codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS | WORLD HEALTH ORGANIZATION

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METHODOLOGY AND PRINCIPLES FOR EXPOSURE ASSESSMENT IN THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD
(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 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. 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. At the 31st session of the Codex Committee on Food Additives and Contaminants (CCFAC), the delegation of the United Kingdom presented "Methodology and Principles for Exposure Assessment in the Codex General Standard for Contaminants and Toxins in Food" (CX/FAC 99/13), which proposed dietary exposure assessment methodology to support the GSC. The CCFAC concluded that the delegation of the United Kingdom should further develop this methodology as an Annex for the GSC with the assistance of a drafting group comprising other national delegations.[1] The draft versions of the attached papers were circulated earlier this year to the drafting group and comments received have been taken into account in the final version.

PURPOSE

4. The proposed dietary assessment methodology is detailed in the attached Annex 1. Use of this methodology enables MLs to be set for primary, unprocessed food commodities in international trade on a sound scientific basis. In this paper, practical guidance on the use of the exposure methodology developed from that described in CX/FAC 99/13 is provided. An illustration of the proposed methodology, in which limits for lead are proposed, is attached as Annex 2. If the proposed exposure assessment methodology can be agreed, then it will be included in the GSC as an Annex to the Standard.

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[1] ALINROM 99/12A, paras. 100-104.

CONCLUSIONS AND RECOMMENDATIONS

5. 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 Annex 1 should be incorporated into the General Standard for Contaminants and Toxins in Food as an Annex to the Standard.

ANNEX 1

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

1. The methodology set out in this document is an elaboration of the principles for the establishment of Maximum Limits (MLs) for contaminants in food in Annex 1 of the GSC. This methodology enables MLs to be set for chemical contaminants in primary, unprocessed food commodities in international trade, but does not address the management of genotoxic chemicals for which no safe dose can be assigned and where even very low concentrations may present a health risk. In such cases, it may be helpful to develop specific quantitative risk assessments in order to assist appropriate risk management decisions. 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 for most consumers.

2. The exposure assessment comprises four steps with each step considering a number of criteria. Figure 1 illustrates the overall methodology.

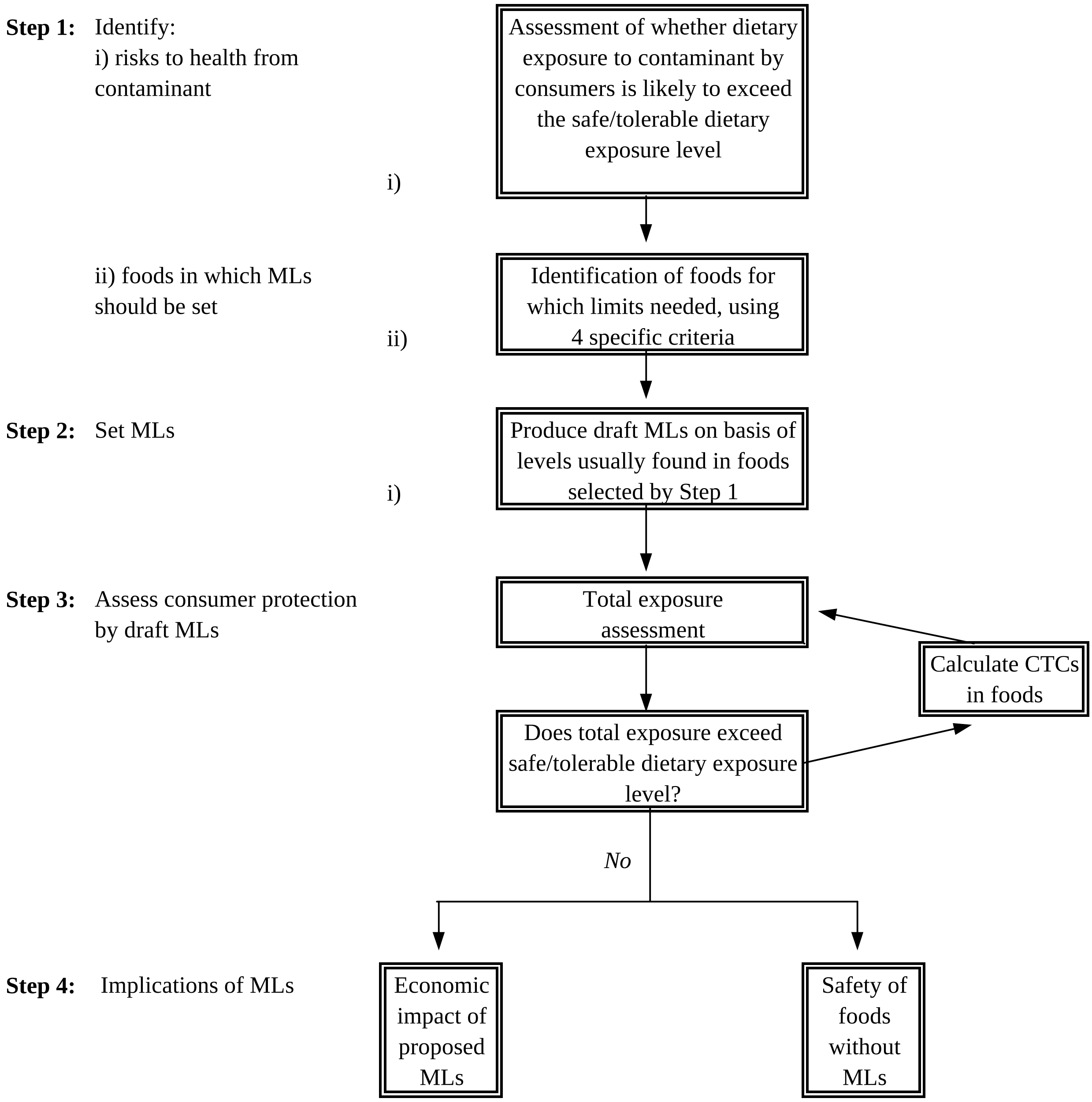
- The first step considers whether the dietary exposure to a contaminant requires the development of MLs to protect public health. If elevated levels of a contaminant are possible, with the potential for high level consumers or vulnerable subgroups of the population to exceed the safe/tolerable dietary exposure level, then MLs may be required. If so, it 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 in order to propose draft MLs.

- The third step then assesses the total exposure from food containing the contaminant at the draft MLs. This is done for each of the thirteen FAO/WHO regional diets, proposed in “Progress Report by WHO on the Revision of GEMS/Food Regional Diets” (CX/PR 99/3), to assess if the draft MLs provide sufficient protection for consumers in each regional/cultural group. If the exposure from any diet is higher than the relevant safe/tolerable dietary exposure level for that contaminant, then a further stage is required to revise the draft MLs. In this stage, an assessment is made of whether any of the draft MLs are a cause for toxicological concern. Revised final MLs can then be set if necessary.

- The fourth step considers the practical implications of setting the MLs with particular attention to possible effects on trade.

Table 1: General Procedure for Establishing Maximum Levels (MLs) for Contaminants in Individual Foods



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 exceed the safe/tolerable dietary exposure level?

3. One of the aims of setting standards is to reduce the levels of contaminants to the lowest reasonably achievable. However, the dietary exposure to a contaminant by consumers should not exceed the safe/tolerable dietary exposure level established on the basis of expert toxicological advice. 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. If there are concerns about a contaminant for which no safe/tolerable dietary exposure level has been established, such as a Provisional Tolerable Weekly Intake (PTWI) or Tolerable Daily Intake (TDI), then advice should be obtained from JECFA.

ii) Identification of foods for which MLs are required

4. International limits established to facilitate trade should also serve to protect consumers on a global basis. However, this does not imply that exceeding these limits will necessarily constitute a health risk.

5. Where a contaminant has acute toxicity, limits on the maximum concentrations of that contaminant in food are necessary to protect consumers. However, for most contaminants it is the long-term or chronic toxicity effects that are of concern. For such contaminants, limits are only necessary for those foods or food groups that are significant for the total dietary exposure of consumers to the contaminant and preferably where the limits could be achieved by Good Manufacturing Practice or the use of measures directed at the source(s) of the contaminants. 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. This stage also enables national resources to focus on those foods where significant reductions in concentrations of contaminants could be achieved.

6. In addition to the criteria given in Annex I of the GSC, four specific criteria are used to identify foods for which limits for contaminants should be set.

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

7. 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, have the potential to reduce the concentrations of the contaminant in food. As it may take some time for the actions to be effective, it may be necessary to agree a timescale within which the ML is phased in.

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

8. This figure has been chosen to ensure that all foods that provide a significant contribution to dietary exposures are considered. The food groups should be those currently broadly defined in CX/PR 99/3. However, 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. 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.

9. To fulfil this criterion the food must be traded from one country to another country where there may be very different dietary patterns. There must be evidence that the food would directly increase the dietary exposure by consumers in the importing country 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.

Criterion 4: Although the dietary exposure from a food commodity is lower than 5%, an ML would have an important role in the management of food contamination and environmental monitoring.

10. This allows MLs to be set for food groups that can have elevated levels of contaminants, although their contribution to the overall dietary exposure to those contaminants is low.

Step 2: Setting the ML

11. In this step, draft MLs can be formulated at the upper end of the range of contaminant concentrations normally found in those foods selected by Step 1. These data should be evaluated carefully to ensure that they are as representative as possible of current values for the contaminant in those foods and have been measured using reliable and sensitive analytical methodology.

Step 3: Estimating the dietary exposure from foods with MLs

12. The third, and most important, step assesses the potential total dietary exposure from foods containing the contaminant at the draft MLs to ensure that these provide sufficient protection for most consumers. In order to determine the acceptability of the draft MLs, the total dietary exposure from foods assigned MLs can be calculated using the consumption data in Table 1. It is desirable that above-average food consumption figures are used in the 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.

13. It is therefore recommended that the thirteen proposed FAO/WHO regional/cultural diets are used in the process of setting MLs for contaminants in traded foods in order to reflect dietary and cultural diversity. (Any future development of these diets can be incorporated in this Step.) The FAO/WHO regional diets, currently used to make estimates of dietary exposure of pesticides 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. Details of the countries assigned to the regional/cultural diets (from CX/PR 99/3) are given at the Appendix to this document.

Table 2: Average Consumption in Regional Dietary Groups
(weighted averages - g/person/day)

Food Group	A	B	C	D	E	F	G	H	I	J	K	L	M
apples and products	1.3	66.0	17.4	39.1	64.2	59.6	8.9	12.5	3.8	0.8	8.5	21.4	43.5
Bananas	34.5	17.5	11.0	3.0	25.4	30.2	15.5	42.6	18.5	3.6	78.7	32.2	30.6
citrus fruit	4.7	79.5	56.5	17.8	54.7	57.6	10.1	60.4	8.5	1.0	66.1	37.7	104.0
other fruits	20.2	163.5	95.4	68.5	83.3	58.6	55.7	81.0	23.4	40.0	58.8	73.2	65.2
Fruit (total)	183.5	403.1	246.8	154.9	263.2	228.3	98.9	258.2	101.5	106.9	276.9	192.4	310.2
Potatoes	16.4	186.4	60.3	250.4	243.9	230.6	31.2	48.0	27.5	2.1	50.8	49.0	157.9
Roots and tubers (total)	392.1	187.2	65.1	250.4	244.3	230.6	111.8	93.4	356.1	344.4	172.1	110.0	165.8
all cucurbits	5.0	30.9	26.2	21.7	14.3	13.6	14.7	5.7	4.2	1.4	6.1	16.0	14.3
tomatoes and products	11.8	164.8	121.1	59.6	43.1	31.4	14.7	27.5	12.3	11.9	34.5	12.8	98.5
Onions	4.2	55.3	33.1	24.0	26.4	14.9	17.7	11.1	6.4	8.6	11.7	34.6	27.9
other fresh vegetables	23.5	97.2	48.3	43.4	55.8	24.2	125.0	18.8	38.5	57.1	20.4	114.1	24.5
dried or dehydrated vegetables	0.2	0.5	0.5	0.1	0.5	0.5	0.2	0.0	0.1	0.1	0.0	1.7	0.2
Vegetables (total)	59.6	451.2	270.5	223.6	261.2	172.7	209.8	92.0	77.5	89.3	85.8	276.7	277.4
Maize	65.6	17.0	62.0	13.0	16.8	2.2	31.1	247.8	241.3	55.3	67.3	55.1	31.7
Wheat	67.1	406.3	436.4	405.5	238.2	228.4	170.3	111.5	66.3	45.0	118.3	106.9	241.8
rice, husked equivalent	47.4	22.9	62.4	27.8	8.9	10.5	307.5	44.3	27.6	56.8	119.5	246.9	22.2
other cereals	25.3	0.2	1.1	0.2	1.3	8.5	1.3	6.9	2.1	3.9	0.8	1.4	0.2
Cereals (total)	255.3	448.1	602.8	482.5	295.0	324.5	492.2	410.6	359.8	409.7	292.8	379.3	310.3
soyabean oil	1.1	9.3	6.4	3.9	9.2	9.3	2.3	11.8	1.5	0.9	26.6	8.3	41.6
Vegetable oils (total)	14.2	62.6	36.6	22.6	41.7	31.6	16.1	24.6	19.0	26.8	37.9	29.2	59.5
sugar., refined	17.0	75.8	74.0	71.6	96.4	98.4	24.9	106.0	43.6	23.1	116.2	54.7	84.8
Sweeteners (total)	19.2	85.3	82.1	80.0	112.3	111.8	37.6	120.8	48.6	25.8	137.1	80.2	166.1
meat products, other	5.3	7.1	3.2	2.8	5.3	6.1	1.0	3.0	4.8	4.5	0.8	1.3	2.2
Sheep	6.8	13.6	12.0	9.7	7.4	4.8	2.9	3.1	5.3	8.2	1.9	1.6	6.1
Bovine	14.4	42.6	15.3	50.9	53.5	55.7	6.7	37.1	22.7	13.3	62.9	21.0	118.9
Pork	6.9	68.3	0.1	39.0	120.4	77.1	32.3	24.2	3.8	3.3	19.4	46.1	71.4
Poultry	7.3	46.7	25.1	22.8	44.4	17.6	8.7	37.5	11.2	5.2	46.9	39.2	101.5
Meat (total)	33.4	131.6	30.6	102.4	186.6	143.7	42.9	67.4	36.6	29.3	85.0	70.0	198.6
Fish	18.6	61.0	15.1	22.1	41.4	86.6	25.2	29.5	23.8	21.4	20.0	137.6	56.0
Pulses	31.0	23.7	17.9	9.6	7.5	3.2	16.3	31.9	17.6	24.1	36.3	8.9	10.4
Brassica	2.4	33.1	11.4	54.7	45.0	39.0	22.2	6.2	5.5	0.1	4.4	55.2	15.8
oil crops	13.4	12.0	10.4	4.8	7.6	3.6	23.9	8.9	9.5	16.0	14.2	25.1	12.6
cocoa, coffee, tea	2.7	13.0	5.9	4.5	22.4	25.0	1.4	7.2	2.0	4.4	8.3	8.7	18.2
Spices	2.8	1.3	2.9	0.4	1.4	0.8	2.5	1.0	1.5	2.0	0.5	1.9	1.6
Eggs	3.3	31.1	11.4	27.4	33.8	30.6	14.2	24.3	5.7	5.5	19.2	34.5	32.6
Milk	44.9	274.8	113.9	317.0	344.8	472.5	73.0	177.2	91.5	104.7	250.6	102.1	379.1
alcohol, including beer and wine	90.9	176.1	6.8	70.5	339.1	184.4	24.0	102.4	109.2	109.5	100.8	138.7	272.4

(Data from CX/PR 99/3)

14. It is very unlikely that consumers would receive all of their food with contaminant concentrations equal to the ML. Nevertheless, a proportion of the foods could be at or around the ML. In the absence of sufficient data, it is assumed that the contaminant concentration in 50% of the foods for which a ML is equal to the ML, with a typical or average concentration in the remaining 50%. This is a justifiable first step in testing the acceptability of the ML values as it is unlikely to underestimate the exposure. It does, however, mean that the typical or average values must be selected with care.

15. While these assumptions will produce an overestimate of dietary exposure, if this estimate is still below the PTWI/TDI then the MLs can be accepted with confidence. If the calculated total dietary exposures are higher than the PTWI/TDI, then one or more of the proposed MLs may be too high. To check this, an assessment is made of whether any of the MLs is a cause for toxicological concern.

16. A Calculated Tolerable Concentration (CTC) is estimated as in (1) below for each food commodity for which a draft ML has been set and for each regional/cultural diet in turn to take account of the differences in food consumption and patterns of food contamination. The consumption data used to calculate the dietary exposures for the ML foods are in all cases taken from Table 2.

17. The CTC is an assessment of the highest level of a contaminant that could be present in a food without an average consumer of the contaminated food exceeding the Provisional Tolerable Weekly Intake (PTWI) or Tolerable Daily Intake (TDI) for the contaminant established by JECFA, after allowing for exposure from the rest of the diet. This exposure is accounted for by adding the exposure from the other foods with MLs to a proportion of the total exposure from <u>all</u> food in that dietary group. Annex I of the GSC specifies that foods with proposed MLs should account for 80% of total dietary exposure from a contaminant. Thus, a figure of 20% of the exposure from <u>all</u> foods is added. This overestimate of exposure from the average diet is likely to take account of the low exposure from air and water for most consumers.

Exposure from rest of the diet

(1)
$$\text{CTC for food with ML (mg/kg)} = \frac{\text{PTWI, for 60 kg person (mg/day)} - \text{total dietary exposure from other foods with MLs (mg/day)} - \text{20\% of total dietary exposure from } \underline{\text{all}} \text{ food (mg/day)}}{\text{Consumption value for food with ML (g/day)}}$$

18. The next stage enables a revised ML to be proposed by comparing the lowest CTC from the regional diets for each food commodity with the draft ML selected in Step 2. These final MLs are selected from the geometric scale recommended in Annex I of the GSC. The aim here is to propose a ML that is as low as reasonably achievable, but is unlikely to cause serious economic impact. There are two possible outcomes:

- the CTC is higher than the draft ML - an ML based on the draft ML may be established which does not raise concern for human health. As the draft ML takes account of the normal distribution of the contaminant, it is unlikely to cause serious economic impact.
- the CTC is lower than the draft ML - 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 that contain inherently elevated concentrations of certain contaminants.

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

Step 4: Considering the practical implications of setting the MLs

20. There are two issues to consider. Firstly, what economic impacts are the proposed MLs likely to have in practice? Secondly, how do countries ensure that foods where MLs have not been established are safe for consumption by their own population?

i) What economic impacts are the proposed MLs likely to have in practice?

21. 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. A trade issue may arise owing to health concerns involving a contaminant in food commodities for which no ML has been proposed because of its 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, followed by an assessment by CCFAC.

ii) How does a country ensure that foods where MLs have not been established are safe for consumption by their own population?

22. National authorities should be encouraged to monitor the foods with MLs as they, in effect, act as indicators of how well source-control measures are implemented. National authorities should also be encouraged to monitor the foods without MLs particularly where local problems have been identified. For quality control purpose it is advisable to analyse raw or primary products but in order to estimate dietary exposure it is more useful to determine the residue concentrations in foods as consumed. Total diet (market basket) surveys should be used to determine the overall trend of dietary exposure within the population as a whole or in specific groups of concern. It may be appropriate to establish a specific Codex ML when there is evidence that the health of specific consumers may be at stake.

References

Codex General Standard for Contaminants and Toxins in Food

Methodology and principles for exposure assessment in the Codex General Standard for Contaminants (CX/FAC 99/13)

Progress Report by WHO on the Revision of GEMS/Food Regional Diets (CX/PR 99/3)

Appendix: Country Assignments to the 13 Proposed WHO Regional/Cultural diets

Dietary group	Country	Dietary group	Country	Dietary group	Country
A	Angola	D	Albania	G	Afghanistan
A	Burundi	D	Armenia	G	Bangladesh
A	Cameroon	D	Azerbaijan	G	Cambodia
A	Central African Republic	D	Belarus	G	China
A	Comoros	D	Bosnia and Herzegovina	G	India
A	Congo, Democratic Republic of	D	Bulgaria	G	Indonesia
A	Côte d'Ivoire	D	Georgia	G	Laos
A	Djibouti	D	Iran, Islamic Rep of	G	Mongolia
A	Eritrea	D	Kazakhstan	G	Myanmar
A	Ethiopia	D	Kyrgyzstan	G	Nepal
A	Gabon	D	Moldova, Republic of	G	Pakistan
A	Guinea	D	Romania	G	Sri Lanka
A	Guinea Bissau	D	Russian Federation	G	Thailand
A	Liberia	D	Tajikistan	G	Vietnam
A	Madagascar	D	The former Yugoslav Republic of Macedonia		
A	Mauritius	D	Turkmenistan	H	Bolivia
A	Rwanda	D	Ukraine	H	El Salvador
A	Sao Tome & Principe	D	Uzbekistan	H	Fiji
A	Seychelles			H	Guatemala
A	Sierra Leone	E	Austria	H	Haiti
A	Somalia	E	Belgium	H	Honduras
A	Uganda	E	Croatia	H	Mexico
A	Yemen	E	Czech Republic	H	Nicaragua
		E	Denmark	H	Panama
B	Cyprus	E	France	H	Paraguay
B	Greece	E	Germany	H	Peru
B	Israel	E	Hungary	H	Saint Kitts & Nevis
B	Italy	E	Ireland	H	St. Vincent & Grenadine
B	Lebanon	E	Malta		
B	Portugal	E	Netherlands	I	Botswana
B	Spain	E	Poland	I	Cape Verde
B	Turkey	E	Slovakia	I	Ghana
B	United Arab Emirates	E	Slovenia	I	Kenya
		E	Switzerland	I	Lesotho
C	Algeria	E	United Kingdom	I	Malawi
C	Egypt	E	Yugoslavia	I	Mozambique
C	Iraq			I	Namibia
C	Jordan	F	Estonia	I	Reunion
C	Kuwait	F	Finland	I	South Africa
C	Libya Arab Jamahiriya	F	Iceland	I	Swaziland
C	Morocco	F	Latvia	I	Togo
C	Saudi Arabia	F	Lithuania	I	United Republic of Tanzania
C	Syrian Arab Republic	F	Norway	I	Zambia
C	Tunisia	F	Sweden	I	Zimbabwe

Dietary group	Country	Dietary group	Country
J	Burkina Faso	L	Brunei Darussalam
J	Chad	L	French Polynesia
J	Congo, Republic of	L	China, Hong Kong
J	Gambia	L	Japan
J	Mali	L	Kiribati
J	Mauritania	L	Democratic People's Republic of Korea
J	Niger	L	Republic of Korea
J	Nigeria	L	Madagascar
J	Senegal	L	Malaysia
J	Sudan	L	Maldives
		L	New Caledonia
K	Antigua & Barbuda	L	Papua New Guinea
K	Aruba (Netherlands)	L	Philippines
K	Bahamas	L	Solomon Islands
K	Barbados	L	China (Taiwan Province)
K	Belize	L	Vanuatu
K	Bermuda		
K	Brazil	M	Argentina
K	Colombia	M	Australia
K	Costa Rica	M	Canada
K	Cuba	M	Chile
K	Dominica	M	New Zealand
K	Dominican Republic	M	United States
K	Ecuador	M	Uruguay
K	French Guyana		
K	Grenada		
K	Guadeloupe		
K	Guyana		
K	Jamaica		
K	Martinique		
K	Saint Lucia		
K	Suriname		
K	Trinidad and Tobago		
K	Venezuela		

ANNEX 2

METHODOLOGY FOR SETTING MLS AND ASSESSING THE EXPOSURE FROM FOODS WITH MLS, USING LEAD AS AN EXAMPLE

1. This paper demonstrates the methodology for setting MLs and assessing the exposure from foods assigned MLs outlined in Paper 1, using lead as an example. The information used to prepare this paper includes comments received from members of CCFAC on the papers relating to Maximum Levels for Lead (CX/FAC 94/20, 95/18, 96/23 and 99/19), GEMS/Food information and proposed FAO/WHO regional diets (CX/PR 99/3). 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 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 214.3 μg/day for 60 kg person). This conclusion was reached taking into account the most sensitive groups of the population. Lead exposure from food was reviewed in CX/FAC 94/20, 95/18, 96/23 and 99/19. The latter paper states that the use of source-directed measures have lead to decrease in the contamination of food by lead. 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 can be 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 paper CX/FAC 99/19 identifies typical concentrations of lead in broad food groups. These data have been used with FAO/WHO consumption data for each regional diet from CX/PR 99/3 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.

Table 1: Lead exposure from regional dietary groups

		Group A			Group B			Group C			Group D			Group E		
Food Group	Average lead content (ug/kg)	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure
apples and products	25	1.3	0.0	0.1	66.0	1.7	2.1	17.4	0.4	1.1	39.1	1.0	1.8	64.2	1.6	1.9
bananas	25	34.5	0.9	1.8	17.5	0.4	0.6	11.0	0.3	0.7	3.0	0.1	0.1	25.4	0.6	0.8
citrus fruit	25	4.7	0.1	0.2	79.5	2.0	2.6	56.5	1.4	3.5	17.8	0.4	0.8	54.7	1.4	1.6
other fruits	25	20.2	0.5	1.1	163.5	4.1	*5.3*	95.4	2.4	*5.9*	68.5	1.7	3.1	83.3	2.1	2.5
Fruit (total)	*25*	183.5	4.6	*9.5*	403.1	10.1	**13.1**	246.8	6.2	**15.2**	154.9	3.9	*7.0*	263.2	6.6	*7.9*
potatoes	50	16.4	0.8	1.7	186.4	9.3	**12.1**	60.3	3.0	*7.4*	250.4	12.5	**22.6**	243.9	12.2	**14.6**
Roots and tubers (total)	*50*	392.1	19.6	**40.8**	187.2	9.4	**12.2**	65.1	3.3	*8.0*	250.4	12.5	**22.6**	244.3	12.2	**14.6**
all cucurbits	20	5.0	0.1	0.2	30.9	0.6	0.8	26.2	0.5	1.3	21.7	0.4	0.8	14.3	0.3	0.3
tomatoes and products	20	11.8	0.2	0.5	164.8	3.3	4.3	121.1	2.4	*6.0*	59.6	1.2	2.1	43.1	0.9	1.0
onions	20	4.2	0.1	0.2	55.3	1.1	1.4	33.1	0.7	1.6	24.0	0.5	0.9	26.4	0.5	0.6
other fresh vegetables	20	23.5	0.5	1.0	97.2	1.9	2.5	48.3	1.0	2.4	43.4	0.9	1.6	55.8	1.1	1.3
dried vegetables	20	0.2	0.0	0.0	0.5	0.0	0.0	0.5	0.0	0.0	0.1	0.0	0.0	0.5	0.0	0.0
Vegetables (total)	*20*	59.6	1.2	2.5	451.2	9.0	**11.7**	270.5	5.4	**13.3**	223.6	4.5	*8.1*	261.2	5.2	*6.2*
maize	30	65.6	2.0	4.1	17.0	0.5	0.7	62.0	1.9	4.6	13.0	0.4	0.7	16.8	0.5	0.6
wheat	30	67.1	2.0	4.2	406.3	12.2	**15.8**	436.4	13.1	**32.2**	405.5	12.2	**21.9**	238.2	7.1	*8.5*
rice, husked equivalent	30	47.4	1.4	3.0	22.9	0.7	0.9	62.4	1.9	4.6	27.8	0.8	1.5	8.9	0.3	0.3
other cereals	30	25.3	0.8	1.6	0.2	0.0	0.0	1.1	0.0	0.1	0.2	0.0	0.0	1.3	0.0	0.0
Cereals (total)	*30*	255.3	7.7	**15.9**	448.1	13.4	**17.5**	602.8	18.1	**44.5**	482.5	14.5	**26.1**	295.0	8.9	**10.6**
soyabean oil	20	1.1	0.0	0.0	9.3	0.2	0.2	6.4	0.1	0.3	3.9	0.1	0.1	9.2	0.2	0.2
Vegetable oils	*20*	14.2	0.3	0.6	62.6	1.3	1.6	36.6	0.7	1.8	22.6	0.5	0.8	41.7	0.8	1.0

Key: Figures in bold = more than 10% of the diet
Figures in italics = more than 5% of the diet

(total)																
sugar., refined	10	17.0	0.2	0.4	75.8	0.8	1.0	74.0	0.7	1.8	71.6	0.7	1.3	96.4	1.0	1.2
Sweeteners (total)	*10*	19.2	0.2	0.4	85.3	0.9	1.1	82.1	0.8	2.0	80.0	0.8	1.4	112.3	1.1	1.3
meat products, other	20	5.3	0.1	0.2	7.1	0.1	0.2	3.2	0.1	0.2	2.8	0.1	0.1	5.3	0.1	0.1
sheep	20	6.8	0.1	0.3	13.6	0.3	0.4	12.0	0.2	0.6	9.7	0.2	0.3	7.4	0.1	0.2
bovine	20	14.4	0.3	0.6	42.6	0.9	1.1	15.3	0.3	0.8	50.9	1.0	1.8	53.5	1.1	1.3
pork	20	6.9	0.1	0.3	68.3	1.4	1.8	0.1	0.0	0.0	39.0	0.8	1.4	120.4	2.4	2.9
poultry	20	7.3	0.1	0.3	46.7	0.9	1.2	25.1	0.5	1.2	22.8	0.5	0.8	44.4	0.9	1.1
Meat (total)	*20*	33.4	0.7	1.4	131.6	2.6	3.4	30.6	0.6	1.5	102.4	2.0	3.7	186.6	3.7	4.5
fish	100	18.6	1.9	3.9	61.0	6.1	*7.9*	15.1	1.5	3.7	22.1	2.2	4.0	41.4	4.1	4.9
pulses	50	31.0	1.6	3.2	23.7	1.2	1.5	17.9	0.9	2.2	9.6	0.5	0.9	7.5	0.4	0.4
brassica	100	2.4	0.2	0.5	33.1	3.3	4.3	11.4	1.1	2.8	54.7	5.5	*9.9*	45.0	4.5	*5.4*
oil crops	50	13.4	0.7	1.4	12.0	0.6	0.8	10.4	0.5	1.3	4.8	0.2	0.4	7.6	0.4	0.5
cocoa, coffee, tea	5	2.7	0.0	0.0	13.0	0.1	0.1	5.9	0.0	0.1	4.5	0.0	0.0	22.4	0.1	0.1
spices	100	2.8	0.3	0.6	1.3	0.1	0.2	2.9	0.3	0.7	0.4	0.0	0.1	1.4	0.1	0.2
eggs	25	3.3	0.1	0.2	31.1	0.8	1.0	11.4	0.3	0.7	27.4	0.7	1.2	33.8	0.8	1.0
milk	2	44.9	0.1	0.2	274.8	0.5	0.7	113.9	0.2	0.6	317.0	0.6	1.1	344.8	0.7	0.8
alcohol (beer and wine)	100	90.9	9.1	**18.9**	176.1	17.6	**22.9**	6.8	0.7	1.7	70.5	7.1	**12.7**	339.1	33.9	**40.5**
Total dietary exposure			48.1			77.0			40.7			55.5			83.6	

<u>Key</u>: Figures in bold = more than 10% of the diet
Figures in italics = more than 5% of the diet

Table 1: Lead exposure from regional dietary groups (contd.)

		Group F			Group G			Group H			Group I			Group J		
Food Group	Average lead content (ug/kg)	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure
apples and products	25	59.6	1.5	2.2	8.9	0.2	0.6	12.5	0.3	0.7	3.8	0.1	0.2	0.8	0.0	0.0
bananas	25	30.2	0.8	1.1	15.5	0.4	1.0	42.6	1.1	2.4	18.5	0.5	0.9	3.6	0.1	0.2
citrus fruit	25	57.6	1.4	2.1	10.1	0.3	0.7	60.4	1.5	3.3	8.5	0.2	0.4	1.0	0.0	0.0
other fruits	25	58.6	1.5	2.1	55.7	1.4	3.6	81.0	2.0	4.5	23.4	0.6	1.2	40.0	1.0	2.0
Fruit (total)	*25*	228.3	5.7	8.4	98.9	2.5	*6.4*	258.2	6.5	**14.3**	101.5	2.5	*5.1*	106.9	2.7	*5.2*
potatoes	50	230.6	11.5	**16.9**	31.2	1.6	4.1	48.0	2.4	5.3	27.5	1.4	2.8	2.1	0.1	0.2
Roots and tubers (total)	*50*	230.6	11.5	**16.9**	111.8	5.6	**14.5**	93.4	4.7	**10.3**	356.1	17.8	**35.6**	344.4	17.2	**33.7**
all cucurbits	20	13.6	0.3	0.4	14.7	0.3	0.8	5.7	0.1	0.3	4.2	0.1	0.2	1.4	0.0	0.1
tomatoes and products	20	31.4	0.6	0.9	14.7	0.3	0.8	27.5	0.6	1.2	12.3	0.2	0.5	11.9	0.2	0.5
onions	20	14.9	0.3	0.4	17.7	0.4	0.9	11.1	0.2	0.5	6.4	0.1	0.3	8.6	0.2	0.3
other fresh vegetables	20	24.2	0.5	0.7	125.0	2.5	6.5	18.8	0.4	0.8	38.5	0.8	1.5	57.1	1.1	2.2
dried vegetables	20	0.5	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.1	0.0	0.0
Vegetables (total)	*20*	172.7	3.5	*5.1*	209.8	4.2	**10.9**	92.0	1.8	4.1	77.5	1.6	3.1	89.3	1.8	3.5
maize	30	2.2	0.1	0.1	31.1	0.9	2.4	247.8	7.4	**16.4**	241.3	7.2	**14.5**	55.3	1.7	3.3
wheat	30	228.4	6.9	**10.0**	170.3	5.1	**13.3**	111.5	3.3	*7.4*	66.3	2.0	4.0	45.0	1.4	2.6
rice, husked equivalent	30	10.5	0.3	0.5	307.5	9.2	**24.0**	44.3	1.3	2.9	27.6	0.8	1.7	56.8	1.7	3.3
other cereals	30	8.5	0.3	0.4	1.3	0.0	0.1	6.9	0.2	0.5	2.1	0.1	0.1	3.9	0.1	0.2
Cereals (total)	*30*	324.5	9.7	**14.3**	492.2	14.8	**38.4**	410.6	12.3	**27.2**	359.8	10.8	**21.6**	409.7	12.3	**24.1**

Key: Figures in bold = more than 10% of the diet
Figures in italics = more than 5% of the diet

soyabean oil	20	9.3	0.2	0.3	2.3	0.0	0.1	11.8	0.2	0.5	1.5	0.0	0.1	0.9	0.0	0.0
Vegetable oils (total)	*20*	31.6	0.6	0.9	16.1	0.3	0.8	24.6	0.5	1.1	19.0	0.4	0.8	26.8	0.5	1.1
sugar., refined	10	98.4	1.0	1.4	24.9	0.2	0.6	106.0	1.1	2.3	43.6	0.4	0.9	23.1	0.2	0.5
Sweeteners (total)	*10*	111.8	1.1	1.6	37.6	0.4	1.0	120.8	1.2	2.7	48.6	0.5	1.0	25.8	0.3	0.5
meat products, other	20	6.1	0.1	0.2	1.0	0.0	0.1	3.0	0.1	0.1	4.8	0.1	0.2	4.5	0.1	0.2
sheep	20	4.8	0.1	0.1	2.9	0.1	0.2	3.1	0.1	0.1	5.3	0.1	0.2	8.2	0.2	0.3
bovine	20	55.7	1.1	1.6	6.7	0.1	0.3	37.1	0.7	1.6	22.7	0.5	0.9	13.3	0.3	0.5
pork	20	77.1	1.5	2.3	32.3	0.6	1.7	24.2	0.5	1.1	3.8	0.1	0.2	3.3	0.1	0.1
poultry	20	17.6	0.4	0.5	8.7	0.2	0.5	37.5	0.8	1.7	11.2	0.2	0.4	5.2	0.1	0.2
Meat (total)	*20*	143.7	2.9	4.2	42.9	0.9	2.2	67.4	1.3	3.0	36.6	0.7	1.5	29.3	0.6	1.1
fish	100	86.6	8.7	**12.7**	25.2	2.5	*6.5*	29.5	3.0	*6.5*	23.8	2.4	4.8	21.4	2.1	4.2
pulses	50	3.2	0.2	0.2	16.3	0.8	2.1	31.9	1.6	3.5	17.6	0.9	1.8	24.1	1.2	2.4
brassica	100	39.0	3.9	5.7	22.2	2.2	*5.8*	6.2	0.6	1.4	5.5	0.6	1.1	0.1	0.0	0.0
oil crops	50	3.6	0.2	0.3	23.9	1.2	3.1	8.9	0.4	1.0	9.5	0.5	1.0	16.0	0.8	1.6
cocoa, coffee, tea	5	25.0	0.1	0.2	1.4	0.0	0.0	7.2	0.0	0.1	2.0	0.0	0.0	4.4	0.0	0.0
spices	100	0.8	0.1	0.1	2.5	0.3	0.6	1.0	0.1	0.2	1.5	0.2	0.3	2.0	0.2	0.4
eggs	25	30.6	0.8	1.1	14.2	0.4	0.9	24.3	0.6	1.3	5.7	0.1	0.3	5.5	0.1	0.3
milk	2	472.5	0.9	1.4	73.0	0.1	0.4	177.2	0.4	0.8	91.5	0.2	0.4	104.7	0.2	0.4
alcohol (beer and wine)	100	184.4	18.4	**27.0**	24.0	2.4	*6.2*	102.4	10.2	**22.6**	109.2	10.9	**21.9**	109.5	11.0	**21.5**
Total dietary exposure			68.3			38.5			45.3			50.0			51.0	

Key: Figures in bold = more than 10% of the diet
Figures in italics = more than 5% of the diet

Table 1: Lead exposure from regional dietary groups (contd.)

		Group K			Group L			Group M		
Food Group	Average lead content (ug/kg)	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure	Consumption (g/day)	Lead dietary exposure (ug/day)	% of total dietary exposure
apples and products	25	8.5	0.2	0.5	21.4	0.5	0.8	43.5	1.1	1.4
bananas	25	78.7	2.0	4.3	32.2	0.8	1.2	30.6	0.8	1.0
citrus fruit	25	66.1	1.7	3.6	37.7	0.9	1.4	104.0	2.6	3.5
other fruits	25	58.8	1.5	3.2	73.2	1.8	2.8	65.2	1.6	2.2
Fruit (total)	*25*	276.9	6.9	**15.1**	192.4	4.8	*7.3*	310.2	7.8	**10.3**
potatoes	50	50.8	2.5	5.5	49.0	2.5	3.7	157.9	7.9	**10.5**
Roots and tubers (total)	*50*	172.1	8.6	**18.7**	110.0	5.5	*8.3*	165.8	8.3	**11.0**
all cucurbits	20	6.1	0.1	0.3	16.0	0.3	0.5	14.3	0.3	0.4
tomatoes and products	20	34.5	0.7	1.5	12.8	0.3	0.4	98.5	2.0	2.6
onions	20	11.7	0.2	0.5	34.6	0.7	1.0	27.9	0.6	0.7
other fresh vegetables	20	20.4	0.4	0.9	114.1	2.3	3.4	24.5	0.5	0.7
dried vegetables	20	0.0	0.0	0.0	1.7	0.0	0.1	0.2	0.0	0.0
Vegetables (total)	*20*	85.8	1.7	3.7	276.7	5.5	*8.4*	277.4	5.5	*7.4*
maize	30	67.3	2.0	4.4	55.1	1.7	2.5	31.7	1.0	1.3
wheat	30	118.3	3.5	*7.7*	106.9	3.2	4.8	241.8	7.3	*9.7*
rice, husked equivalent	30	119.5	3.6	*7.8*	246.9	7.4	**11.2**	22.2	0.7	0.9
other cereals	30	0.8	0.0	0.1	1.4	0.0	0.1	0.2	0.0	0.0
Cereals (total)	*30*	292.8	8.8	**19.1**	379.3	11.4	**17.2**	310.3	9.3	**12.4**
soyabean oil	20	26.6	0.5	1.2	8.3	0.2	0.3	41.6	0.8	1.1
Vegetable oils	*20*	37.9	0.8	1.6	29.2	0.6	0.9	59.5	1.2	1.6

Key: Figures in bold = more than 10% of the diet
Figures in italics = more than 5% of the diet

(total)										
sugar., refined	10	116.2	1.2	2.5	54.7	0.5	0.8	84.8	0.8	1.1
Sweeteners (total)	*10*	137.1	1.4	3.0	80.2	0.8	1.2	166.1	1.7	2.2
meat products, other	20	0.8	0.0	0.0	1.3	0.0	0.0	2.2	0.0	0.1
sheep	20	1.9	0.0	0.1	1.6	0.0	0.0	6.1	0.1	0.2
bovine	20	62.9	1.3	2.7	21.0	0.4	0.6	118.9	2.4	3.2
pork	20	19.4	0.4	0.8	46.1	0.9	1.4	71.4	1.4	1.9
poultry	20	46.9	0.9	2.0	39.2	0.8	1.2	101.5	2.0	2.7
Meat (total)	*20*	85.0	1.7	3.7	70.0	1.4	2.1	198.6	4.0	*5.3*
fish	100	20.0	2.0	4.4	137.6	13.8	**20.8**	56.0	5.6	*7.5*
pulses	50	36.3	1.8	3.9	8.9	0.4	0.7	10.4	0.5	0.7
brassica	100	4.4	0.4	1.0	55.2	5.5	*8.3*	15.8	1.6	2.1
oil crops	50	14.2	0.7	1.5	25.1	1.3	1.9	12.6	0.6	0.8
cocoa, coffee, tea	5	8.3	0.0	0.1	8.7	0.0	0.1	18.2	0.1	0.1
spices	100	0.5	0.1	0.1	1.9	0.2	0.3	1.6	0.2	0.2
eggs	25	19.2	0.5	1.0	34.5	0.9	1.3	32.6	0.8	1.1
milk	2	250.6	0.5	1.1	102.1	0.2	0.3	379.1	0.8	1.0
alcohol (beer and wine)	100	100.8	10.1	**21.9**	138.7	13.9	**21.0**	272.4	27.2	**36.3**
Total dietary exposure			46.0			66.2			75.1	

Key: Figures in bold = more than 10% of the diet
Figures in italics = more than 5% of the diet

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.

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 those food groups providing major contributions to the dietary exposure to lead as cereals, roots and tubers, vegetables, fruit and wine (see figures in bold in Table 1). This is supported by the latest published summary of GEMS/Food (1980-1988) information on dietary exposures to lead and by more recent unpublished GEMS/Food data for 1990-1994 (Moy personal communication). 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. These figures are given in italics in Table 1. All the foods identified by Criterion 2 also fulfil this criterion.

Criterion 4: Although the dietary exposure from a food commodity is lower than 5%, a ML would have an important role in the management of food contamination and environmental monitoring.

7. This criterion would apply particularly to liver and kidney. However, the FAO/WHO consumption data do not at present allow these foods to be distinguished from other meat products, although this would be desirable.

8. The foods for which MLs are required are selected by the above criteria to be cereals, roots and tubers, vegetables, brassica, fruit, fish and wine (shown in shaded rows). Annex 1 of the GSC specifies that foods with proposed MLs should account for at least 80% of total dietary exposure from a contaminant. Between them, these foods account for between 84-94% of dietary exposure to lead from the foods listed in the Table.

Step 2: Setting the ML

9. 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?

10. 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) information and from national comments to CCFAC since 1991, although the manner 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, roots/tubers, vegetables, brassica, fruit, fish 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	**0.5**
Roots/tubers	0.08	<0.005 - 0.11	**0.1**
Vegetables (except root, tubers and brassica)	0.6	<0.005 - 2.4	**2.0**
Brassica (and leafy vegetables)	0.2	(not available)	**0.2**
Fruit	0.13	<0.005 - 0.16	**0.2**
Fish	0.3	<0.005 - 0.82	**0.8**
Wine	(not available)	0.06 - 0.15	**0.2**

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).

Step 3: Estimating the dietary exposure from foods with MLs

11. In order to determine the acceptability of the draft MLs, the total dietary exposure from foods assigned MLs can be calculated. To do this, it is assumed that the contaminant concentration in 50% of the foods for which a ML is equal to the ML, with a typical or average concentration in the remaining 50%. Although this assumption will certainly cause an overestimate of normal dietary exposure, if this falls below the PTWI then the MLs can be accepted with confidence.

12. The total dietary exposure to lead for each regional diet is estimated using the assumptions given above to yield the figures shown in Table 3:

Table 3: Dietary exposures to lead from foods with MLs

Total dietary exposure (µg/person/day)													
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**PTWI**
202.1	698.8	476.6	420.8	470.3	384.5	382.6	270.3	242.0	264.8	235.1	514.6	483.8	**214.3**

13. It can be seen that, other than for Group A only, the calculated total dietary exposures are all higher than the PTWI for lead (equivalent to 214.3 µg/day for 60 kg person), particularly so for the dietary exposure for Group B. Since all the dietary exposures are too high, then one or more of the proposed MLs may be set too high. The acceptability of the MLs may be checked against the Calculated Tolerable Concentrations (CTCs) to determine whether any of the MLs could give cause for toxicological concern.

14. The CTC for each food group is calculated as in (1) below so that consumers in specific regional dietary groups would have a dietary exposure below the PTWI for lead, after allowing for the average exposure from the rest of the diet. This exposure is accounted for by adding the exposure from the other foods with MLs to a proportion of the total exposure from all food in that dietary group. The consumption figure for the selected food is taken from Table 1, while the figures for the dietary exposures for the ML foods are in each case taken from this Table also.

(1)

$$\text{CTC for food with ML} = \frac{\text{PTWI, for 60 kg person} - \overbrace{\text{total dietary exposure from other foods with MLs} - 20\%\text{ of total dietary exposure from all food}}^{\textit{Exposure from rest of the diet}}}{\text{Consumption value for food with ML}}$$

15. An example using data from Table 1 to calculate the CTC for cereals in the Group A regional diet is given below:

Food	Dietary exposure (µg /day)	Consumption figure from Table 1 (g/day)
Cereals	7.7	255.3
Roots/tubers	19.6	392.1
Vegetables (except roots/tubers and brassica)	1.2	59.6
Brassica (and leafy vegetables)	0.2	2.4
Fruit (includes fruit juice)	4.6	183.5
Fish	1.9	18.6
Wine	9.1	9.1

$$\text{CTC (cereals)} = \frac{\text{PTWI (for 60 kg person)} - \text{Total dietary exposure from other foods with MLs} - 20\%\text{ dietary exposure from all foods}}{\text{Consumption (cereals)}}$$

$$= \frac{214.3 - [19.6 + 1.2 + 0.2 + 4.6 + 1.9 + 9.1] - [48.1]/5}{255.3}$$

$$= \frac{(214.3 - 36.6 - 9.6)}{255.3}$$

$$\therefore \text{CTC (cereals)} = \frac{214.3 - 46.2\ \mu g}{255.3\ g} = 0.66\ \mu g/g\ (mg/kg)$$

16. Table 4 compares the CTCs for cereals, roots and tubers, vegetables, brassica, fruit, fish and wine calculated for all regional diets. The wide range of values for each food group reflects the differing consumption of the food groups between the various regional diets.

Table 4: CTCs for cereals, roots/tubers, vegetables, brassica, fruit, fish and wine

	Calculated Tolerable Concentration (mg/kg)													
Food	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**Lowest CTC**
Cereals	0.66	0.32	0.31	0.35	0.44	0.46	0.38	0.43	0.47	0.41	0.6	0.4	0.46	**0.31**
Roots/tubers	0.46	0.74	2.7	0.66	0.55	0.65	1.6	1.8	0.49	0.51	1.0	1.3	0.86	**0.46**
Vegetables	2.7	0.31	0.65	0.7	0.49	0.83	0.84	1.8	2.1	1.8	2.0	0.53	0.5	**0.31**
Brassica	67	4.0	15	2.9	2.8	3.7	7.9	27	29	1570	38	2.7	8.6	**2.7**
Fruit	0.9	0.35	0.71	1.0	0.49	0.63	1.8	0.67	1.6	1.5	0.63	0.76	0.46	**0.35**
Fish	8.7	2.2	11	7.0	3.1	1.7	7.0	5.7	6.7	7.4	8.4	1.1	2.5	**1.1**
Wine	1.9	0.84	25	2.3	0.46	0.85	7.3	1.7	1.5	1.5	1.8	1.1	0.6	**0.46**

17. The draft MLs in Table 2 are then compared with the lowest CTCs in Table 4 to propose final MLs (Table 5). The use of the lowest CTCs would ensure that consumers from other dietary Groups are protected. The aim is to propose an ML as low as reasonably achievable which is unlikely to cause serious economic impact. There are two possible outcomes:

- the CTC is higher than the draft ML – a final ML based on the draft ML may be established which does not raise concern for human health.
- the CTC is lower than the draft ML - the final ML should reflect the CTC value and be set as low as reasonably achievable.

The final MLs are selected from the range of values proposed in Annex I of the GSC.

Table 5: Comparison of draft MLs with CTCs to propose final MLs

Food	Draft MLs (mg/kg)	CTC (mg/kg)	**Proposed final MLs (mg/kg)**	Codex MLs (mg/kg)
Cereals	0.5	**0.31**	**0.2**	0.2
Roots/tubers	0.1	**0.46**	**0.1**	-
Vegetables (except roots/tubers and brassica)	2.0	**0.31**	**0.2**	0.1
Brassica (and leafy vegetables)	0.2	**2.7**	**0.2**	0.3
Fruit	0.2	**0.35**	**0.2**	0.1
Fish	0.8	**1.13**	**0.5**	0.2
Wine	0.2	**0.46**	**0.2***	0.2

Shaded figures used as basis for final MLs
* Standards for wine fall within the remit of the OIV - current limit is 0.2 mg/kg.

18. The range of Codex MLs proposed in CX/FAC 99/19 for each food group are given in Table 5 for reference. The MLs proposed in this paper 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.

19. Where the CTC is lower than the draft ML, as with cereals and vegetables, the proposed final ML is reduced to the nearest lower value in the geometric scale included in Annex 1 of the GSC. For the other food commodities, the draft MLs are all lower than the relevant CTCs and can be accepted as they are unlikely to have an adverse impact on human health. The values are also similar to those in the geometric scale.

Table 6: Dietary exposures to lead from foods, using proposed MLs

Total dietary exposure (µg/person/day)													
Group A	**Group B**	**Group C**	**Group D**	**Group E**	**Group F**	**Group G**	**Group H**	**Group I**	**Group J**	**Group K**	**Group L**	**Group M**	**PTWI**
105.5	210.2	139.0	141.7	180.6	158.8	113.7	118.5	112.4	117.7	108.9	174.3	173.6	**214.3**

20. A further assessment of the total dietary exposure from foods assigned MLs can then be calculated. As the exposure for all dietary Groups from foods with the proposed MLs is now lower than the PTWI, they 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. 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.

21. 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 Annex I of CX/FAC 99/19 are small, although a separate category for roots and tubers 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 meat or milk and milk fat, no ML is proposed.

REFERENCES

- Draft Maximum Levels for Lead (CX/FAC 99/19).
- 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.
- Dr G Moy (personal communication).
- Progress Report by WHO on the Revision of GEMS/Food Regional Diets (CX/PR 99/3)

Table 7: Proposed MLs for lead in food

CODE NO.		FOOD	PROPOSED ML (MG/KG)	CODEX ML AT STEP 5 (MG/KG)
FC 1 **FS 12** **FT 26**	**FP 9** **FB 18** **FI 30**	**Fruit**	**0.2**	**0.1**
VA 35 **VC 45**	**VO 50** **VR 75**	**Vegetables, except brassica (VB), leafy vegetables (VL) and mushrooms**	**0.2**	**0.1**
VR589		**Roots and tubers**	**0.1**	**0.1 (as Vegetables)**
VL 53	**VB 40**	**Brassica and leafy vegetables (except spinach)**	**0.2**	**0.3**
C 81 **VD70** **VP60**		**Cereal products, except bran** **Pulses** **Legume vegetables**	**0.2**	**0.2**
WF 115 **WS 125**	**VD 120**	**Fish**	**0.5**	**0.2**
FF 269		**Wine**	**0.2**	**0.2**
LM (unspecified)		**Infant formula** [a]	**0.02**	**0.02**[b]

Notes

a Not yet assessed by this methodology in absence of relevant data.

b Value applies to the product ready for use, provided that appropriate methods of analysis are developed.