

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 14 C

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-fifth Session

Arusha, United Republic of Tanzania, 17 - 21 March 2003

### PROPOSED DRAFT PRINCIPLES FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS

The following comments have been received from Japan, Australia, Thailand, United Kingdom, Denmark:

#### JAPAN:

##### ANNEX 1

##### 1. Title

We propose to change the title to read, “CCFAC Policies for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups”.

Rationale: The text is being developed to ensure transparency in the procedures of exposure assessment. As (1) this text does not cover all procedures involved in exposure assessment, and (2) CCFAC does not perform exposure assessment, we believe it more appropriate to use the term “policies” than “principles”. In addition, the term “policies” is used in the body of the text, namely, in para. 1.

##### 2. Para. 1, 3rd line

We proposed to reword the third line to read, “policies elaborated by CCFAC in consultation with JECFA with the aim of increasing ...”

Rationale: These policies are being elaborated by the CCFAC in relation to exposure assessment performed by JECFA. As in the case of “risk assessment policy” in general, they shall be developed taking into consideration advice of JECFA.

##### 3. Para. 1, 2nd indent

To clarify the sentence, we recommend that cross reference be added to this indent.

##### 4. Component 4

In order to clarify the sentence and to reflect actual situations we propose to modify the component to read, “If requested by CCFAC, JECFA will assess the **potential** impact of **different** agricultural and production practices on **exposure to that contaminant or toxin in food**.”

5. Para. 3, title

We propose to change the title to read, “Criteria for selecting food or food groups **for which maximum level(s) should be set for a contaminant or toxin**”.

6. Para. 3, text

We further propose to change the term “total dietary exposure” in paragraph 3 to “PTDI”.

Rationale: The objective of setting ML(s) for a contaminant or a toxin is to protect the health of consumers by ensuring that the estimated intake does not exceed the PTDI or other toxicological endpoint. The selection of food or food groups which contribute significantly in the dietary intake shall therefore be determined by the dietary intake of each food or food group in comparison with the PTDI or other relevant toxicological endpoint rather than the total dietary exposure. If the estimated intake of a contaminant in a certain food exceeds 10% of the total dietary exposure but the total dietary exposure is far below the PTDI or other relevant toxicological endpoint, this implies that there is only low risk arising from eating the food of concern and other foods, i.e., we can conclude that there is no need to establish MLs for that contaminant.

We believe that there is a need to clarify who, CCFAC or JECFA, should take action specified in the text.

We recall that several sessions ago there was a report from WHO on the expansion of the five regional diets to 13 diets. We would appreciate information on the current situation of that proposal.

## ANNEX 2

In the table, the flow of actions is not clear enough and the flow chart does not provide sufficiently clear information on whose responsibility each action is. In addition there are some discrepancies between the table and the chart. We have tried to combine the table and chart to have only one scheme for easier reference.

## AUSTRALIA:

As discussed at the 34<sup>th</sup> Session Codex Committee on Food Additives and Contaminants, March 2002 the Committee agreed that the CCFAC Principles for Exposure Assessment of Contaminants and Toxins in Foods (Annexes I,II and III of CX/FAC 02/17 ) would be circulated for comment at Step 3 of the procedure. The Committee further agreed that the Principles would be revised by the drafting group (Alinorm 03/12 Footnote 5) for circulation, additional comment and further consideration at the next session.

In reference to the above documents Australia wishes to provide the following comments on the entire Proposed Draft principles, including Annexes I, II and III of CX/FAC 02/17.

### General

The 34<sup>th</sup> CCFAC agreed to circulate the Principles for Exposure Assessment of Contaminants and Toxins in Foods (Annexes I, II, and III of CX/FAC 02/17). In developing the first draft of the paper, CCFAC directed

that the Drafting Group elaborate on Annex 4 of the Report of the joint FAO/WHO Workshop on Methodology for Exposure Assessment of Contaminants and Toxins in Food (held on 7-8 June 2000; WHO/SDE/PHE/FOS/00.5), also taking into consideration the technical Annex on Distribution curves of Contaminants in Food Products (CX/FAC 00/15-Add 1).

Australia, as part of the Drafting Group, welcomes the opportunity to further refine the Proposed Draft Principles For Exposure Assessment Of Contaminants And Toxins In Foods. Whilst the current draft of the paper is an excellent beginning, Australia believes that in its current format it is confusing and repetitive as to the purpose and needs to be focussed on principles for exposure assessment, rather than referring to risk assessment policy, exposure assessment policy and dietary assessment policy in the same paper. A general comment is that the information is not expressed as principles, and the title of the draft paper may need to be changed and an alternate word such as “procedures” substituted for “principles”.

At the 34<sup>th</sup> session of CCFAC, the Committee decided that it was critical that JECFA formally discuss the Draft Principles. As a result, JECFA will be formally discussing the Proposed Draft Principles For Exposure Assessment Of Contaminants And Toxins In Foods at its meeting in June 2002. Australia supported this suggestion and we await the JECFA deliberations with interest.

### Specific Comments

#### CCFAC Policy For Risk Assessment Of Contaminants And Toxins In Foods

Paragraphs 1&2: The statements in these paragraphs do not constitute a policy for exposure assessment since only some aspects of dietary exposure assessment are covered. It should be noted that the Codex risk assessment policy (1995) states that exposure assessment should be through all routes, as in most cases an ADI or PTWI is supposed to cover all sources of exposure (though in practice the dietary assessment is the only one undertaken, other potential sites of exposure are taken into account in the risk characterisation step).

Paragraph 2: The third sentence should read “The estimate of the **percentage** contribution of specific foods or food groups to the total exposure from a contaminant in diet....”

Paragraph 3: The second sentence talks about “...draft standards or **draft codes of practice** for specific contaminants and toxins sent for consideration and adoption by CAC are currently not supported by exposure assessments that identify foods that contribute significantly to exposure.” It would not be expected that **Codes of Practice** be supported by a risk assessment/dietary exposure assessment, and reference to “draft codes of practice” should be removed from this section. Developing a standard or code of practice are different risk management options depending on results of the risk assessment.

Paragraph 6: The purpose of the paper should focus to “propose policy for **exposure assessment** as a part of the methodology used to perform risk assessment that serves to inform risk management recommendations made by CCFAC for contaminants and toxins in foods.” Where appropriate, the term “risk assessment” should be replaced by “exposure assessment” throughout this paragraph. The policy does not guide JECFA in how to perform a risk assessment, but rather sets out some criteria to facilitate exposure assessment, which is part of risk assessment. The criteria that support the policy decisions need to be referred to from the latter part of the document (e.g. “see below”).

Paragraph 7: The heading preceding this section is incorrect and should be changed to read “Developing A Draft CGSCTF Annex On CCFAC Policy For **Exposure Assessment**”.

Paragraph 8: The heading preceding this section is incorrect and needs to be changed to read “Basic components of **exposure assessment** performed by JECFA”.

The text mentions “the conduct of transparent, consistent, science-based exposure assessments...”. The text should be clarified as to whether the “exposure” assessment refers to total exposure or dietary exposure.

The proposed layout of the “basic components” is very confusing. Component 1 appears to cover the risk assessment process including the risk characterisation step. Other components (2-4) are some of the steps necessary for risk management (in conjunction with information requests from JECFA) to decide which food commodities for which to set a Maximum Level. JECFA has no capacity to undertake **component 4**. Indeed, at the 34<sup>th</sup> CCFAC, the JECFA Secretariat indicated this fact to the Committee.

Australia also believes that for dietary exposure assessments at an international level, rather than the five GEMS/Food Regional Diets, the thirteen clusters of FAO/WHO regional diets being developed by WHO should be used as soon as possible since these take into account different patterns of food consumption within continents and also differentiates geographical regions.

#### **Under Component 1: Estimation of the total dietary exposure to a contaminant or toxin from food by JECFA:**

Paragraph 9: The description of the estimation of the total dietary exposure to a contaminant or toxin from food by JECFA is simplistic and applies to a point estimate of dietary exposure only. JECFA have in the recent past also used probabilistic techniques for some contaminants (aflatoxin, dioxin).

The paragraph also mixes a dietary exposure estimate (food consumption x concentration levels) with risk characterisation, which is step 4 of the risk assessment process (comparison of estimate with reference health standard). Both these steps together constitute a dietary exposure assessment.

Paragraph 10: The first line states that the use of national total diet data may be used by JECFA “to provide more accurate estimates of total dietary exposure”. The line should read “total diet or duplicate diet exposure assessments”. It should be pointed out that these are not the only types of national data that may be used, as there are assessments based on individual dietary records.

It is not clear in the text to paragraph 10 which GEMS/Food database is being referred to. In Australia’s view, the database for contaminants refers to contaminant concentration data collated from different countries (may be a mixture of data sources e.g. total diet, routine monitoring etc.). If this refers to the regional diet prepared by the GEMS/Food program then this should be clarified – these are based on food balance sheet data and as such, express apparent food consumption per capita and cannot be used to estimate dietary exposure for sub-populations. JECFA would not normally base a risk assessment on single national studies though JECFA may refer to them. Generally, at an international level, it is not possible to do dietary assessments on sub-populations.

To our knowledge the WHO (GEMS/Food program) are attempting to build up databases of individual food consumption data from a limited number of countries that do these type of surveys, they tend to be from European developed countries, and the primary purpose of this database is to enable the Joint Meeting on Pesticide Residues (JMPR) to undertake acute dietary exposure assessments for pesticide residues for children < 6 years old and the remainder of the population.

Australia reiterates that for dietary exposure assessments, rather than the five GEMS/Food Regional Diets, the thirteen clusters of FAO/WHO regional diets should be used.

#### **Under Component 2: Identify foods or food groups that contribute significantly to exposure to that contaminant or toxin:**

Paragraph 12: The paragraph should firstly state the primary reason(s) why you would want to identify these foods – presumably in order to set MLs. In Australia, and the UK, these criteria have been used as a means of selecting commodity groups for which to set MLs. However, in Australia, we have set MLs for other commodities that did not contribute 5% to total exposure but had unusually high contaminant concentrations (e.g. cadmium in offal).

Australia questions whether criteria © is possible and whether it should be included at all since it is our view that dietary exposure assessments for sub-populations cannot be done in practice. If included at all, these

criteria might only be used to indicate potential areas of concern, for which individual country comments should be called for and assessed.

**Under Component 3: Generate distribution curves for concentrations of the contaminant in specific foods or food groups if CCFAC requests such information:**

Paragraph 14: This paragraph states “Distribution curves for specific foods, may be requested by CCFAC and generated by JECFA, as additional information for consideration of risk management options”. The reason for the need for distribution curves needs to be stated clearly in this paragraph. Australia believes that the reason for distribution curves was that they would be used to decide where the top cut-off point would be set for a ML (rather than used as a set percentage violation type approach to decide on a reasonable cut-off). If a probabilistic dietary exposure assessment had been undertaken by JECFA, then these curves may already be available for some food/contaminant combinations. It should be specified that what are being referred to are concentration distribution curves in the text. There are always problems at an international level in dealing with data from different sources – individuals vs. composite samples, mean vs. median data, treatment of LOQs, different analytical methods etc. Accordingly, some reference to the problem may be required and JECFA would need to specify criteria for how the data have been treated, accepted for use and sorted etc. If curves were to be generated from the aggregate data (e.g. mean/median and standard deviation), then there will need to be a statement that a policy decision has to be made on what type of distribution curve to generate and the basis for that decision should be made clear – e.g. normal, lognormal curves.

Paragraph 15: This is a vague and open-ended statement and the purpose of this paragraph is not clear. It should be deleted.

**Under Component 4: Assess the agricultural and production practices and their potential impact on contaminant levels in food:**

Paragraph 16: JECFA does not have the capacity to undertake this proposed work (see comments Paragraph 8)

Paragraph 19: JECFA does risk assessments at the request of countries and bodies other than CCFAC.

Paragraph 20: The text in this paragraph, which reads “levels of intake” should be changed to “levels of exposure” since the term “exposure”, has been used consistently throughout the paper.

Paragraph 22: The text in paragraph 22 in the first sentence beginning “An initial consideration is usually based on a position paper (risk evaluation) prepared by a Member State,…” should be changed to read “An initial consideration is usually based on a **preliminary risk evaluation** performed by a Member **Country**”.

Paragraph 23: The text should be altered to read “CCFAC…may decide to request a **scientific** risk assessment…from JECFA…”.

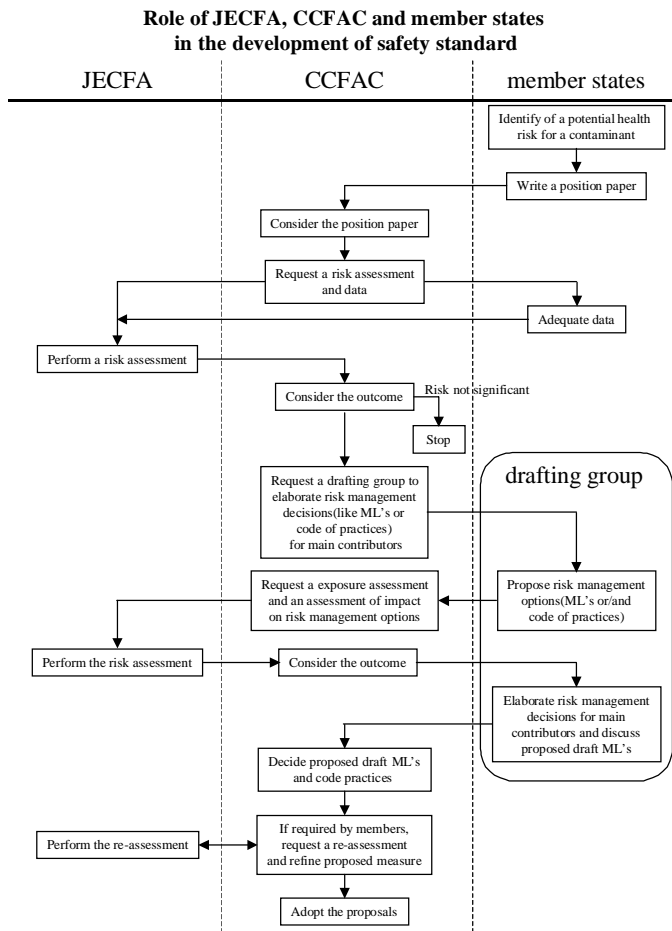
Paragraphs 24 and 25: Both these paragraphs appear to repeat information given previously in the document and should be removed.

Paragraphs 27, 28 and 29: These paragraphs are very process oriented and appear unnecessary and could be deleted.

Annex 1: The Annex is not acceptable as presented, and needs to be changed in relation to the above comments.

Annex 2: Point 15 of the Table on JECFA/CCFAC responsibilities needs to be clarified as to its purpose or should be removed.

Annex 3: The Flow Chart requires further work to shorten and simplify. (Note: Australia has not suggested anything specific here, but there are far too many symbols. Some of the flow chart is incorrect. Australia will endeavour to work on this to simplify).



## THAILAND:

1. Both Component 1 and Component 2 of the exposure assessment refer to GEMS/Food Regional Diets for exposure assessment. We are of the opinion that five GEMS/Food Regional Diets were established according to the geographical regions but probably did not give a prominence on the similarity in food consumption in each region whereas the thirteen clusters of FAO/WHO regional/cultural diets (which is being developed by GEMS/Food) are established according to the similarity in food consumption with less emphasis on geographical regions. Therefore, in order to have an accurate and appropriate food consumption data for the estimation of the total dietary exposure, we would like to propose that food consumption data should be based on both geographical regions as well as similarity in food consumption of the same group.
2. Component 3 in the Proposed Draft is obtained by using available data on contaminant levels to construct distribution curves for specific foods or food groups and then the proposed draft maximum levels will be developed taking into account the obtained distribution curves. We are of the opinion that the above mentioned method which is based on statistical principle is rather complicated. We, therefore would like to propose that some examples should be given in the Proposed Draft so that member countries could consider whether the methodology is appropriate or not.

## UNITED KINGDOM:

**The UK has the following comments on the above paper which overall we consider suggests a sound approach. We would offer the following specific comments -**

- **Paragraph 6** – it is not clear what the purpose is of JECFA expressing dietary exposure as a percentage of tolerable intake. Is this used further, for example in prioritisation of the CCFAC risk plan? If so, this should be stated. If not, why is JECFA asked to perform this calculation?
- **Paragraphs 10 - 14** – may be aided by the inclusion of dossiers (possibly as an Annex) of a case study.
- **Paragraph 12** - *this suggests CCFAC will pursue the ALARA principle for all contaminants/toxins, but this is only appropriate for those with non-threshold effects (e.g. genotoxic carcinogenicity). If intakes of contaminants are within the TDI, should JECFA drive for ever lower exposure?*
- **Annex II** – *it would be helpful if there were some distinction between the different risk assessment evaluations by JECFA at different stages of the process (left hand column).*

Finally, we would wish to point out that it is not possible to calculate the contribution of a food or food group to the total consumption / exposure if statistics such as mean or high level consumption / exposure are used. This is because the data for each group is based on different underlying populations. In addition, when comparing exposure from a food group to a TDI, it may be that an individual food within that group is contributing the majority of the exposure. Hence other foods in the group may be low risk in terms of exposure to that chemical.

## DENMARK:

Denmark appreciates the work by Australia and France. However, we do have some general and more specific comments to the paper as it stands now.

In general, we find the paper very useful and a good supplement to the Codex general standard for contaminants and toxins in foods preamble and annex I which both contain elements on the same issue. Therefore, we propose to include the text in a revision of the preamble and annex 1 to the GSCTF instead of having the text as another annex to the GSCTF.

If the exposure assessment paper is to be maintained as an annex to the GSCTF the title of the paper should be revised according to its content. Denmark propose the following title: “CCFAC policy for principles of ranking of hazards for risk assessment”.

### **Step 2: Identification of foods/food groups that contribute significantly to total dietary exposure of the contaminant or toxin**

Denmark finds, that the criteria are too rigid and should leave mere room for national diets or specific consumer groups like vegetarians or persons suffering of allergy. An example for illustration of the problem with only having a reference to the GEMS food regional diets:

In Denmark we eat a lot of dark bread based on rye. Rye bread is a staple foodstuff for the whole Danish population and is consumed in large amounts. In general one of the daily meals are based on rye bread. However – as this is a consumption pattern only for Denmark it will not be shown in the GEMS Food Regional Diet for Europeans as Denmark is only a small subpopulation of the European population.

Therefore, the criteria should be more broad and also refer to national diets or diets for specific consumer groups.

Concerning the reference to 5 % or 10 % of the TDI we find that the text should leave room for flexibility taking into account other relevant aspects like trade problems. Annex II

After having worked with the risk analysis in more details in the Nordic project ”A practical Approach to the Application of the Risk Analysis Process”<sup>1</sup>, we have a few comments to this annex. We find the annex useful, but it could be even more useful with a few corrections in order to make the text a bit more precise.

*Third column, second box:* we propose ”Write a position paper, including a risk profile for the hazard”.

*Second column, second box:* we propose ”Establish a risk assessment policy for the conduct of a risk assessment and request a risk assessment, including information of the uncertainties of the result”

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<sup>1</sup> Nordic Council of Ministers, TemaNord 2002:510, ISBN 92-893-0743-9