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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DRAFT AND PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM

COMMENTS AT STEP 6 AND AT STEP 3

(IN RESPONSE TO CL 2004/9-FAC AND CL 2004/27-FAC)

The following comments have been received from Australia, Canada, European Community, Japan, and South Africa

AUSTRALIA

PROPOSED CODEX MAXIMUM LEVELS FOR CADMIUM

The 35th Session of the CCFAC decided to return the proposed draft maximum levels for cadmium in rice, polished; soybean (dry); molluscs (including cephalopods); and, peanuts to Step 3 and to forward the remaining proposed draft maximum levels to the 26th Session of the Codex Alimentarius Commission for adoption at Step 5. The 26th Session of the Codex Alimentarius Commission decided to return the proposed draft maximum levels to Step 3.

At the 36th Session, the Committee decided to discontinue the work on developing maximum levels for cadmium in fruits; meat of cattle, pigs, sheep, and poultry; horsemeat; herbs, fungi (edible); celeriac; soybeans (dry); and, peanuts as no levels were necessary because these foods were no major contributors to cadmium intake.

The Delegation of Japan proposed a maximum level of 0.4 mg/kg for cadmium in polished rice. The Delegation explained that the level of 0.2 mg/kg was not achievable in Japan as a result of the higher background levels of cadmium due to geological characteristics of the soil. The Delegation also explained that the probabilistic exposure assessment conducted by Japan using national data revealed that the level of 0.4 mg/kg would not cause any public health concern. This position was supported by several other delegations. The Delegation of the EC mentioned that the PTWI could be easily exceeded by consuming rice coNtaining cadmium at this maximum level especially for young children.

In view of the above discussion, the Committee decided to replace the current proposed draft maximum level of 0.2 mg/kg for polished rice by a proposed draft ML of 0.4 mg/kg. The Committee further decided to forward the proposed draft maximum levels for cadmium in rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables, to the Codex Alimentarius Commission for preliminary adoption at Step 5.

The Committee had an extensive discussion on the maximum levels for and the classification of molluscs. Several delegations expressed concern that the proposed level of 1.0 mg/kg was not reasonably achievable for oysters, scallops, and cephalopods when included the viscera due to the natural occurrence of the cadmium contamination at higher levels than 1.0 mg/kg. The Committee considered a proposal to divide the category IM 0150 Molluscs (including cephalopods) in three sub-categories IM 0151 Marine bivalve molluscs, IM 1005 Scallops without digestive caecum, and IM 0152 Cephalopods with maximum levels of 1.0, 1.0, and 2.0 mg/kg respectively. The Committee also noted a proposal to break out oysters at a proposed ML of 3.0 mg/kg or to remove oysters from the proposed maximum levels.

The Committee could not agree on the maximum levels and classification of the category IM 0150 Molluscs (including cephalopods) and decided to leave it unchanged while JECFA undertook its exposure assessment in 2005.

The Committee agreed to request JECFA to conduct risk assessments for rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; other vegetables; and molluscs, taking into account three different levels, i.e., the proposed draft maximum levels, one level lower and one level higher than the proposed draft maximum levels, with distribution curves for the cadmium contamination in these foods. JECFA agreed to evaluate exposure for additional levels in the sub-categories of molluscs and to inform the Committee on the basis of the data submitted. The Committee noted that JECFA would carry out the exposure assessment in February 2005 and encouraged Codex Members to submit their raw national occurrence and consumption data to WHO GEMS/Food.

Status of the proposed draft Maximum Levels for Cadmium

The 36th Session of the CCFAC forwarded the proposed draft maximum levels for cadmium in rice polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables to the Codex Alimentarius for preliminary adoption at Step 5 while returning the proposed draft maximum level for molluscs (including cephalopods) to Step 3 for circulation, comments, and consideration at its next Session.

The 27th Session of the Codex Alimentarius Commission (July 2004) adopted at Step 5 several proposed draft texts forwarded by the 36th CCFAC, including Draft Maximum Levels for cadmium in wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables.

Australian Position

Australia supports the elaboration of MLs for cadmium in those foods that contribute significantly to dietary exposure on a global basis. The MLs in these foods should be based on the principles established by Codex for setting maximum levels for contaminants.

Australia agreed with the decision of the Committee to forward the proposed draft maximum levels for cadmium in rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; and, other vegetables, to the Codex Alimentarius Commission for preliminary adoption at Step 5.

Australia agrees with the decision of the 36th CCFAC to replace the current proposed draft maximum level of 0.2 mg/kg for polished rice by a proposed draft ML of 0.4 mg/kg. Australia can support the proposed draft ML of 0.4 mg/kg for polished rice.

Australia believes that the significance of molluscs to total dietary intake of cadmium on a global basis is questionable. An assessment of the sources of dietary exposure to cadmium should be made and MLs established only for those foods that are significant to the total exposure on a global basis. Therefore, Australia agrees with the decision of the Committee to request JECFA to conduct risk assessments for rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; other vegetables; and molluscs, taking into account three different levels, i.e., the proposed draft maximum levels, one level lower and one level higher than the proposed draft maximum levels, with distribution curves for the cadmium contamination in these foods. Australia agrees that JECFA evaluate exposure for additional levels in the sub-categories of molluscs and to inform the Committee on the basis of the data submitted.

Australia believes that if MLs for molluscs are to be set, as defined by the principles quoted below, then a ML of 2.0 mg/kg is reasonably achievable for all molluscs (including marine bivalve molluscs, scallops and cephalopods).

Australia also considers it essential that the product to which the proposed MLs apply is clearly defined. The product definition needs to be included in the draft standard to ensure that there is no misunderstanding about the application of the proposed MLs

BACKGROUND

Cadmium in the Australian Environment

Cadmium is a widespread naturally-occurring element present in all soils, rocks and waters. Background concentrations of cadmium in soils and natural waters are derived from the parent rock geology. Due to the highly weathered nature of the Australian continent, cadmium concentrations in both soils and waters are generally low by world standards. Cadmium is added to the environment through both natural (e.g. volcanic activity) and anthropogenic processes (e.g. fossil fuel combustion, soil amendments, effluent waters, etc.). In Australia, low levels of urban and industrial activity have minimised the magnitude of cadmium pollution through atmospheric sources, or through disposal or re-use of sewage and industrial waste-waters and solids.

Widespread, but low level, cadmium contamination of agricultural soil has occurred, due to the presence of cadmium as an impurity in phosphatic fertilisers. However, cadmium concentrations in soils are still significantly lower than those reported for many other countries (e.g. USA, Europe), due to the prevalence of relatively low input agricultural systems in Australia. Current and predicted rates of cadmium addition to soil continue to be low by world standards.

Uptake of cadmium by plants can be influenced by a number of factors including soil type, soil pH and the level of certain other elements and micronutrients (particularly zinc). Often, these are more important than the soil cadmium concentration in controlling cadmium accumulation by crops. Thus, Australia's National Cadmium Minimisation Strategy has included changes in farmer management practices as a key component of cadmium minimisation, rather than focussing only on minimising cadmium inputs.

In surveys of agricultural crops known to accumulate cadmium (e.g. potatoes, wheat, etc) cadmium concentrations in Australia have been found to be similar or lower than those reported in other countries. Higher cadmium concentrations in crops are usually associated with cultivation in sandy, acidic, saline or zinc-deficient soils, rather than the cadmium concentrations in the soil per se.

Cadmium levels in open oceans reflect background levels in the natural environment. Higher values may occur in inshore and estuarine waters and sediments due to contamination from human activity on land. Compared to the northern hemisphere, the low intensity of industrialisation and low population densities in Australia result in relatively low levels of cadmium emissions to estuarine and marine environments. Local pollution occurs in some areas, but in general the marine environment is not significantly contaminated by cadmium as a result of human activity. Where high levels of cadmium in marine biota occur, these are not widely or consistently related to human or industrial activity. Marine biota in some environments regarded as pristine (remote from any industrial or human activity) exhibit high cadmium concentrations, suggesting geogenic sources.

MOLLUSCS

Extensive Australian data on levels of cadmium in molluscs reflect the occurrence of natural levels of cadmium in aquatic animals living in unpolluted oceans. Molluscs contain naturally high levels of cadmium, which is concentrated in the viscera of molluscs. (The level of cadmium is also highly species-specific).

Australia previously submitted data on cadmium levels in molluscs. The samples from which the Australian data were obtained are from unprocessed product representing the commercial catch from the major fishing areas of Australia. It comprises a wide range of species representing taxonomic and ecological groupings as well as different feeding habits, and also represents a range of sizes and where possible, both genders, within species. The levels of cadmium in Australian molluscs represent naturally-occurring background levels in the ocean, and would not be expected to differ significantly from the levels in wild-caught molluscs elsewhere in the world. The distribution of molluscs in Australian waters cover a wide range of bio-geographic regions with various geologic substrates, flora and fauna as well as physical and chemical factors. These variables contribute to the large range of average levels found in populations of molluscs, in which some isolated regions can be significantly higher than others, due to the nature of substrate rocks.

GENERAL PRINCIPLES FOR SETTING MAXIMUM LEVELS FOR CONTAMINANTS

To meet its objectives of protecting the health of consumers and promoting fair practices in food trade, it is important that Codex ensures the standards set for contaminants are based on scientific risk analysis. Principles to be met in elaborating MLs for contaminants are set out in the preamble to the General Standard for Contaminants and Toxins. These state that MLs shall be set:

Only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade;

Only for those foods that are significant for the total exposure of the consumer to the contaminant;

As low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade.

CANADA

With regard to the document Proposed Draft Maximum Level for Cadmium in polished rice (ALINORM 04/27/12, Appendix XXIII) returned to Step 3 for further consideration by CCFAC, we have no objection to the Maximum Level proposed for polished rice. In particular, we have undertaken an exposure assessment for children, aged 6 - 11 years, using Canadian rice consumption data for this age group and have determined that they would not be at risk from exposure to rice containing a level of cadmium up to this proposed maximum level.

EUROPEAN COMMUNITY

Proposed Draft Maximum Levels for Cadmium - response To Alinorm 04/27/12, Appendix XXIII

The European Community has examined the proposed maximum levels for cadmium as given in Appendix XXIII of ALINORM 04/27/12 to reflect the discussions of the 36th CCFAC.

The European Community supports the proposed draft maximum levels for cadmium in the listed foods, with the following comments.

1. General comments reiterated from 36th CCFAC

The EU Member States have recently collated data on the occurrence of cadmium in different foods and intake estimates have been made. Cereals and vegetables were identified to contribute two thirds of the mean dietary cadmium intake. Levels in these products in particular should be kept low. Mean levels of dietary intake were reported for average adult consumers to be up to 38% of the Provisional Tolerable Weekly Intake (PTWI = 7 µg/kg.bw). Higher intakes were reported for young children, up to 65% of the PTWI. Therefore, it is important for the protection of children and high level consumers to set maximum levels which are as low as reasonably achievable (ALARA) to help ensure that the PTWI is not exceeded.

Moreover, the summary report from the 61st meeting of the JECFA held in June 2003 concluded on cadmium that some high level consumers may exceed the PTWI. Main dietary sources highlighted in the report were rice, wheat, starchy roots/ tubers, molluscs and non-leafy vegetables. These conclusions support the need to set maximum levels which are ALARA.

2. Molluscs

Regarding the proposed maximum level of 1.0 mg/kg for molluscs, we reiterate comments previously expressed to CCFAC. Molluscs should be separated into two listings, for bivalve molluscs and for cephalopods (cuttlefish, octopus, squid). The maximum level of 1.0 mg/kg should apply to each listing, but for cephalopods it should be stated that the level applies to the product excluding the viscera.

Bivalve molluscs	1 mg/kg
Cephalopods (excluding viscera)	1 mg/kg

At the 36th CCFAC uncertainty was indicated regarding the achievability of 1 mg/kg for cadmium in scallops. Certain parts of scallops which are not normally eaten can contain higher levels of cadmium. However, the maximum level of 1 mg/kg would apply only to the edible parts (the adductor muscle and gonad).

The following example of data from November 2003 on cadmium in scallops was collected by the UK from uncontaminated waters off the coast of Scotland. The data show the patterns of cadmium levels in the whole shellfish compared with the levels in the edible adductor muscle and gonad:

Whole (mg/kg)	Muscle (mg/kg)	Gonad (mg/kg)
3.539	0.199	0.373
3.652	0.209	0.318
3.121	0.124	0.082
3.560	0.153	0.160
3.888	0.089	0.128
6.748	0.127	0.169
4.726	0.231	0.213
3.451	0.147	0.104
4.487	0.116	0.180
3.086	0.142	0.118
6.571	0.256	0.258
3.953	0.208	0.201
11.561	0.207	0.290
5.240	0.238	0.389
4.137	0.159	0.171
4.781	**0.174**	**0.210**

3. Rice

The European Community supports a maximum level of 0.2 mg/kg cadmium in rice. However, further to discussions at the 36th CCFAC it is noted that in some geographical regions levels might exceed this value. It is also possible that high levels might reflect particular varieties of rice.

If levels of cadmium in rice were to be regularly above 0.2 mg/kg this would contribute considerably towards dietary exposure. People who eat a lot of rice from regions containing the higher levels of cadmium could be significantly exposed. Moreover, rice and rice-based products are frequently eaten by young children which may be more at risk due to their proportionately higher intake levels per kg body weight.

For example, for cadmium the PTWI is 7 µg/kg body weight, which is 420 µg/ week for an average 60 kg adult and 105 µg/ week for a 15 kg child. If rice contains 0.4 mg/kg cadmium, 100 g rice alone would contribute 10% of the PTWI for the adult and 40% of the PTWI for the child.

The proposal at 36th CCFAC to increase the draft maximum level from 0.2 mg/kg to 0.4 mg/kg for cadmium in rice cannot be supported in view of the significant contribution towards the PTWI and the risk to consumers.

JAPAN

Background

The 27th Codex Alimentarius Commission adopted the Proposed Draft Maximum Levels for cadmium at Step 5 and advanced them to Step 6 as proposed, with the exception of the proposed draft maximum level for cadmium in polished rice, which was returned to Step 3 for further consideration by the Codex Committee on Food Additives and Contaminants (CCFAC), due to the concern that the maximum level proposed could result in intakes exceeding the PTWI in certain populations. In noting that cadmium was scheduled for evaluation by Joint FAO/WHO Expert Committee on Food Additives (JECFA) in February 2005, the Commission requested CCFAC to take careful account of the results of this evaluation (ALINORM 04/27/41, para.68).

General Comments

It is important that decision on MLs shall be based on scientific risk assessment including exposure assessment.

We have recalculated dietary intakes of cadmium to reflect the decision of the 36th CCFAC on the proposed draft MLs (Appendix XXIII of ALINORM 04/27/12). The resulting estimates include Cd intakes from those foods for which MLs are proposed as well as those for which no MLs are considered, such as fruits, meats and soybean. The 95th percentile dietary intake of cadmium calculated using probabilistic approach is below the PTWI of 7 g/kg-bw/wk. We believe that the draft and proposed draft MLs can ensure the protection of the health of consumers (see Annex). For the reason above, we support the draft MLs in wheat grain, potato, stem and root vegetables, leafy vegetables and other vegetables, and proposed draft ML in polished rice and molluscs.

Rice

The GSCTF states that MLs shall be set as low as reasonably achievable (the ALARA principle) and that providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade (the third indent of the *Establishment of maximum levels for contaminants* in Annex I). The government of Japan has taken risk management measures for reducing cadmium-contamination of rice, such as removing the soils identified as polluted, or developing and encouraging the use of such agricultural practices as to decrease cadmium uptake by rice plants. Despite these efforts, the level of 0.2 mg/kg is not yet achievable as a result of the higher background levels of cadmium due to the geological characteristics of the soil. The probabilistic exposure assessment mentioned above indicated that the maximum level of 0.4 mg/kg for rice would not cause public health concern. Therefore, setting the maximum level at 0.4 mg/kg is in accordance with the GSCTF.

Molluscs

We have already submitted comments to the CCFAC regarding the amendment of a food group

Executive Summary of "Research on Estimation of Cadmium Exposure Level in Japanese Residents"

1. Method

Estimating the current dietary intakes of cadmium were used probabilistic approach on the data available in Japan on food consumption and occurrence of cadmium in agricultural and fishery commodities. Dietary intakes were estimated on a basis of the draft and proposed draft MLs. The process is below;

1) A pooled data of National Nutrition Survey conducted in Japan for 6 years from 1995 through 2000 and the data of cadmium surveillance were used as the food consumption data and cadmium concentration data.

2) Lognormal distribution was presumed as the theoretical distribution of food consumption level and Cd concentration.

3) Cd intake estimates were calculated using Monte Carlo simulation by multiplying randomly picked food consumption level (from distribution) and cadmium concentration for each item and summing up calculated intake estimates for all items. In calculating, cadmium concentration exceeding the draft or proposed draft MLs of each item were excluded.

4) The process was repeated 100 000 times.

2. Result

The average of Cd intake calculated at 3.3 g/kg-bw/wk was less than a half of the current PTWI of 7 g/kg-bw/wk. The 95th percentile of Cd intake calculated at 6.85 g/kg-bw/wk did not exceed the current PTWI (see attached table bellow).

Estimated Dietary Intake of Cadmium

Unit: µg/kg-bw/wk

	Cd intake
Arithmetic Mean	3.33
50th percentile	2.86
90th percentile	5.54
95th percentile	6.85

3. Remarks

This report has been submitted for 64th JECFA in September 2004.

Comments of the Government of Japan on the Proposed Draft Maximum Levels for Cadmium in Molluscs (including Cephalopods) at Step 3

Background

1. The 61st Joint FAO/WHO Expert Committee on Food Additives (JECFA) estimated dietary intake of cadmium from various foodstuffs and concluded that the following foods contributed 10% or more to the PTWI in at least one of the GEMS/Food regions are; rice, wheat, starchy roots/tubers, and molluscs (JECFA/61/SC).

2. The 36th Codex Committee on Food Additives and Contaminants (CCFAC) had an extensive discussion on the maximum levels for and the classification of the category IM 0150 Molluscs, but could not agree on them (ALINORM 04/27/12, para. 179). The Committee decided to leave it unchanged while JECFA undertook its exposure assessment in 2005 and returned the proposed draft maximum level for molluscs (including cephalopods) to Step 3 for circulation, comments, and consideration at its next Session (ALINORM 04/27/12, para. 182).

3. The Committee agreed to request JECFA to conduct risk assessments for rice, polished; wheat grain; potato; stem and root vegetables; leafy vegetables; other vegetables; and molluscs, taking into account three different levels, i.e., the proposed draft maximum levels, one level lower and one level higher than the proposed draft maximum levels, with distribution curves for the cadmium contamination in these foods. JECFA agreed to evaluate exposure for additional levels in the sub-categories of molluscs and to inform the Committee on the basis of the data submitted (ALINORM 04/27/12, para. 181).

Comments

4. We are of the opinion that CCFAC shall base draft maximum levels on the risk assessment by JECFA as stipulated in Section 1.4.3 of the preamble of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF). Since cadmium is scheduled for the evaluation by 64th JECFA in February 2005, it is important that the 37th CCFAC should take careful account of the results of this evaluation.

5. We also reiterate comments submitted to the 36th CCFAC, regarding the amendment of a food group, as follows:

- The definition of the term “molluscs” in the Codex Classification of Foods and Animal Feeds is “molluscs, including cephalopods”. We propose that this category should be divided into three; marine bivalve molluscs, scallops and cephalopods as specific considerations need to be given for portions of scallops and cephalopods for which maximum levels should apply. Furthermore, we propose that appropriate remarks should be added to the MLs for these commodities.

As a result, the proposed draft ML for molluscs should be amended as follows:

Table: Proposals of Maximum Levels for Cadmium in Molluscs

(underline indicates amended texts)

Code NO.	Food	ML (mg/kg)	Remarks
IM 0151	Marine bivalve molluscs	1.0	Excluding scallops
IM 1005	Scallops	1.0	Without digestive caecum
IM 0152	Cephalopods	1.0	Without viscera

SOUTH AFRICA

Proposed draft Maximum Level for Cadmium in Molluscs (including Cephalopods) at Step 3

Background

At the 36th Session, a level of 0.1 mg/kg for **cadmium in molluscs** was returned to **Step 3** for comments and further discussions at the next CCFAC meeting, due to lack of consensus on establishing levels of:

1.0 mg/kg for Marine bivalves

1.0 mg/kg for Scallops, and

2.0 mg/kg for Cephalopods with a proposal of 3.0 mg/kg for Oysters or no level.

Comments

South Africa does not understand the necessity for breaking down these species and setting different levels and the reasoning for possibly exempting **Oysters**. We believe that if a limit of 3 mg/kg for Oysters is considered safe, then the same should apply to the other categories.

Marine bivalves and **Scallops**, naturally, have cadmium levels exceeding 1.0 mg/kg and therefore, in our situation, the proposed levels would be difficult to achieve. We have not experienced any problems with cadmium levels in **Cephalopods** and would easily comply with the proposed limit. Furthermore, we would like to point out that **Molluscs** are considered niche products and are not widely consumed in South Africa, and therefore do not contribute significantly to dietary cadmium exposure.

South Africa therefore supports a more achievable level of 3.0 mg/kg, which we consider to be safe and that should apply in all the requested categories.