processed tomato concentrates from 1.5 mg/kg to 0.05 mg/kg. Because there were only 21 number of samples in the occurrence data for consideration. More data should be collected.

USA

The United States agrees with the 15 recommendations listed under paragraph 56 of the document.