codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
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The Hague, The Netherlands, 22-26 March 1999

DRAFT MAXIMUM LEVELS FOR LEAD
(Prepared by Denmark)

REQUEST FOR COMMENTS AND INFORMATION

Governments and interested international organizations wishing to submit comments on the following Position Paper on Lead are invited to do so **no later than 31 January 1999** as follows: Ms. S.P.J. Hagenstein, Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 EK The Hague, The Netherlands (Telefax: +31 70 378.6141; E-mail: s.p.j.hagenstein@mkg.agro.nl), with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

INTRODUCTION

1. The "Draft Standard for Lead in Food" (CX/FAC 96/23) was presented to the 28th Codex Committee on Food Additives and Contaminants (CCFAC) in 1996 by the Danish delegation. This standard was based upon a "Discussion Paper on Lead" (CX/FAC 95/18) by Sweden and Denmark and on comments received in writing and discussion in CCFAC over several years. Once adopted, the standard will become a part of the General Standard on Contaminants and Toxins in Foods.

2. The 28th and 29th CCFAC agreed to a few variations of the levels proposed in the draft standard for lead in various food groups, and the revised version of the document was adopted at step 5 by the 22nd session of the Codex Alimentarius Commission (CAC) 1997. The variations agreed mainly reflect progress in the use of source-directed measures having led to a decrease in contamination of food by lead, as well as improved methods of analysis and in particular quality assurance of analytical results, also producing with certainty lower contents of lead in e.g. meat and fish (Jorhem et al. 1996, Engman and Jorhem 1998). Moreover, the CCFAC agreed in 1997 that proposals for change of the draft standard should be accompanied by appropriate scientific argumentation.

3. The 30th Session of the CCFAC 1998 discussed the proposed draft maximum levels for lead as they were adopted at step 5 by the 22nd CAC 1997 (ALINORM 97/12A Appendix X) and comments

submitted in response to CL 1997/15-FAC, and the Committee agreed that Denmark would review the draft maximum levels in light of the discussion and also include a risk assessment for children.

4. Hence this review presents the revised Draft Standard for Lead (Annex 1) accompanied by a similarly revised table (Annex 2), showing the typical exposure and theoretical maximum daily intake of lead, calculated taking into account the revised ML's. It should be noted that the proposal aims at including all groups of foodstuffs that contribute significantly to the intake of lead. It covers more than 80% of the diet for any group of the population and certainly more than 80% of the intake of lead. The maximum limits are then proposed so that - according to recent and reliable surveys - all foods that are not particularly contaminated by lead will fall within the limits proposed. Comments are given on the foods for which the proposed maximum levels (ML's) have been changed since the adoption at step 5 of the draft standard, and the requested discussion of the exposure of children is presented.

LEAD IN SOME IMPORTANT FOODSTUFFS

5. This section covers comments and changes made to some of the limits proposed in the Draft Standard for Lead in Foods and reiterates some of the reasoning behind the values, in particular for those foodstuffs where changes have been proposed since the Commission endorsed the Standard in 1997. For more details the Discussion Paper on Lead (CX/FAX 95/18) and the Draft Standard for Lead in Food (CX/FAC 96/23) and references therein could be consulted.

6. For fruit a ML of 0.1 mg/kg is proposed and recent surveys with appropriate quality assurance show that there are no difficulties in respecting this ML. In the 30th CCFAC, a special ML for small fruit and berries (with edible peel) of 0.3 mg/kg was proposed, and this ML is included in Annex 1. As no supporting evidence was presented, this ML is noted in square brackets.

7. For meat of cattle, sheep and pork the ML has been reduced from 0.1 to 0.05 mg/kg following the 30th CCFAC. This is based, in particular, upon the evidence presented in a review of trace elements in beef and pork by Jorhem (Jorhem *et al.* 1996), showing that in meat imported from a large number of countries to Sweden the content of lead was below the detection limit of 0.007 mg/kg fresh weight. These results are well in accordance with other surveys of lead in meat and meat products, indicating that the radically lower results found for metals in meat over the last ten years than previously are due mainly to improvements in analytical methodology and especially in quality assurance, but also to some degree to the awareness of lead as a health problem which initiated the source-related efforts to reduce lead in foods. In consequence, the ML for fat from meat and poultry has been reduced similarly.

8. For similar reasons it was agreed in the 30th CCFAC to reduce the ML for fish from 0.5 to 0.2 mg/kg, with the understanding that the limit applies to fish muscle. A recent review (Engman and Jorhem, 1999) with many references has highlighted that for the analysis of fish, too, lacking quality control procedures have in the past led to publication of results that probably were much too high. In general, the better the quality assurance the lower are the results found for trace metals in fish. Levels of lead well below 0.1 mg/kg were found in all samples of fish from uncontaminated waters in several studies using modern quality control.

9. For fruit juices the 30th CCFAC proposed to reduce the ML from 0.1 to 0.05 mg/kg. Considering that fruit normally contain much less than 0.05 mg/kg lead, and that this lead is mainly found in and on the peel, due to environmental contamination, there should not be problems connected with a ML of 0.05 mg/kg, provided production technology is used that does not contaminate the juice. Moreover, fruit juice may be consumed in rather large quantities, and often by children.

10. For infant formulae, the 30th CCFAC agreed to add to the Draft Standard a remark to the

effect that the ML proposed applies to the product "ready for use".

CHILDREN AND LEAD

11. Children are more susceptible to the adverse effects of lead, both because they eat more food relative to their body mass than adults, they absorb lead more readily than adults and their major organs, including the brain, are under development (Carrington and Bolger, 1992; Carrington *et al.* 1996). Hence infants and small children are more sensitive to exposure to lead from the diet and other sources than adults.

12. The hazard identification points to the most significant effect from lead being reduced cognitive development and intellectual performance in children, whereas the concern for adults is increased blood pressure and cardiovascular disease. JECFA states as hazard characterisation that on average the intelligence quotient is reduced by 1-3 points for each 10 μg/dl increment in the blood lead concentration (41st JECFA, 1993). Furthermore, studies have not indicated a threshold for effects. JECFA cites uncertainties in study results below 10-15 μg/dl lead in blood, but points out that there is some evidence of cognitive defects in the 7-8 μg/dl range. Levels of concern for lead in blood are 10 μg/dl for infants, young children and pregnant women, and 30 μg/dl for adults, according to the methods used by the FDA and other international health organisations (Carrington *et al*. 1996).

13. The quantitative evaluation of the hazard is expressed by the 25 μg/kg bodyweight Provisionally Tolerable Weekly Intake (PTWI, 41st JECFA 1993), which for a child of an age of two years and weighing 10 kg, is equivalent to a total daily intake of 36 μg lead. The PTWI has also been found to correspond to a 6 μg lead/dl blood level, which is very close to the levels associated with observed adverse effects. This means that there is reason to look particularly into the diet of infants and young children in order to discuss whether the ML's proposed will provide adequate protection.

14. Children may be exposed to lead both from food, from drinking water and air, as well as from non-food sources such as lead-based paints, soil and dust. Only food falls within the CCFAC terms of reference. The exposure assessment for small children presented here, including food only as a source of lead, is based upon a study that the Danish Veterinary and Food Administration recently has conducted for children of one, two and three years of age (Groth, Larsen and Fagt, 1999). The basis includes a comprehensive study of children's diets and data from the National Monitoring System which for many years has provided comprehensive information on the content of contaminants in foods sold in Denmark. Some of the results of this study are in Annexes 3 and 4. Whereas the data show that the daily intake of lead from food for the small children in average (7.3, 8.9 and 9.2 μg/day, respectively) as well as the intake of lead from food for the most exposed children (15.4, 15.6 and 16.9 μg/day) both are below the levels of concern, the safety margin up to the PTWI, if any, is small. The situation may well be less problematic in Denmark than in some other countries, due to the implementation of source-related measures, such as use of non-leaded petrol and that lead-soldered cans have been phased out some years ago. There is reason to endeavour to reduce as far as possible the exposure of children, in particular, to lead (Bolger *et al.* 1996).

15. For small children, like for adults, there are several almost equally important lead sources contributing to the daily intake (Annex 4). The most important ones are fruit and fruit juices, vegetables, cereals and cereal products and beverages, according to the Danish study (Larsen et al., 1999). Because of the large consumption, milk and milk products as well as beverages, including fruit juices become important sources of lead in children's diet, even if the content of lead in these foods is very small.

REFERENCES

General

Draft Standard for Lead in Food (CX/FAC 96/23) and references therein.

Discussion Paper on Lead (CX/FAC 95/18)

Draft Maximum Levels for Lead (ALINORM 97/12A Appendix X)

Comments submitted in response to CL 1997/15 FAC from Poland, Slovakia, ISDI, France and USA.

General Standard on Contaminants and Toxins in Food.

Draft Code of Practice on Source Related Measures to Reduce Contamination of Foodstuffs (CX/FAC 96/20 and CX/FAC 98/20)

Draft Methodology and Principles for Exposure Assessment in the Codex General Standard for Contaminants and Toxins in Food (CX/FAC 98/13)

Evaluation of Certain Food Additives and Contaminants. 41st report of the JECFA, WHO Technical Report Series 837. Geneva 1993.

Council of Europe: "Lead in Food" (1994). Council of Europe Press, Strasbourg. Also available in French.

Direction Générale de la Santé (France):"La Diagonale des Métaux", 1994.

MAFF Food Surveillance Paper No. 27 “Lead in Food. Progress Report”, 1989, London.

National Veterinary and Food Administration, Denmark "Food Monitoring in Denmark, 1983 - 1987, 1988 - 1992 and 1993 - 1997". National Veterinary and Food Administration, Copenhagen 1990, 1995 and 1999.

Joint UNEP/FAO/WHO Food Contamination Monitoring and Assessment Programme (GEMS/FOOD) "Assessment of Dietary Intake of Chemical Contaminants, Nairobi 1992.

Specific

1. Jorhem, L., Sundström, B, Engman, J, Åstrand-Yates, C. and Olsson, I. (1996) “Levels of certain trace elements in beef and pork imported to Sweden” Food Additives and Contaminants, **13** No. 7, 737-745.
2. Engman, J. and Jorhem, L. (1998) “Toxic and essential elements in fish from Nordic waters, with the results seen from the perspective of quality assurance”. Food Additives and Contaminants, **14**, No 8, 884-892.
3. Carrington, C.D. and Bolger, P.M. (1992) “An assessment of the Hazards of Lead in Food”, Regulatory Toxicology and Pharmacology **16,** 265 - 277.
4. Carrington, C.D., Bolger, P.M. and Scheuplein, R.J. (1996) “Risk analysis of dietary lead exposure” Food Additives and Contaminants **13** No 1, 61-76.
5. Groth, M., Larsen, E.H. and Fagt, S. To be published.

6. Bolger, P.M., Yess, N.J., Gunderson, E.L., Troxell, T.C: and Carrington, C.D. (1996) “Identification and reduction of sources of dietary lead in the United States”, Food Additives and Contaminants **13** No 1, 53-60.

Annex 1

Proposed draft maximum levels for lead
(At Step 5)

Code No.	Food	ML (mg/kg)	Step	Remarks
FC1 FP9 FS12 FB18 FT26 FI30	Fruit [Small fruit and berries]	0.1 [0.3]	5 5	
VA35 VO50 VC45 VR75	Vegetables Except brassica (VB), leafy vegetables (VL), and mushrooms	0.1	5	
VB40 VL53	Brassica Except kale (480) Leafy vegetables (except spinach)	0.3	5	
C81 VD70 VP60	Cereal products except bran Pulses Legume vegetables	0.2	5	
MM97 PM100	Meat of cattle, sheep and pig Poultry meat	0.05	5	
MF97 PF111 FM183 OC172 OR172	Fat from meat Fat from poultry Milk fat Vegetable oils	0.1	5	
MO97	Edible offal of cattle, pig and poultry	0.5	5	
ML107	Milk[1]	0.02[2]	5	Also secondary (82) milk products (as consumed)
WF115, VD120 WS125	Fish	0.2	5	Fish muscle
WC143	Crustaceans	1.0	5	
IM151	Bivalve Molluscs	2.0	5	
JF175	Fruit juices	0.05	5	Also nectars
FF269	Wine	0.20	5	
LM (unspecified)	Infant formulae	0.02[3]	5	Ready to use

[1] For dairy products an appropriate concentration factor applies, e.g. for cheese a factor of 10 as approximately 10 kg milk is used for 1 kg cheese.

[2] Provided appropriate methods of analysis are developed.

[3] Provided appropriate methods of analysis are developed.

Annex 2

Data used to Calculate Typical Exposure and Theoretical Maximum Daily Intake (TMDI) for Lead

Food	ML mg/kg	Daily intake range (g)	Lead range mg/kg	Typical exposure µg/day	TMDI µg/day
Fruit	0.1	100-500 (200)	0.01-0.1 (0.02)	4	20
Vegetables -except brassica, leafy vegetables, potatoes	0.1	50-500 (200)	0.01-0.05 (0.02)	4	20
Brassica - except kale Leafy vegetables	0.3	10-100 (50)	0.05-0.5 (0.1)	5	15
Cereals Pulses Legume vegetables	0.1	50-500 (200)	0.02-0.1 (0.03)	6	20
Meat of cattle, poultry, pig and sheep	0.05	50-500 (150)	0-0.05 (0.02)	3	7.5
Fat from meat and poultry Vegetable oils	0.05	10-100 (50)	0-0.03 (0.01)	0.5	2.5
Edible offal of cattle, pig and poultry	0.5	0-10 (5)	0.1-0.5 (0.2)	1	2.5
Milk	0.02	200-500 (400)	0-0.01 (0.001)	0.4	8
Fish	0.2	10-50 (30)	0.03-0.5 (0.1)	3	6
Crustaceans	1	0-5 (2)	0.05-3 (0.5)	1	2
Bivalve molluscs	2	0-5 (2)	0.05-3 (0.5)	1	4
Fruit juices	0.05	50-500 (100)	0-0.02 (0.01)	1	5
Wine	0.5	0-500 (100)	0.05-0.1 (0.1)	10	20
Instant formulae	0.02	-	-	-	-
Total				48	146

Annex 3

Daily intake of lead for children (in μg)

Age	Average	90 percentile	Maximum
1	7.3	10.0	15.4
2	8.9	12.3	15.6
3	9.2	11.8	16.9

Annex 4

Intake of lead from various foods (in μg)

Food/Age	1 year	2 years	3 years
Milk and milk products	0.5	0.5	0.5
Bread, cereals	1.3	1.6	1.8
Vegetables	1.1	1.3	1.5
Fruit	1.5	1.6	1.6
Meat and poultry	0.6	0.9	0.9
Fish	0.5	0.7	0.6
Eggs	0.1	0.2	0.2
Sugar	0.3	0.4	0.5
Fats	0.5	0.6	0.6
Beverages	0.9	1.0	1.0