codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: +39(06)5701 Telex: 625825-625853 FAO I Email: Codex@fao.org Facsimile: +39(06)5705.4593

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METHODOLOGY AND PRINCIPLES FOR EXPOSURE ASSESSMENT IN THE CODEX GENERAL STANDARD FOR CONTAMINANTS

(Paper submitted by the United Kingdom)

BACKGROUND

1. The purpose of the Codex General Standard for Contaminants and Toxins in Food (GSC) is to provide a framework for the control of contaminants in foodstuffs. It will include a general procedure for establishing maximum levels (MLs) for contaminants in individual foods for use when this is considered necessary. This will occur only to resolve either a significant health risk or problems in international trade. In the latter case, the intention of setting a limit is to facilitate trade, whilst ensuring that human health is not endangered by a contaminant in the traded food.

2. The Uruguay Round of Multilateral Trade Negotiations endorsed the use of Codex limits, guidelines and other recommendations as representing the international consensus for use in the arbitration of trade disputes involving food safety issues. As a result of this there is a need to strengthen the underlying scientific basis of Codex recommendations, including the exposure methodology for assessing the risks arising from the chemical contamination of food. Annex 1 of the GSC states that proposals for Codex MLs should be accompanied by intake calculations and risk assessments regarding their acceptability and use.

3. The delegation of the United Kingdom presented proposals for dietary exposure assessment methodology to support the Codex General Standard for Contaminants and Toxins in Food at the 30th session of the Codex Committee on Food Additives and Contaminants (CCFAC) (CX/FAC 98/13). The CCFAC concluded that the delegation of the United Kingdom should further develop this methodology and principles for exposure assessment taking account of comments received from other national delegations. In this paper, the exposure methodology described in CX/FAC 98/13 is further considered with data from the draft Codex Standard for Lead (most recent version CX/FAC 96/23 as amended by Appendix X of Alinorm 97/12A) to propose limits for lead to illustrate the proposed methodology (Annex 1). The GSC will include the proposed exposure assessment methodology as an Annex when agreed.

PURPOSE

4. The methodology set out in this document enables MLs to be set for primary, unprocessed food commodities in international trade, but does not address the management of very toxic chemicals where even very low concentrations may present a health risk. In such cases, the best approach is to reduce the concentrations to as low a level as practicable, taking economic and social factors into account. This paper also does not consider exposure from air or water when developing the MLs, as these sources are expected to make only minor contributions to the overall exposure, depending on where the consumer

lives, although both of these sources should be taken into account when assessing total exposure to a contaminant if possible.

5. The methodology comprises four steps representing different aspects of exposure assessment. Each step is split into a number of criteria which consider these aspects in further detail. A diagram illustrating the overall methodology is given in Figure 1.

- The first step of the methodology assesses whether the dietary exposure to a contaminant by consumers is likely to regularly exceed the safe/tolerable dietary exposure level and then identifies foods for which limits should be set.
- The second step assesses the data available on concentrations of the contaminant occurring in these food commodities to set draft MLs. These are then compared with estimates of the concentrations which could be allowed in each food such that an above-average consumer would have a dietary exposure below a relevant safety limit, allowing for exposure from the rest of the diet. MLs can then be proposed which reflect the usual distribution
- The third step assesses the total exposure from the whole diet to assess if the proposed MLs provide sufficient protection for consumers.
- The fourth step considers the practical implications of setting the MLs, particularly as they should not unnecessarily obstruct trade.

STEP 1: IDENTIFICATION OF HEALTH RISK AND IDENTIFICATION OF FOODS FOR WHICH MLS ARE REQUIRED

i) Is dietary exposure to contaminant by consumers likely to regularly exceed the safe/tolerable dietary exposure level?

6. There is always a potential health risk associated with contaminants in food and therefore one of the aims of standards is to reduce the levels of contaminants to the lowest reasonably achievable. However, the dietary exposure to a contaminant by consumers should not regularly exceed the safe/tolerable dietary exposure level established on the basis of expert toxicological advice. A recommendations from the Joint FAO/WHO Expert Committee on Food Additives (JECFA), based on a full evaluation of an adequate toxicological data base, is the main basis for decisions on specific contaminants by CCFAC. National intake assessments should also be taken into account. If there are concerns on a contaminant for which a Provisional Tolerable Weekly Intake (PTWI) or Tolerable Daily Intake (TDI) has not been established, then it should be referred to CCFAC for consideration.

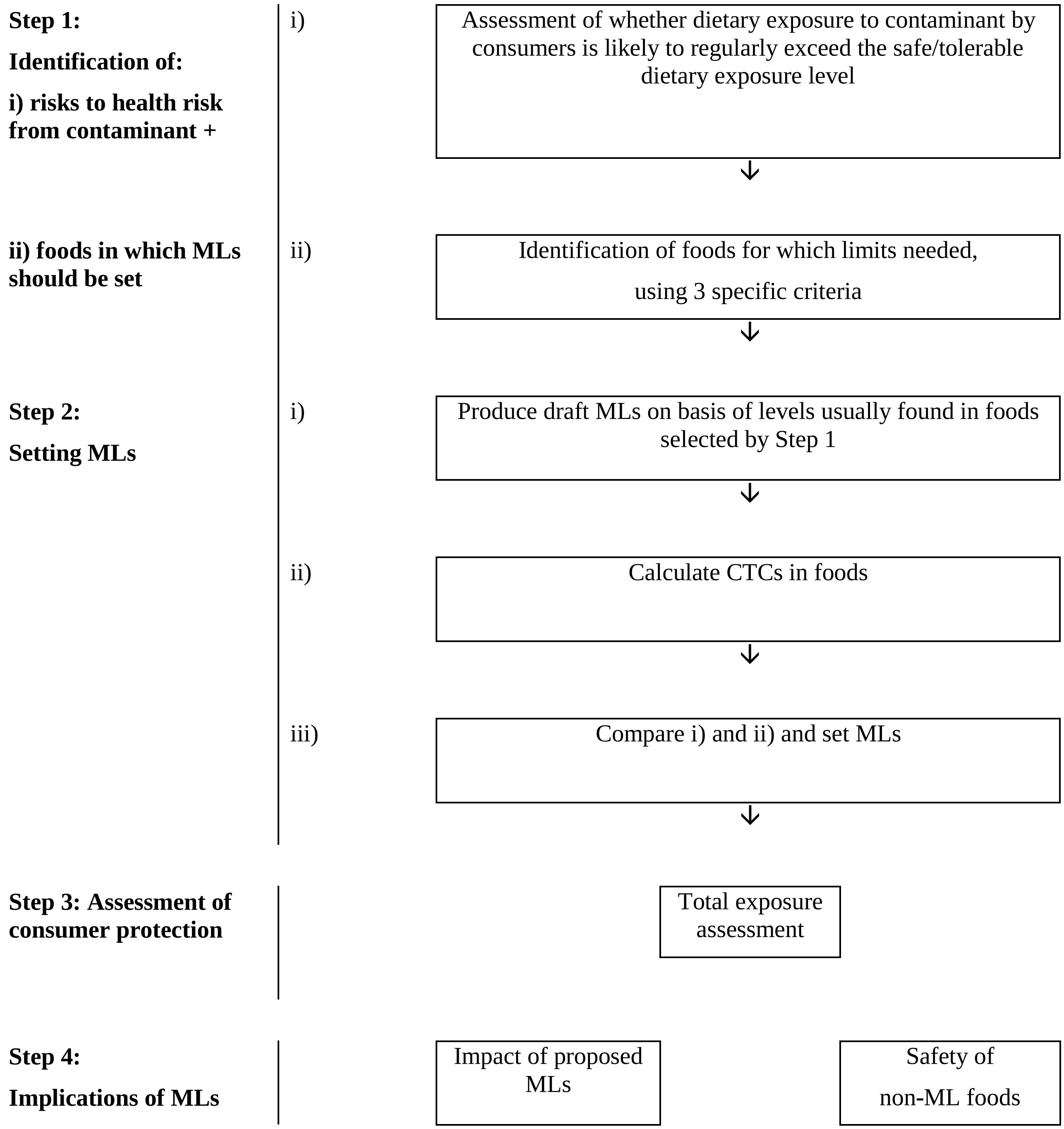
ii) Identification of foods for which MLs are required

7. The aim is to set limits for contaminants in only those foods or food groups that are significant for the total dietary exposure of consumers to the contaminant and preferably where limits can be achieved by Good Manufacturing Practice or other similar practices. This stage identifies the foods most likely to present a hazard and thus emphasises the value of MLs as measures to decrease overall dietary exposure of the contaminant world-wide. In addition, this stage enables national resources to be targeted at the identified foods where significant reductions in concentrations of contaminants can be achieved by measures directed at the source(s) of the contaminants.

8. International limits established to facilitate trade should also serve to protect consumers on a global basis. This does not imply that exceeding these limits will necessarily constitute a health risk. Setting MLs encourages continued reductions in the concentrations which can be achieved due to decreasing environmental contamination or by improved manufacturing/processing practices and helps promote such reductions throughout the World.

9. In addition to the criteria given in Annex I of the GSC, three specific criteria were developed for the purposes of the proposed methodology to identify foods for which limits for contaminants should be set.

Figure 1: General procedure for establishing Maximum Levels (MLs) for contaminants in individual foods



Criterion 1: The application of source-directed measures would ensure that the ML could be achieved in all foods.

10. To fulfil this criterion, actions to i) eliminate or control the source of the contamination and, ii) to identify and separate contaminated items/lots/consignments of food from food fit for human consumption should reduce the concentrations of the contaminant in food. It is likely to take several years for all exporting countries to implement appropriate source-directed measures to achieve the MLs. It may be necessary to agree a timescale (for example, 3 or 5 years) within which the ML is phased in. These timescales can differ for each food commodity.

Criterion 2: The food or food group contributes more than 10% of the total dietary exposure in at least one regional diet.

11. This figure has been chosen to ensure that all foods which provide a significant contribution to dietary exposures are considered. Subject to further expert advice and the availability of information about consumption patterns, this criterion could be refined in the future. The food groups should initially be broadly defined, but individual foods or small food groups can be listed separately and can be assigned a different ML (or be exempted) when there are inherent differences in levels of contamination and adequate risk management requires a more specific approach.

12. There may be a need to establish separate local limits for these foods in order to protect vulnerable groups of consumers where other means of controlling consumer exposure are not available. Other non-food sources of contaminants, for example water, are best managed at a national or regional level according to any national controls.

Criterion 3: The food commodity for which a specific ML is to be set is traded internationally and contributes to a significantly higher dietary exposure in at least 2 regions, i.e. the potential contribution is more than 5% of the total dietary exposure of more than one region.

13. To fulfil this criterion the food must be traded from one country to another country (say Y) where there may be very different dietary patterns. There must be evidence that the food would directly increase the dietary exposure by consumers in country Y beyond what would be considered safe, due to their high consumption of the food. Evidence must show that dietary patterns in importing countries will cause consumers to exceed safety levels.

STEP 2: SETTING THE ML

14. The second step sets the MLs in foods selected in Step 1 by asking;
What information is available on concentrations of the contaminant occurring in that food commodity?

- What is the maximum concentration of a contaminant that can be tolerated in a food such that an above-average consumer of that food would have a dietary exposure below the relevant safety limit, after allowing for exposure from the rest of the diet?
- How do the concentrations in a) and b) compare and what ML can be set as a result?

i) What information is available on concentrations of the contaminant occurring in that food commodity?

15. This stage involves the evaluation of the distribution of contaminant concentrations found in practice in individual foods with a knowledge of the ability of source-directed measures to control and/or reduce high levels. A range of draft MLs can then be formulated at the upper end or just above the range of contaminant concentrations normally found in the food.

ii) What is the maximum concentration of a contaminant that can be tolerated in a food?

16. The second step in setting MLs is to estimate a Calculated Tolerable Concentration (CTC) for each of the food commodities selected by Step 1 so that an above-average consumer of the contaminated food would have a dietary exposure below the PTWI or TDI for the contaminant established by JECFA, after allowing for the average exposure from the rest of the diet. The average exposure is allowed for by adding a set percentage of the total dietary exposure from those foods identified by Step 1. In the absence of an international consensus, it is proposed that this should be 20%. This approach is in line with the Draft Criteria for the Establishment of Maximum Levels in Foods of Annex I of the GSC (CX/FAC 96/15) which specifies that foods with proposed MLs should account for 80% of total dietary exposure from a contaminant. It is recognised that this figure is subject to debate and data collected by the Global Environmental Monitoring System (GEMS/Food) could be used to refine this figure.

17. It is desirable that above-average food consumption figures are used in the initial calculation of potential dietary exposure to contaminants when setting MLs, to ensure that even high level consumers are protected. The availability of reliable global consumption data is still a problem however. It is

therefore recommended that the existing five FAO/WHO regional diets, or refinements of these regional diets, are used in the process of setting contaminant MLs for traded foods.

18. The FAO/WHO regional diets, currently used to make estimates of dietary exposure of pesticides[1] are based on FAO Food Balance Sheet (FBS) data. The FBS data probably reflect above-average consumption for consumers for most foods, as food wastage is not taken into account, but may underestimate the consumption of home-grown or minor foods.

19. Each regional diet should be used in turn to calculate proposed CTCs and to assess dietary exposure to take account of the differences in food consumption and patterns of food contamination. In the absence of information on the distribution of intakes, it is suggested that the highest consumption figures from the existing regional diets be used for calculations until further expert advice becomes available on this matter and is accepted as a suitable basis for international risk assessment procedures.

20. The CTCs can then be calculated from the regional consumption data for the food commodity for which the CTC is to be set and the PTWI/TDI for the contaminant. The lowest CTC for each food commodity can then be taken into the next stage. An example of the calculation used is given in Annex 1.

iii) How do the concentrations in i) and ii) compare and what ML can be set as a result?

21. The next stage involves comparing the draft MLs with the CTC values resulting from the above evaluation. The aim is to propose an ML as low as reasonably achievable. There are two possible outcomes:

- the draft ML is lower than the CTC - an ML based on the draft ML may be established which should not cause serious economic impact.
- the draft ML is higher than the CTC - the resulting ML should be as low as reasonably achievable. This means that the CCFAC will need to discuss the likely economic consequences and review the health aspects of the proposed ML(s). It may be necessary to set a higher ML in foods which contain inherently elevated concentrations of certain contaminants.

22. In all cases, MLs should not be lower than a level which can be analysed with methods of analysis that can be readily applied in normal product control laboratories, unless health considerations necessitate a lower detection limit which can only be achieved by means of a more elaborate method of analysis.

STEP 3: ESTIMATING THE DIETARY EXPOSURE FROM FOODS WITH MLS

23. The third step assesses the potential total dietary exposure of consumers from foods containing the contaminant at the ML to ensure that the proposals provide sufficient protection for almost all consumers. This assumption will produce an over-estimate of dietary exposure, but if this estimate is still below the PTWI/TDI then the MLs can be accepted with confidence. If the dietary exposure does not fall below the PTWI/TDI, then either the MLs should be revised to ensure that dietary exposure does fall below the PTWI/TDI or additional consumption data and information on the distribution of contaminant concentrations within the ML foods is required to be able to make more realistic calculations about the intake.

24. It is recognised that the approach proposed in this paper will inevitably include errors, but these cannot be quantified easily.

STEP 4: CONSIDERING THE PRACTICAL IMPLICATIONS OF SETTING THE MLS

i) What economic impact will the proposed MLs have?

25. The likely costs to business of complying with the proposed MLs should be assessed to ensure that the MLs do not pose unnecessary burdens on business or the economies of members of the World Trade Organisation.

ii) How does a country ensure that the non-ML foods are safe for consumption by their own population?

26. A trade issue may arise involving a contaminant in food commodities for which no ML has been proposed because of their low average contribution to the total dietary exposure of the contaminant. In such a case, the countries involved should provide information on the health risks involved to JECFA for its view. Following this, an assessment by CCFAC of the matter would be desirable. Even when the average contribution to the intake is low, it may be appropriate to establish a Codex ML when there is evidence that the health of specific consumers may be at stake.

27. It would be desirable for national authorities to monitor concentrations in foods without MLs to ensure that dietary exposure from these foods remains low.

CONCLUSIONS AND RECOMMENDATIONS

The Committee is invited to:

- endorse the methodology used for establishing limits for contaminants in foods that make significant contributions to total dietary exposure; and
- agree that a paper which explains the methodology in detail should be incorporated into the General Standard.

REFERENCES

1. Guidelines for Predicting Dietary Intake of Pesticide Residues. Report prepared by the Joint UNEP/FAO/WHO Food Contamination Monitoring Programme in collaboration with Codex Committee on Pesticide Residues. World Health Organisation, Geneva (1989).

2. WHO Guidelines for the Study of Dietary Intakes of Chemical Contaminants. Report prepared by the Joint UNEP/FAO/WHO Food Organisation Monitoring Programme. World Health Organisation Offset Publication No. 87, Geneva (1985).

ANNEX 1: SETTING MLS FOR LEAD IN FOOD.

1. This Annex demonstrates the methodology for setting MLs, using lead as an example. The information used to prepare this paper includes comments received since 1991 from members of CCFAC on the draft Codex Standard for Lead[1], GEMS/Food information and FAO/WHO regional diets. It is assumed that any other national data on concentrations of lead in food would be similar to the data used in this paper.

STEP 1: IDENTIFICATION OF HEALTH RISK AND IDENTIFICATION OF FOODS FOR WHICH MLS ARE REQUIRED

i) Is dietary exposure to contaminant by consumers likely to regularly exceed the safe/tolerable dietary exposure level?

2. Lead was discussed most recently by JECFA in 1993, when a PTWI of 25 μg/kg b.w. for all age groups (equivalent to 214 μg/day for 60 kg person). This conclusion was reached taking into account the most sensitive groups of the population. Item1.11 of Annex IV - B to the General Standard for Contaminants reviews lead exposure from food. This review states that although the average exposure to lead from food is decreasing, there are indications of potential health problems for some high level consumers and the safety margin between estimated exposures and the PTWI for lead is small. It also concludes that exposure to lead should be reduced and that limits for lead in food should be harmonised. This should prevent the marketing of foods that are grossly contaminated. The MLs could also assist in stimulating further national measures aimed at reducing the contamination of foods with lead. The most recent exposure data available for average consumers adds only a few micrograms from exposure via air and water to the exposure from food, depending on the composition of the diet and where the consumer lives.

ii) Identification of foods for which MLs are required

3. The draft Codex Standard for Lead[1] identifies typical concentrations of lead in broad food groups. These data have been used with FAO/WHO consumption data for each regional diet to produce Table 1, dietary exposures to lead from food groups of the various regional diets. The figures for the fruit food group includes citrus juices. Figures for wine consumption have been compiled by the UK Brewers and Licensed Retailers Association from data supplied by brewers associations and central statistical offices in other countries.

Criterion 1: The application of source-directed measures would ensure that the ML could be achieved in all foods.

4. Most of the foods listed in Table 1 fulfil this criterion as current actions are reducing concentrations of lead in food, such as the continuing reduction of lead in petrol in many countries. Although the concentrations of lead in fish, crustaceans and molluscs are primarily influenced by the seabed geochemistry of the feeding areas, localised pollution for other reasons may result in elevated concentrations in fishery products. A similar argument applies to meat.

Criterion 2: The food or food group contributes more than 10% of the total dietary exposure in at least one regional diet.

5. Table 1 identifies major contributors to the dietary exposure to lead as cereals, potatoes, vegetables, fruit and wine (see figures in shading in Table 1). This is supported by the latest published summary of GEMS/Food (1980-1988) information on dietary exposures to lead[2] and by more recent unpublished GEMS/Food data for 1990-1994[3]. The average lead concentrations mentioned in Table 1 are derived from an evaluation of the published surveillance data and apply to the primary, unprocessed product as traded, unless specific processed products are mentioned.

Criterion 3: The food commodity for which a specific ML is to be set is traded internationally and contribute to a significantly higher dietary exposure in at least two countries, i.e. the potential contribution is more than 5% of the total dietary exposure of more than one region.

6. All the foods identified by Criterion 2 also fulfil this criterion. In addition, leafy vegetables, meat (but not liver and kidney) and crustaceans and molluscs fulfil this criterion (figures in bold in Table 1).

7. The foods for which MLs are required are selected by the above criteria to be cereals, potatoes, vegetables, leafy vegetables, fruit, meat, fish, crustaceans and molluscs and wine.

Table 1: Lead intakes from regional diets

		Middle East			Far East			Africa			Latin America			Uropea		
Food	Average lead content (µg/kg)	Consumption (g/day)	Lead intake (µg/day)	% of total intake	Consumption (g/day)	Lead intake (µg/day)	% of total intake	Consumption (g/day)	Lead intake (µg/day)	% of total intake	Consumption (g/day)	Lead intake (µg/day)	% of total intake	Consumption (g/day)	Lead intake (µg/day)	% of total intake
Cereals	30	432.0	13.0	**36.9**	452.5	13.6	**34.0**	319.5	9.6	**25.3**	253.5	7.6	**14.9**	226.5	6.8	*8.9*
Potatoes	50	61.8	3.1	*8.8*	108.5	5.4	**13.6**	321.3	16.1	**42.4**	159.3	8.0	**15.7**	242.0	12.1	**15.9**
Sugars & honey	10	95.3	1.0	2.7	50.5	0.5	1.3	42.7	0.4	1.1	104.0	1.0	2.0	105.3	1.1	1.4
Nuts & oilseeds	50	4.3	0.2	0.6	17.7	0.9	2.2	14.8	0.7	2.0	19.3	1.0	1.9	11.8	0.6	0.8
Vegetable oils/fats	20	38.3	0.8	2.2	14.7	0.3	0.7	24.2	0.5	1.3	25.5	0.5	1.0	48.0	1.0	1.3
Tea/coffee	5	8.0	0.0	0.1	1.5	0.0	0.0	0.5	0.0	0.0	5.3	0.0	0.1	14.0	0.1	0.1
Fungi	20	5.1	0.1	0.3	15.5	0.3	0.8	5.0	0.1	0.3	3.4	0.1	0.1	9.6	0.2	0.3
Spices	100	2.3	0.2	0.7	2.0	0.2	0.5	1.6	0.2	0.4	0.3	0.0	0.1	0.3	0.0	0.0
Bulb vegetables	20	29.8	0.6	1.7	28.7	0.6	1.4	12.3	0.2	0.6	17.6	0.4	0.7	36.4	0.7	1.0
Root/tuber veg.	50	7.6	0.4	1.1	17.5	0.9	2.2	5.0	0.3	0.7	9.7	0.5	1.0	27.6	1.4	1.8
Fruiting vegetables	20	112.1	2.2	*6.4*	33.7	0.7	1.7	31.9	0.6	1.7	59.4	1.2	2.3	105.0	2.1	2.8
Pulses	50	20.8	1.0	3.0	26.8	1.3	3.4	17.5	0.9	2.3	21.0	1.1	2.1	9.3	0.5	0.6
Legumes	50	13.8	0.7	2.0	16.5	0.8	2.1	5.0	0.3	0.7	7.6	0.4	0.7	31.6	1.6	2.1
Stem vegetables	20	7.1	0.1	0.4	15.0	0.3	0.8	5.0	0.1	0.3	3.3	0.1	0.1	12.6	0.3	0.3
*Total above vegetables**	50	191.2	5.1	**14.5**	138.2	4.6	**11.5**	76.7	2.4	*6.2*	118.6	3.5	*6.9*	222.5	6.5	*8.5*
Brassica	100	11.1	1.1	3.2	26.2	2.6	*6.6*	5.0	0.5	1.3	14.1	1.4	2.8	45.4	4.5	*6.0*
Leafy vegetables	100	7.6	0.8	2.2	15.0	1.5	3.8	5.0	0.5	1.3	9.4	0.9	1.8	30.1	3.0	3.9
Total leafy vegetables	100	18.7	1.9	*5.1*	41.2	4.1	*9.4*	10.0	1.0	2.6	23.5	2.4	4.4	75.5	7.6	*9.0*

Key: Figures in italics = more than 5% of the diet

Figures in bold = more than 10% of the diet

* Does not include potatoes or leafy vegetables.

Table 1: Lead intakes from regional diets (contd.)

		Middle East			Far East			Africa			Latin America			Uropea		
Food	Average lead content (µg/kg)	Consumption (g/day)	Lead intake (µg/day)	% of total intake	Consumption (g/day)	Lead intake (µg /day)	% of total intake	Consumption (g/day)	Lead intake (µg/day)	% of total intake	Consumption (g/day)	Lead intake (µg/day)	% of total intake	Consumption (g/day)	Lead intake (µg/day)	% of total intake
Citrus fruit	25	58.9	1.5	4.2	6.3	0.2	0.4	5.3	0.1	0.3	55.2	1.4	2.7	52.9	1.3	1.7
Pome fruit	25	10.8	0.3	0.8	7.5	0.2	0.5	0.3	0.0	0.0	6.5	0.2	0.3	51.3	1.3	1.7
Stone fruit	25	7.6	0.2	0.5	1.0	0.0	0.1	0.0	0.0	0.0	0.8	0.0	0.0	23.4	0.6	0.8
Berries/soft fruit	25	16.1	0.4	1.1	1.0	0.0	0.1	0.0	0.0	0.0	1.6	0.0	0.1	23.0	0.6	0.8
Misc. fruit	25	127.2	3.2	*9.1*	78.0	2.0	4.9	79.8	2.0	*5.3*	220.0	5.5	**10.8**	63.6	1.6	2.1
Total above fruit	25	220.6	5.5	**15.7**	93.8	2.3	*5.9*	85.4	2.1	*5.6*	284.1	7.1	**14.0**	214.2	5.4	*7.0*
Poultry	20	30.8	0.6	1.8	12.7	0.3	0.6	5.5	0.1	0.3	25.3	0.5	1.0	52.8	1.1	1.4
Meat	20	37.5	0.8	2.1	33.4	0.7	1.7	24.0	0.5	1.3	47.2	0.9	1.9	156.3	3.1	4.1
Animal oils/fats	20	0.5	0.0	0.0	1.5	0.0	0.1	0.3	0.0	0.0	5.0	0.1	0.2	10.0	0.2	0.3
Total above meat	20	68.8	1.4	3.9	47.6	1.0	2.4	29.8	0.6	1.6	77.5	1.6	1.6	219.1	4.4	*5.8*
Liver/kidney	200	4.1	0.8	2.3	1.3	0.3	0.7	2.7	0.5	1.4	6.3	1.3	2.5	12.6	2.5	3.3
Fish	100	12.8	1.3	3.6	25.5	2.6	*6.4*	31.6	3.2	*8.3*	38.0	3.8	*7.5*	33.4	3.3	4.4
Crustaceans & molluscs	500	0.3	0.2	0.4	6.3	3.2	*7.9*	0.5	0.3	0.7	2.3	1.2	2.3	12.1	6.1	*7.9*
Eggs	25	14.5	0.4	1.0	13.0	0.3	0.8	3.6	0.1	0.2	11.8	0.3	0.6	37.5	0.9	1.2
Milk	2	132.3	0.3	0.8	32.7	0.1	0.2	42.2	0.1	0.2	167.8	0.3	0.7	337.8	0.7	0.9
Wine	100	no data	-	-	3.3	0.3	0.8	1.1	0.1	0.3	113.0	11.3	**22.2**	171.0	17.1	**22.4**

Key: Figures in italics = more than 5% to diet

Figures in bold = more than 10% of the diet

STEP 2: SETTING THE ML

8. This stage sets the MLs in foods selected in Step 1.

i) What information is available on concentrations of the contaminant occurring in that food commodity?

9. Table 2 presents surveillance data from different countries to demonstrate the range of lead concentrations reported in the nine selected commodities. These have been summarised from the most recent GEMS/Food (1990-1994)[3] information and from national comments to CCFAC since 1991, although the way in which the foods were selected, analysed and reported differ. The continuing review of current data available on lead concentrations in food should enable more realistic comparisons to be made and may lead to some changes in the dietary exposure estimates in Table 1 and in the draft MLs.

Table 2: Range of lead levels reported in cereals, potatoes, vegetables, leafy vegetables, fruit, meat, fish, crustaceans and molluscs and wine (individual samples)

Food	GEMS/Food * 90th %ile (mg/kg)	CCFAC comments since 1991# (mg/kg)	**Draft MLs (mg/kg)**
Cereals	0.32	<0.005 - 0.26	**0.3**
Potatoes	0.08	<0.005 - 0.11	**0.11**
Vegetables (except potatoes and leafy vegetables)	0.6	<0.005 - 2.4	**2.4**
Leafy vegetables	0.2	(not available)	**0.2**
Fruit	0.13	<0.005 - 0.16	**0.15**
Meat	0.13	<0.005 - 0.12	**0.15**
Fish	0.3	<0.005 - 0.82	**0.8**
Crustaceans and molluscs	1.2	(not available)	**1.2**
Wine	(not available)	0.06 - 0.15	**0.15**

Notes

* This includes 1990 - 1994 data from China, Iran, Japan, Singapore, Australia, Canada, Guatemala and Qatar. No data for canned food included.

\# Taken from comments made to CCFAC by Denmark (23rd session), US (24th session), Norway (25th), Sweden (25th), Japan (25th), Finland (26th) and Canada (26th).

ii) What is the maximum concentration of a contaminant that can be tolerated in a food?

10. The Calculated Tolerable Concentration (CTC) is calculated so that a high level (above-average) consumer would have a lead dietary exposure below the PTWI for lead after allowing for the average exposure from the rest of the diet (20% of exposure from all ML foods). This is done for each food commodity selected in Step 1 and for each regional diet. An example of the calculation is given below. The consumption figure for the high level consumption is the highest consumption value for the selected food from Table 1, while the figures for the dietary exposures for the ML foods are in each case taken from this Table also.

Consumption x CTC < PTWI - Σdietary exposure from other ML foods - average exposure from rest of diet

An example using data from Table 1 to calculate the CTC for cereals in the Far East regional diet is given below:

Food	Intake (µg /day)	Consumption figure from Table 1 (g/day)
Cereals	13.6	452.5
Potatoes	5.4	108.5
Vegetables (except potatoes and leafy vegetables)	4.6	138.2
Leafy vegetables	4.1	41.2
Fruit (includes fruit juice)	2.3	93.8
Meat	1	47.6
Fish	2.6	25.5
Crustaceans and molluscs	3.2	6.3
Wine	0.3	3.3

These figures can then used to calculate the CTC for cereals in the Far East diet as below.

452.5g x CTC < PTWI - Σ dietary exposure from other ML foods - 20% dietary exposure from all ML foods

$$< 214.3 - [5.4 + 4.6 + 4.1 + 2.3 + 1.0 + 2.6 + 3.2 + 0.3] - [13.6 + 5.4 + 4.6 + 4.1 + 2.3 + 1.0 + 2.6 + 3.2 + 0.3]/5$$

452.5g x CTC < (214.3 - 23.5 - 7.9) µg/day

$$\therefore \text{CTC} < \frac{214.3 - 28.2\ \mu g}{452.5\ g} = 0.4\ \mu g/g\ (mg/kg)$$

11. Table 3 compares the CTCs for cereals, potatoes, vegetables, leafy vegetables, fruit, meat, fish, crustaceans and molluscs and wine calculated for all regional diets to generate the lowest CTCs for comparison with surveillance data.

Table 3: CTCs for cereals, potatoes, vegetables, leafy vegetables, fruit, meat, fish, crustaceans and molluscs and wine

Food	Calculated Tolerable Concentration (mg/kg)					
	Middle East	Far East	Africa	Latin America	Uropea	**Lowest CTC**
Cereals	0.44	0.40	0.57	0.65	0.6	**0.4**
Potatoes	2.9	1.6	0.58	1.0	0.59	**0.58**
Vegetables (except potatoes and leafy vegetables)	0.95	1.3	2.3	1.4	0.61	**0.61**
Leafy vegetables	9.5	4.2	35	6.8	1.8	**1.8**
Fruit	0.82	1.8	2.0	0.58	0.63	**0.58**
Meat (inc. poultry)	2.6	3.6	5.8	2.0	0.61	**0.61**
Fish	14	6.7	5.5	4.3	4.0	**4.0**
Crustaceans and molluscs	631	30	363	73	12	**12**
Wine	-	51	156	1.5	0.86	**0.86**

iii) How do the concentrations in i) and ii) compare and what ML can be set as a result?

11. The draft MLs in Table 2 are then compared to the lowest CTCs in Table 3 to propose MLs (Table 4). These MLs are selected from the range of values proposed in Annex IV - B of the GSC. The aim is to propose an ML as low as reasonably achievable which is unlikely to cause serious economic impact. In the case of a low CTC, the resulting ML should be as low as reasonably achievable. The range of Codex MLs proposed in Appendix X of Alinorm 97/12A for each food group are given in Table 4 for reference. The MLs proposed in this Annex relate to the food group in general but there may be a need to set separate MLs for minor foods within the main food groups. If this is the case, the underlying conversion factors used by other Codex Commodity Committees could be used.

Table 4: Comparison of surveillance data with CTCs to propose MLs

Food	Draft MLs (mg/kg)	CTC (mg/kg)	**Proposed MLs (mg/kg)**	Codex MLs (mg/kg)
Cereals	0.3	0.4	**0.2**	0.2
Potatoes	0.11	0.58	**0.1**	-
Vegetables (except potatoes and leafy vegetables)	2.4	0.61	**0.5**	0.1
Leafy vegetables	0.2	1.8	**0.2**	0.3
Fruit	0.15	0.58	**0.1**	0.1
Meat	0.15	0.61	**0.1**	0.1

Fish	0.8	4.0	**0.5**	0.5
Crustaceans and molluscs	1.2	12	**1.0**	0.5-2.0
Wine	0.15	0.86	**0.2***	0.2

* Standards for wine fall within the remit of the OIV - current limit is 0.2 mg/kg.

STEP 3: ESTIMATING THE DIETARY EXPOSURE FROM FOODS WITH MLS

13. In order to determine the acceptability of the proposed MLs, the total dietary exposure from foods assigned MLs can be calculated. To do this, it is assumed that the lead concentrations in all foods consumed are equal to the MLs. Although this assumption will certainly cause an over-estimate of normal dietary exposure, if this falls below the PTWI then the MLs can be accepted with confidence. If the dietary exposure does not fall below the PTWI additional consumption data and information on the distribution of lead concentrations within these foods would be required.

14. The total dietary exposure for each regional diet is estimated using the assumptions given above to yield the figures shown in Table 5:

Table 5: Dietary exposures to lead from foods with MLs

Region	Total dietary exposure (µg/person/day)
Middle East	227.6
Far East	212.5
Africa	163.4
Latin America	210.7
Uropea	302.2
PTWI	**214.3**

15. It can be seen that the calculated total dietary exposures are close to or lower than the PTWI for lead (equivalent to 214.3 µg/day for 60 kg person), except for the dietary exposure for Uropea. Since this figure is too high, then one or more of the proposed MLs may be set too high. The only commodities with proposed MLs higher than 0.2 mg/kg are vegetables, fish and crustaceans. Of these, only vegetables contribute more than 10% to the total dietary exposure of more than two regional diets. Reducing the proposed ML to the next lowest value, 0.2 mg/kg, gives the figures in Table 6, which are all below the PTWI.

Table 6: Dietary exposures to lead from foods with MLs, revised ML for vegetables

Region	Total dietary exposure (µg/person/day)
Middle East	151.1
Far East	157.3
Africa	132.7
Latin America	163.3
Uropea	213.2
PTWI	**214.3**

16. The exposure from foods with the proposed MLs may be considered to ensure the safety of even high level consumers. The calculated exposures also compare well with the latest GEMS/Food (1990-1994) information on lead dietary exposure from market basket studies in Australia, China, Guatemala and Japan in which the mean dietary exposures were reported to be between <10 and 170 µg/person/day, with the 90th percentile reported in Japan and Guatemala between 50 and 260 µg/person/day. Comments to CCFAC from Canada, Sweden, Denmark, The Netherlands, UK, Finland and the USA reported dietary exposures of between 28 to 250 µg/person/day.

PROPOSED MLS FOR LEAD IN FOOD.

17. The final outcome of the above procedure is the MLs given in Table 7 below for food commodities identified by Codex classification number. Differences from the proposals in Appendix X of Alinorm 97/12A are small, although a separate category for potatoes is included. Where it is considered that MLs are not required as the food commodity makes only a low average contribution to the total lead intakes, such as milk and milk fat, no ML is proposed.

REFERENCES

1. Draft Codex Standard for Lead (most recent version CX/FAC 96/23, amended by Appendix X of Alinorm 97/12A).
2. Galal-Gorchev H. Dietary intake, levels in food and estimated intake of lead, cadmium, and mercury. Food Additives and Contaminants, 1993, Vol. 10, No. 1, 115-128.
3. Dr G Moy (personal communication).

Table 7: Proposed MLs for lead in food

CODE NO.	FOOD	PROPOSED ML (MG/KG)	CODEX ML AT STEP 5 (MG/KG)
FC 1 FP 9 FS 12 FB 18 FT 26 FI 30 JF 175	Fruit	0.1	0.1
VA 35 VO 50 VC 45 VR 75 VD 70 VP 60	Vegetables, except brassica (VB), leafy vegetables (VL) and mushrooms	0.1	0.1
VR589	Potatoes	0.1	0.15
VL 53 VB 40	Leafy vegetables (except spinach)	0.2	0.3
C 81	Cereal products, except bran	0.2	0.2
MM 97 PM 100 MF 97 PF 111	Meat and fat of cattle, pigs, sheep, poultry	0.1	0.1
WF 115 WD 120 WS 125	Fish	0.5	0.5
WC 143	Crustaceans		1.0
	}	1.0	
IM 151	Bivalve molluscs		2.0
FF 269	Wine	0.2	0.2
LM	Infant formula [b]	0.02	0.02[a]

Notes

a Provided that appropriate methods of analysis are available.

b Not yet assessed by this methodology in absence of relevant data. Value applies to the product ready for use