APPENDIX II

AMENDMENTS TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS COMMISSION

Rule IV Coordinators

1.-2. [no change]

3. The functions of the Coordinators shall be:

(i) to appoint the Chairperson of the Coordinating Committee where such committee has been set up under Rule XI.1(b)(ii) for the region or group of countries concerned.

~~(i)~~**(ii)** to assist and coordinate the work of the Codex Committees set up under Rule XI.1(b)(i) in their region or group of countries in the preparation of draft standards, guidelines and other recommendations for submission to the Commission

~~(ii)~~**(iii)** to assist the Executive Committee and the Commission, as required, by advising them of the views of countries and recognized regional intergovernmental and non-government organizations in their respective regions on matters under discussion or of interest;

Rule IV (paragraph 3 (i) renumbered 3 (ii) as above)

[FRENCH ONLY]

aider aux travaux des comités du Codex créés **pour leur région ou groupe de pays** en vertu de l'Article XI.1b)i) et les coordonner, ~~dans leur région ou groupe de pays~~ en ce qui concerne la préparation de projets de normes, de lignes directrices et autres recommandations à soumettre à la Commission;

Rule V Executive Committee

1. The Executive Committee shall consist of the Chairperson and the Vice-Chairpersons of the Commission, and the Coordinators appointed on the basis of Rule IV together with seven further Members elected by the Commission at regular sessions from among the Members of the Commission, one each coming from the following geographic locations: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, South-West Pacific. Not more than one delegate from any one country shall be a member of the Executive Committee. Members elected on a geographic basis shall hold office from the end of the session of the Commission at which they were elected until the end of the second succeeding regular session and shall be eligible for re-election if they have not served for more than two years in their current term, but after having served two consecutive terms shall be ineligible to hold such office for the next succeeding term. **Members elected on a geographic basis are expected to act within the Executive Committee in the interest of the Commission as a whole.**

2.-7. [no change]

Rule XI Subsidiary Bodies

1.-9. [no change]

10. The Members who shall be responsible for appointing Chairpersons of subsidiary bodies established under Rule XI.1(b)(i) ~~and Rule XI.1(b)(ii)~~ shall be designated at each session by the Commission and shall be eligible for re-designation. All other officers of subsidiary bodies shall be elected by the body concerned and shall be eligible for re-election.

11. [no change]

(Secretariat to take care of possible consequential changes)

APPENDIX III

AMENDMENTS TO THE GUIDE TO THE PROCEDURE FOR THE REVISION AND AMENDMENT OF CODEX STANDARDS AND ARRANGEMENTS FOR THE AMENDMENTS OF CODEX STANDARDS ELABORATED BY CODEX COMMITTEES WHICH HAVE BEEN ADJOURNED *SINE DIE*

GUIDE TO THE PROCEDURE FOR THE AMENDMENT ~~REVISION~~ AND REVISION ~~AMENDMENT~~ OF CODEX STANDARDS AND RELATED TEXTS

1~~3~~. The procedure for amending or revising a Codex standard is laid down in paragraph 8 of the Introduction to the Procedure for the Elaboration of Codex Standards and Related Texts. This Guide provides more detailed guidance on the existing procedure for the amendment and revision of Codex standards and related text.

2~~4~~. When the Commission has decided to amend or revise a standard, the unrevised standard will remain the applicable Codex standard until the amendment to the standard or the revised standard has been adopted by the Commission.

3. For the purpose of this Guide:

Amendment means any addition, change or deletion of text or numerical values in a Codex standard or related text, may be editorial or substantive, and concerns one or a limited number of articles in the Codex text. In particular, amendments of an editorial nature may include but are not limited to:

- correction of an error;
- insertion of an explanatory footnote; and
- updating of references consequential to the adoption, amendment or revision of Codex standards and other texts of general applicability, including the provisions in the Procedural Manual.

Finalization or updating of methods of analysis and sampling as well as alignment of provisions, for consistency, to those in similar standards or related texts adopted by the Commission may be handled by the Commission in the same manner as amendments of an editorial nature, as far as the procedure described in this Guide is concerned.

Revision means any changes to a Codex standard or related text other than those covered under "amendment" as defined above.

The Commission has the final authority to determine whether a proposal made constitutes an amendment or a revision, and whether an amendment proposed is of an editorial or substantive nature.

4~~2~~. Proposals for the amendment or revision of Codex standards and related texts should be submitted to the Commission by the subsidiary body concerned, by the Secretariat, or a member of the Commission where the subsidiary body concerned is not in existence or has been adjourned *sine die*. In the latter case, proposals should be received by the ~~Commission's~~ Secretariat in good time (not less than three months) before the session of the Commission at which they are to be considered. ~~The proposer of an amendment should indicate the reasons for the proposed amendment and should also state whether the proposed amendment had been previously submitted to and considered by the Codex committee concerned and/or the Commission. If the proposed amendment has already been considered by the Codex committee and/or Commission, the outcome of the consideration of the proposed amendment should be stated.~~ The proposal should be accompanied by a project document (see Part 2 of the Elaboration Procedures) unless the Executive Committee or the Commission decides otherwise. However, if the amendment proposed is of an editorial nature, the preparation of a project document is not required.

5~~3~~. Taking into account ~~such information regarding the proposed amendment, as may be supplied in accordance with paragraph 1 above, and~~ the outcome of the on-going critical review conducted by the

Executive Committee, the Commission ~~will~~ decides whether the amendment or revision of a standard is necessary. If the Commission decides in the affirmative, one of the following courses of action will be taken:

(i) In the case of an amendment of an editorial nature, it will be open to the Commission to adopt the amendment at Step 8 of the Uniform Procedure (see Part 3 of the Elaboration Procedures).

(ii) ~~If the proposer of the amendment is a Codex committee, it would be open to the Commission to decide that the proposed amendment be circulated to governments for comments prior to further consideration by the sponsoring Codex Committee.~~ In the case of an amendment proposed and agreed upon by a subsidiary body ~~Codex Commitee~~, it will also be open to the Commission to adopt the amendment at Step 5 of the Uniform Procedure (see Part 3 of the Elaboration Procedures) ~~or Step 8 as appropriate, where in its opinion the amendment is either of an editorial nature or of a substantive nature but consequential to provisions in similar standards adopted by it at Step 8~~.

(iii) In other cases, the Commission will approve the proposal as new work and the approved new work ~~and the proposer of the amendment is other than a Codex committee, the proposed amendment~~ will be referred ~~for consideration~~ to the appropriate subsidiary body ~~Codex committee~~, if such body ~~committee~~ is still in existence. If such body ~~committee~~ is not in existence, the Commission will determine how best to deal with the new work ~~proposed amendment~~.

[Paragraphs 1 and 2 of the "Arrangements" are removed.]

6~~5~~. ~~In the case w~~Where Codex subsidiary bodies have been abolished or dissolved, or Codex committees have been adjourned *sine die*, the Secretariat keeps under review all Codex standards and related texts elaborated by these bodies ~~originating from Codex Committees adjourned *sine die* and to~~ determines the need for any amendments, in particular those arising from decisions of the Commission ~~, in particular amendments of the type mentioned in para. 1(a), (b), (c), (d) and those of (e) if of an editorial nature. If a need to amend the standard appears appropriate~~. If the need for amendments of an editorial nature is identified then the Secretariat should prepare proposed amendments ~~a text~~ for consideration and adoption by ~~in~~ the Commission. If the need for amendments ~~of the type in para (f) and those of (e)~~ of a substantive nature is identified, the Secretariat, in cooperation with the national secretariat of the adjourned Committee if applicable, ~~and, if possible, the Chairperson of that Committee,~~ should ~~agree on the need for such an amendment and~~ prepare a working paper containing ~~the wording of a proposed amendment and~~ the reasons for proposing ~~such~~ amendments and the wording of such amendments as appropriate, and request comments from members of the Commission ~~Member Governments~~: (a) on the need to proceed with such an amendment and (b) on the proposed amendment itself. If the majority of the replies received from members of the Commission ~~Member Governments~~ is affirmative on both the need to amend the standard and the suitability of the proposed wording for the amendment or an alternative proposed wording, the proposal should be submitted to the Commission ~~with a request to approve the amendment of the standard concerned~~ for consideration and adoption. In cases where replies do not appear to offer an uncontroversial solution then the Commission should be informed accordingly and it would be for the Commission to determine how best to proceed.

AMENDMENTS TO THE GENERAL PRINCIPLES OF THE CODEX ALIMENTARIUS

Purpose of the Codex Alimentarius

1. The Codex Alimentarius is a collection of internationally adopted food standards and related texts[1] presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. ~~The Codex Alimentarius also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures intended to assist in achieving the purposes of the Codex Alimentarius~~. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

Scope of the Codex Alimentarius

2. The Codex Alimentarius includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined. The Codex Alimentarius includes provisions in respect of food hygiene, food additives, ~~pesticide~~ residues of pesticides and veterinary drugs, contaminants, labelling and presentation, methods of analysis and sampling, and import and export inspection and certification. ~~It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures.~~

Nature of Codex Standards

3. Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

4~~3~~. Codex standards and related texts contain requirements for food aimed at ensuring for the consumer a safe ~~sound~~, wholesome food product free from adulteration, correctly labelled and presented. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain, as appropriate, the sections ~~criteria~~ listed therein.

Revision of Codex Standards

5~~4~~. The Codex Alimentarius Commission and its subsidiary bodies are committed to revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related text shall be revised or removed in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts ~~using the same procedures as followed for the elaboration of a new standard~~. Each member of the Codex Alimentarius Commission is responsible for identifying, and presenting to the appropriate committee, any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts.

[1] These include codes of practice, guidelines and other recommendations.

AMENDMENTS TO THE PRINCIPLES CONCERNING THE PARTICIPATION OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN THE WORK OF THE CODEX ALIMENTARIUS COMMISSION

1.-5. [no change]

6. Review of "Observer Status"

The Directors-General may terminate observer status if an Organization no longer meets the criteria in sections 3 and 4 above ~~that applied at the time it was granted observer status~~, or for reasons of exceptional nature, in accordance with the procedures set out in this section. […]

DEFINITIONS FOR THE PURPOSE OF THE CODEX ALIMENTARIUS

[for inclusion in Section I]

Codex maximum level for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity.

Good Manufacturing Practice in the Use of Food Additives means that:

- the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical nutritional or other technical effect in food;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;
- the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

PROCEDURES FOR CONSIDERATION OF THE ENTRY AND REVIEW OF FOOD ADDITIVE PROVISIONS IN THE GENERAL STANDARD FOR FOOD ADDITIVES

[for inclusion in Section II]

SCOPE

The Codex General Standard for Food Additives is intended to include food additive provisions for standardised and non-standardised foods in the Codex Alimentarius.

The following text describes the data and information that should be submitted to the Codex Committee on Food Additives when requesting the Committee to initiate work to add or revise food additive provisions in the Codex General Standard for Food Additives. The decisions required to establish acceptance or rejection of new proposals are also elaborated.

Provisions for the use of processing aids (e.g., most enzyme preparations, clarifying and filtering aids, extraction solvents) are not included in the General Standard for Food Additives.

INITIATION OF WORK

Revision

The food additive provisions of the General Standard for Food Additives may be revised by the Committee on Food Additives after requests submitted by Codex Committees, Codex members, or the Codex Alimentarius Commission. Information to support amendment of the General Standard for Food Additives shall be provided by the proposing body. Supporting information provided to the Committee on Food Additives should include, as appropriate:

- Specifications for the food additive;
- A summary of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) safety evaluation of the food additive;
- The food categories or sub-categories in which the additive is intended to be used;
- An indication of the technological need / justification for the additive, referencing one or more of the General Principles for the Use of Food Additives of the GSFA (Section 3);
- Maximum use levels for the food additive in the specified food categories:
    - For additives with a numerical Acceptable Daily Intake (ADI), a numerical maximum use level for each specified use although for certain cases, a level of GMP may be appropriate;
    - For additives with an ADI Not Specified or Not Limited, a recommendation to list the additive in Table 3 accompanied by additional proposals for inclusion in Tables 1 and 2 for use in the food categories listed in the Annex to Table 3, as appropriate;
    - For additives with an " acceptable" ADI, either a numerical maximum use level for the acceptable level of treatment of a food or a level of GMP, consistent with the JECFA evaluation.
- A justification of the maximum use levels from a technological point-of-view; and an indication, by means of the procedure indicated in Annex A of the General Standard for Food Additives or an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of the General Standard for Food Additives.
- A reasoned statement that consumers will not be misled by the use of the additive.

The Committee on Food Additives shall consider all amendments to the General Standard for Food Additives proposed by Codex Committees, Codex members, or the Codex Alimentarius Commission.

Review

The food additive provisions for the General Standard for Food Additives shall be reviewed by the Committee on Food Additives on a regular basis and revised as necessary in light of revisions of the risk assessment by JECFA or of changing technological need and justification for use.

- If JECFA changes an ADI to a Temporary ADI, the food additive provisions of the General Standard for Food Additives may remain unchanged until the ADI has been withdrawn or the full status has been restored by JECFA.
- If JECFA withdraws an ADI the food additive provisions of the General Standard for Food Additives shall be amended by removing all provision for the use of the additive.

The following additional guidance is provided regarding the information to be submitted:

- Identity of the food additive
    - Food additives shall have been evaluated by JECFA and either assigned a full numerical or non-numerical ("not specified" or "not limited") ADI, or deemed to be acceptable for a particular use.
    - Food additives shall have been assigned an International Numbering System number.
- Functional effect of the food additive
    - The functional class list used in *Class Names and the International Numbering System* (CAC/GL 36-1989) should be used.
- Proposed use of the food additive
    - The appropriate food categories from the food category system (Annex B of the General Standard for Food Additives) and maximum use levels should be specified.
    - With regard to the acceptable maximum use level:
        - A numerical use level should be provided for a food additive assigned a numerical ADI. However, in some cases, reporting the use level as good manufacturing practice ("GMP") may be appropriate.
        - For a food additive assigned a non-numerical ("not specified" or " not limited") ADI that is listed in Table 3 of the General Standard for Food Additives, a numerical or good manufacturing practice ("GMP") use level should be provided for any request to list the additive in a food category in the Annex to Table 3.
        - For some food additives, the ADI has been reported on a specific basis (e.g., "as phosphorus" for phosphates; "as benzoic acid" for benzoates). For consistency, the maximum use level for these additives should be reported on the same basis as the ADI.
- Justification for the use and technological need of the food additive
    - Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives should be included.
- Safe use of the food additive
    - An intake assessment of the proposed use of the food additive, in accordance with Section 3.1 of the Preamble of the General Standard for Food Additives, should be included as appropriate.
- Justification that the use does not mislead the consumer
    - A reasoned statement that consumers will not be misled by the use of the additive should be provided.

DOES THE FOOD ADDITIVE USE MEET THE CRITERIA OF SECTION 3.2 OF THE PREAMBLE OF THE GENERAL STANDARD FOR FOOD ADDITIVES?

Section 3.2 of the Preamble of the General Standard for Food Additives establishes the criteria for justifying the use of a food additive. Adherence to these criteria is necessary for the inclusion of the food additive in the General Standard for Food Additives. If the use of the additive does not meet these criteria, it is not considered further and the work is discontinued. If the information provided to justify the use of the additive is inadequate for the Codex Committee on Food Additives to reach a decision, further information on the use and technological justification and need for the food additive will be requested for consideration at the Committee's next session. If this information is not provided by the next session, work on the provision is discontinued.

IS THE FOOD ADDITIVE USED IN STANDARDIZED FOOD?

The Codex Committee on Food Additives, asks the relevant Codex commodity committee to consider the functional classes of additives, additives, and their technological justification for the commodity and to refer back this information by the next available session.. In light of this information, the Codex Committee on Food Additives recommends appropriate conditions of use based on proposals of the commodity committee.

In certain cases, however, it may be appropriate for the Codex commodity committee to develop a list of food additives with associated functional classes and acceptable maximum use levels that would be forwarded to the Codex Committee on Food Additives for endorsement and, ultimately, incorporation into the General Standard for Food Additives. The development of such food additive lists should be consistent with the principles used in the development of the General Standard for Food Additives. However, the development of food additive lists in commodity standards should be restricted as much as possible. For example, an additive may be listed in a commodity standard if it is needed to achieve a technical effect that is not achievable by the use of other additives of the same functional class. Additives may also be listed in a commodity standard if there is a need, based on a safety assessment, to limit the use of the additive. Justification for such exceptions should be provided by the Codex commodity committees to the Codex Committee on Food Additives for consideration.

If the Codex commodity committee has been adjourned, the Codex Committee on Food Additives may revise the food additive provisions in commodity standards under the purview of the adjourned committee, as necessary.

The Codex Committee on Food Additives would consider any proposed revision in light of the principles of technological justification for the use of additives as indicated in Section 3.2 of the Preamble of the General Standard for Food Additives. These revisions, once adopted by the Commission, would be incorporated into the General Standard for Food Additives.

HAS A NON-NUMERICAL ("NOT SPECIFIED" OR "NOT LIMITED") ADI BEEN ASSIGNED?

Yes - Non-Numerical ("Not Specified" or "Not Limited") ADI:

Food additives assigned a non-numerical ADI are proposed for inclusion in Table 3 of the General Standard for Food Additives. Requests for the use of these additives in the food categories listed in the Annex to Table 3 are made by proposing provisions for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives according to the criteria described under "**Consideration of Conditions of Use in the Specific Food Categories**", below.

No - Numerical ADI or Acceptable for Limited Use:

Food additives assigned a numerical ADI or evaluated to be acceptable for one or more particular uses are proposed for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives according to the criteria described under "**Consideration of Conditions of Use in the Specific Food Categories**", below.

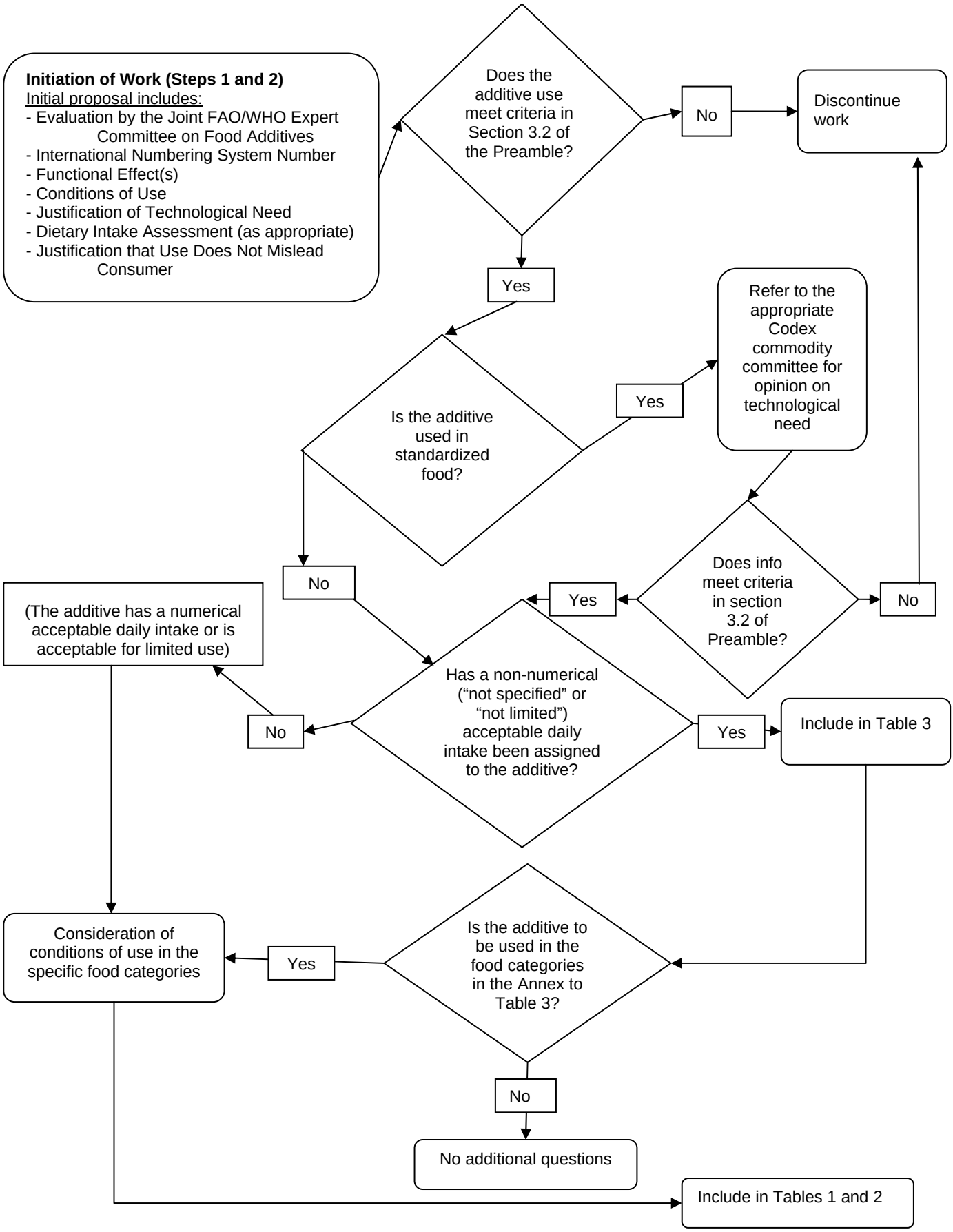
CONSIDERATION OF CONDITIONS OF USE IN THE SPECIFIC FOOD CATEGORIES

The Codex Committee on Food Additives identifies and recommends appropriate food categories and use levels for inclusion in Tables 1 and 2 of the General Standard for Food Additives. For this purpose, the Committee will consider the following general principles for the inclusion of a food additive provision in Tables 1 and 2 of the General Standard for Food Additives:

1. Food additives that share a numerical group ADI will be considered as a group without further restrictions on the use of individual additives in that group. However, in some cases, restrictions on the use of individual additives in that group could be appropriate (e.g., because of public health concerns).
2. Food additives that have multiple functional classes will be considered without further restrictions to their functional class.
3. In general, a numerical use level for a proposed use of a food additive in a food category is given preference over a use level reported as good manufacturing practice ("GMP"). However, exceptions, as noted under "**Initiation of Work**", shall also be taken into account by the Codex Committee on Food Additives on a case-by-case basis.
4. When establishing the acceptable maximum level of use for an additive in a specified food category, the Codex Committee on Food Additives considers the technological justification for the proposed level and the exposure assessment in accordance with Sections 3.1 and 3.2 of the Preamble of the General Standard for Food Additives. If more than one maximum use level is proposed, and the Committee cannot reach consensus on the appropriate maximum use level, the delegations supporting and the delegations opposing the proposed maximum use level should provide additional justification for their proposed levels to address any specific concerns raised by the Committee, by the next available session, to the Codex Committee on Food Additives, for consideration in its next session. Proposals lacking justification will no longer be considered, and the proposed level for which justification has been provided will be forwarded for adoption.
5. To resolve questions related to dietary exposure of food additives, the Codex Committee on Food Additives may request JECFA to perform exposure assessments for the additives based on the acceptable maximum use levels under consideration by the Codex Committee on Food Additives.
6. Acceptable maximum use levels are established as described in the previous sections and the food additive provisions are entered in the General Standard for Food Additives. Each use level represents the highest acceptable maximum use level in the broadest food category for which the use is technologically justified. To the extent possible, the hierarchical structure of the food category system will be used to simplify the listing of the food additive provisions in Tables 1 and 2 of the General Standard of Food Additives. In this regard:

    - If the new use of a food additive is for a broader food category and at a maximum use level that is higher than or equal to those in the sub-categories of the broad food category that are already listed in the General Standard for Food Additives, then the new use in the broader food category supersedes the already-listed provisions. These provisions are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).
    - If the new use of a food additive is for a broader food category and at a lower maximum use level than for the sub-categories of the broad food category that already exist in the General Standard for Food Additives, then the provisions listed in the General Standard for Food Additives are determined according to the hierarchy of the food category system. The highest maximum use level in each food sub-category, whether from an existing provision or from the new use in the broader food category, is entered into the General Standard for Food Additives. Any existing provisions that are superseded by the new use are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).
    - If the new use of a food additive, together with the already-listed provisions in the General Standard for Food Additives, represents use in all of the sub-categories of a broader food category at the same maximum use level, then the use in the broader food category will be listed in the General Standard for Food Additives. The already-listed provisions in the sub-categories are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the provision in the broader food category at Step 8 (if adopted provision at Step 8).

Diagram of procedure for consideration of the entry and review of food additives in the Codex General Standard for Food Additives



AMENDMENTS TO THE PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION OF CODEX SAMPLING PROCEDURES

PURPOSE OF CODEX METHODS OF SAMPLING

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

METHODS OF SAMPLING

Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

Such plans~~These~~ are normally applied to visual defects (e.g. loss of colour, ~~mis-graded for~~ misgrading of size, etc.) and extraneous matter. They are~~will~~ normally ~~be~~ attributes plans, and plans such as those included in Section 3.1 and 4.2 of the ~~FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL 6.5)~~ *General Guidelines on Sampling (CAC/GL 50-2004)* (hereinafter referred to as "General Guidelines") may be applied.

(b) Sampling Plans for Net Contents:

~~These~~ Such plans are ~~sampling plans~~those which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents. Plans such as those included in Section 3.3 and 4.4 of the General Guidelines may be applied.

(c) Sampling Plans for Compositional Criteria:

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation. Plans such as those included in Section 4.3 of the General Guidelines may be applied.

(d) Specific Sampling Plans for Health-related Properties:

Such plans are ~~generally~~ normally applied to heterogeneous conditions, e.g., in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants.

General Instructions for the Selection of Methods of Sampling

~~(a) Official methods of sampling as elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such methods, when attracted to Codex standards, may be revised using Codex recommended sampling terms (to be elaborated).~~

(a) Sampling methods described in the General Guidelines or official methods of sampling elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such official methods may be written using the General Guidelines when attracted to Codex standards.

(b) When selecting appropriate sampling plans, Table 1 in the General Guidelines may be utilized.

(~~b~~c) The appropriate Codex Commodity Committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by the Codex Committee on Methods of Analysis and Sampling, the following:

(i) the basis on which the criteria in the Codex Commodity standards have been drawn up (e.g. whether on the basis that every item in a lot, or a specified high proportion, shall comply with the provision in the standard or whether the average of a set of samples extracted from a lot must comply and, if so, whether a minimum or maximum tolerance, as appropriate, is to be given);

(ii) whether there is to be any differentiation in the relative importance of the criteria in the standards and, if so, what is the appropriate statistical parameter each criterion should attract, and hence, the basis for judgement when a lot is in conformity with a standard.

(~~c~~d) Instructions on the procedure for the taking of samples should indicate the following:

(i) the measures necessary in order to ensure that the sample taken is representative of the consignment or of the lot;

(ii) the size and the number of individual items forming the sample taken from the lot or consignment;

(iii) the administrative measures for taking and handling the sample.

(~~d~~e) The sampling protocol may include the following information:

(i) the statistical criteria to be used for acceptance or rejection of the lot on the basis of the sample;

(ii) the procedures to be adopted in cases of dispute.

GENERAL CONSIDERATIONS

(a) The Codex Committee on Methods of Analysis and Sampling should maintain closest possible relations with all interested organizations working on methods of analysis and sampling.

(b) The Codex Committee on Methods of Analysis and Sampling should organize its work in such a manner as to keep under constant review all methods of analysis and sampling published in the Codex Alimentarius.

(c) In the Codex methods of analysis, provision should be made for variations in reagent concentrations and specifications from country to country.

(d) Codex methods of analysis which have been derived from scientific journals, theses, or publications, either not readily available or available in languages other than the official languages of FAO and WHO, or which for other reasons should be printed in the Codex Alimentarius *in extenso*, should follow the standard layout for methods of analysis as adopted by the Codex Committee on Methods of Analysis and Sampling.

(e) Methods of analysis which have already been printed as official methods of analysis in other available publications and which are adopted as Codex methods need only be quoted by reference in the Codex Alimentarius.

AMENDMENTS TO THE FORMAT FOR CODEX COMMODITY STANDARDS

FOOD ADDITIVES

This section should contain ~~the names of the additives permitted and, where appropriate, the maximum amount permitted in the food. It should be prepared in accordance with guidance given in the section on Food Additives and Contaminants in the *Relations between Commodity Committees and General Committees*,~~ a general reference to the corresponding sections of the General Standard for Food Additives which ~~and may~~ should take the following form:

~~*"The following provisions in respect of food additives and their specifications as contained in section ..... of the Codex Alimentarius are subject to endorsement [have been endorsed] by the Codex Committee on Food Additives."*~~

> *"[Food Additive functional class] used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives in food category x.x.x.x [food category name] or listed in Table 3 of the General Standard for Food Additives are acceptable for use in foods conforming to this standard."*

Exceptions from, or addition to, the General Standard for Food Additives that are necessary for its interpretation with respect to the product concerned should be justified fully, and should be restricted where possible. In cases where it is necessary to explicitly list food additives in a commodity standard, the names of the additives/functional classes permitted and, where appropriate, the maximum amount permitted in the food should be prepared in accordance with guidance given in the section on Food Additives in the *Relations between Commodity Committees and General Committees*, and may take the following form:

> *"The following provisions in respect of food additives and their specifications as contained in section ..... of the Codex Alimentarius are subject to endorsement [have been endorsed] by the Codex Committee on Food Additives."*

Then should follow a tabulation, viz.:

> *"INS number, name of additive, maximum level (in percentage or mg/kg), grouped by functional classes.*

In this section, provisions for flavourings and processing aids should also be included.

CONTAMINANTS

~~*Pesticide Residues:*~~

~~This section should include, by reference, any levels for pesticide residues that have been established by the Codex Alimentarius Commission for the product concerned.~~

~~*Other Contaminants:*~~

~~In addition, this section should contain the names of other contaminants and where appropriate the maximum level permitted in the food, and the text to appear in the standard may take the following form:~~

> ~~"The following provisions in respect of contaminants, other than pesticide residues, are subject to endorsement [have been endorsed] by the Codex Committee on Contaminants in Foods."~~

~~Then should follow a tabulation, viz.:~~

> ~~"Name of contaminant, maximum level (in percentage or mg/kg)."~~

This section should include the following statement:

> *"The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC."*

AMENDMENTS TO THE RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL COMMITTEES

Codex Committees may ask the advice and guidance of committees having responsibility for matters applicable to all foods on any points coming within their province.

The Codex Committees on Food Labelling; Food Additives; Contaminants in Foods; Methods of Analysis and Sampling; Food Hygiene; Nutrition and Foods for Special Dietary Uses; and Food Import and Export Inspection and Certification Systems may establish general provisions on matters within their terms of reference. These provisions should only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise.

Codex Commodity standards shall contain sections on hygiene, labelling and methods of analysis and sampling and these sections should contain all of the relevant provisions of the standard. Provisions of Codex General Standards, Codes or Guidelines shall only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise. Where Codex Committees are of the opinion that the general provisions are not applicable to one or more commodity standards, they may request the responsible Committees to endorse deviations from the general provisions of the Codex Alimentarius. Such requests should be fully justified and supported by available scientific evidence and other relevant information. Sections on hygiene, labelling, food additives and methods of analysis and sampling which contain specific provisions or provisions supplementing the Codex General Standards, Codes or Guidelines shall be referred to the responsible Codex Committees at the most suitable time during Steps 3, 4 and 5 of the Procedure for the Elaboration of Codex Standards and Related Texts, though such reference should not be allowed to delay the progress of the standard to the subsequent steps of the Procedure.

Subject and commodity Committees should refer to the principles and guidelines developed by the Codex Committee on Food Import and Export Inspection and Certification Systems when developing provisions and/or recommendations on inspection and certification and make any appropriate amendments to the standards, guidelines and codes within the responsibility of the individual committees at the earliest convenient time.

FOOD LABELLING [no change]

FOOD ADDITIVES ~~AND CONTAMINANTS~~

Codex commodity committees ~~should prepare a section on food additives in each draft commodity standard and this section should contain all the provisions in the standard relating to food additives. The section should include the names of those additives which are considered to be technologically necessary or which are widely permitted for use in the food within maximum levels where appropriate.~~ shall examine the General Standard for Food Additives with a view toward incorporating a reference to the General Standard. All proposals for additions or revisions to the General Standard in order to establish a reference to the General Standard shall be referred to the Codex Committee on Food Additives. The Codex Committee on Food Additives shall consider such proposals for endorsement. Revisions of a substantive nature that are endorsed by the Food Additives Committee will be referred back to the commodity committee in order to achieve consensus between both committees at an early stage of the step procedure.

Should the Codex commodity committee consider that a general reference to the General Standard for Food Additives does not serve its purpose, a proposal should be prepared and forwarded to the Codex Committee on Food Additives for consideration and endorsement. The commodity committee shall provide a justification for why a general reference to the General Standard would not be appropriate in light of the criteria for the use of food additives established in the Preamble of the General Standard, in particular Section 3.

All provisions in respect of food additives (including processing aids) ~~and contaminants~~ contained in Codex commodity standards should be referred to the Codex Committee on Food Additives ~~or on Contaminants in Foods~~ preferably ~~after~~ before the Standards have been advanced to Step 5 of the Procedure for the Elaboration of Codex Standards or before they are considered by the Commodity Committee concerned at Step 7, though such ~~reference~~ referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.

All provisions in respect of food additives contained in commodity standards will require ~~to be endorsed~~ endorsement by the Codex Committee on Food Additives, on the basis of technological justification

submitted by the commodity committees and ~~of~~ on the recommendations of the Joint FAO/WHO Expert Committee on Food Additives concerning the safety-in-use (acceptable daily intake (ADI) and other restrictions) and an estimate of the potential and, where possible, the actual intake of the food additives, ensuring conformity with the ~~General Principles for the Use of Food Additives~~ Preamble of General Principles for the Use of Food Additives.

~~In preparing working papers for the~~ When forwarding a food additive section of a commodity standard for endorsement by Codex Committee on Food Additives, the Secretariat should prepare ~~make~~ a report to the Committee ~~concerning the endorsement of provisions for food additives (including processing aids), on the basis of the General Principles for the Use of Food Additives. Provisions for food additives should~~ that includes the functional classes and technological justification. With regard to exceptional cases where specific food additives and their maximum levels are given, the report should also indicate the International ~~Numbering~~ System (INS) number, the Acceptable Daily Intake (ADI) assigned by the Joint FAO/WHO Expert Committee on Food Additives, technological justification, proposed level, and whether the additive was previously endorsed ~~(or temporarily endorsed)~~ by the Codex Committee on Food Additives.

When commodity standards are sent to governments for comment at Step 3, they should contain a statement that the provisions "in respect of food additives ~~and contaminants~~ are subject to endorsement by the Codex Committees on Food Additives ~~or on Contaminants in Foods~~ and to incorporation into the General Standard for Food Additives ~~or the General Standard for Contaminants and Toxins in Foods~~".

~~When establishing provisions for food additives, Codex committees should follow the General Principles for the Use of Food Additives and the Preamble of the General Standard for Food Additives. Full explanation should be provided for any departure from the above recommendations.~~

When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the Codex Committee on Food Additives for endorsement and inclusion in the General Standard for Food Additives. When the Codex Committee on Food Additives decides not to endorse specific additives provisions ~~(use of the additive, or level in the end product),~~ the reason should be clearly stated. The section under consideration should be referred back to the commodity ~~C~~committee concerned if further information is needed, or for information if the Codex Committee on Food Additives decides to amend the provision.

When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions for inclusion in the General Standard for Food Additives should be forwarded directly by Codex member ~~countries~~ to the Codex Committee on Food Additives.

~~***Good Manufacturing Practice*** means that:~~

- ~~the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical nutritional or other technical effect in food;~~
- ~~the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;~~

~~the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.~~

Move the above definition of Good Manufacturing Practice in the Use of Food Additives to section "Definitions for the Purposes of the Codex Alimentarius"

FOOD HYGIENE [no change]

METHODS OF ANALYSIS AND SAMPLING [no change]

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

[for inclusion in Section III]

SCOPE

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) as the risk assessment body and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

ROLES OF CCPR AND JMPR IN RISK ANALYSIS

INTERACTION BETWEEN CCPR AND JMPR

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.

3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

4. CCPR and JMPR should continue to develop procedures to enhance communication between the two bodies.

5. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members[2].

6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

7. These requirements should be used by CCPR as a fundamental criterion as described in the Annex in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

ROLE OF CCPR

8. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.

9. CCPR shall base its risk management recommendations, such as MRLs, to the CAC following JMPR's risk assessments of the respective pesticides, and considering, where appropriate, other legitimate factors such as relevant to the health protection of consumers and for the promotion of fair practices in food trade.

10. In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.

11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties as described by JMPR.

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[2] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

12. CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation.

13. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members.

14. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

15. CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan;
- The Criteria for the Establishment of Work Priorities;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food Commodities for which Codex MRLs or Extraneous Maximum Residue Limits (EMRLs) should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritization Process of Compounds for Evaluation by JMPR
- A commitment to provide the necessary data for the evaluation in time.

16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

ROLE OF JMPR

19. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.

20. This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.

21. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses or in specific cases, such as EMRLs, based on monitoring data.

22. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.

23. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

24. JMPR is responsible for evaluating exposure to pesticides. JMPR should strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to GEMS/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members.

25. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

ESTABLISHMENT OF MRLs/EMRLs

Procedure for Proposing Pesticides for Codex Priority Lists

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR[3].

3. Before a pesticide can be considered for the Priority List, it must:

- be available for use as a commercial product; and
- not have been already accepted for consideration.

4. To meet the criteria for inclusion in the priority list, the use of the pesticide must: give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

5. When prioritising new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

(i) If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
(ii) The date when the chemical was nominated for evaluation;
(iii) Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
(iv) The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
(v) Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.

[3] Criteria for Prioritization Process of Compounds for Evaluation by JMPR, Procedural Manual

6. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

(i) If the intake and/or toxicity profile indicate some level of public health concern;

(ii) Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;

(iii) The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation –Not Yet Scheduled;

(iv) The date that data will be submitted;

(v) Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;

(vi) If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and

(vii) The availability of current labels arising from recent national re-evaluations.

7. Once the JMPR has reviewed a chemical, three scenarios may occur:

- the data confirm the existing Codex MRL, it remains in place, or
- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years, or
- insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

MRLs for Commodities of Animal Origin

8. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

9. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g. cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA, and from residues in animal feed do not agree, the higher recommendation will prevail.

MRLs for Processed or Ready-to-eat Foods or Feeds

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities.

MRLs for spices

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

MRLs for fat-soluble pesticides

13 If a pesticide is determined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition:

- When available, it is the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”.
- In the absence of useful information on the distribution of residues in muscle and fat, residues with logPow>3 are likely to be “fat soluble”

14. For fat soluble pesticides, two MRLs are recommended if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk fat or of the residue in whole milk with the MRL for milk.

Establishment of MRLs

15. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticides residues (revised)(1997)[4]. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

16. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs are withdrawn until the remaining MRLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

17. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the ARfD.

18. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

19. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

20. If further refinement is not possible then MRLs are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

21. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

Utilization of Steps 5/8 for elaboration of MRLs

22. Preconditions for utilization of Step 5/8 Procedure

- New MRL circulated at Step 3
- JMPR report available electronically by early February
- No intake concerns identified by JMPR

23. Steps 5/8 Procedure (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8)

[4] Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7

- If the preconditions listed above are met.
- If a delegation has a concern with advancing a given MRL, a concern form should be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably as comments at Step 3, or at the latest, one month after the CCPR session.
- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8.
- If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR as soon as possible but the rest of the MRLs should be advanced to Step 5/8.
- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8.

Establishment of EMRLs

24. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

25. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses haven been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

26. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data[5].

27. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

28. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

29. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLs while it also agreed not to initiate a full exercise of criteria elaboration.

Periodic Review Procedure

30. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to members and interested organizations for comments.

Deleting Codex MRLs

31. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs can be deleted.

[5] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

32. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session (t=0). The proposal will be to delete the existing MRLs at the following session (t=0+1 year).

33. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

MRLs AND METHODS OF ANALYSIS

34. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

35. If no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

[for inclusion in Section III]

SECTION 1. PURPOSE – SCOPE

1. The purpose of this document is to specify Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods.

SECTION 2. PARTIES INVOLVED

2. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* has defined the responsibilities of the various parties involved. The responsibility for providing advice on risk management concerning residues of veterinary drugs lies with the Codex Alimentarius Commission and its subsidiary body, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), while the responsibility for risk assessment lies primarily with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

3. According to its mandate, the responsibilities of the CCRVDF regarding veterinary drug residues in food are:

(a) to determine priorities for the consideration of residues of veterinary drugs in foods;

(b) to recommend maximum residue limits (MRLs) for such veterinary drugs;

(c) to develop codes of practice as may be required;

(d) to consider whether available methods of sampling and analysis for the determination of veterinary drug residues in foods.

4. The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs in relation to proposed MRLs.

5. The CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission.

6. JECFA is primarily responsible for providing independent scientific advice, the risk assessment, upon which the CCRVDF base their risk management decisions. It assists the CCRVDF by evaluating the available scientific data on the veterinary drug prioritised by the CCRVDF. JECFA also provides advice directly to FAO and WHO and to Member governments.

7. Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved, taking into account geographical representation where possible.

SECTION 3. RISK MANAGEMENT IN CCRVDF

8. Risk management should follow a structured approach including:

- preliminary risk management activities;
- evaluation of risk management options; and
- monitoring and review of decisions taken.

9. The decisions should be based on risk assessment, and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*[6].

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[6] *Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors are Taken into Account*, Codex Procedural Manual - Appendix

3.1 Preliminary risk management activities

10. This first phase of risk management covers:

- Establishment of risk assessment policy for the conduct of the risk assessments;
- Identification of a food safety problem;
- Establishment of a preliminary risk profile;
- Ranking of the hazard for risk assessment and risk management priority;
- Commissioning of the risk assessment; and
- Consideration of the result of the risk assessment.

3.1.1 Risk Assessment Policy for the Conduct of the Risk Assessment

11. The responsibilities of the CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in *Risk Assessment Policy for the Setting of MRLs in Food*, established by the Codex Alimentarius Commission.

3.1.2 Establishment of Priority List

12. The CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. The CCRVDF establishes a priority list for assessment by JECFA.

13. In order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:

- A Member has proposed the compound for evaluation;
- A Member has established good veterinary practices with regard to the compound;
- The compound has the potential to cause public health and/or international trade problems;
- It is available as a commercial product; and
- There is a commitment that a dossier will be made available.

14. The CCRVDF takes into account the protection of confidential information in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - Section 7: Protection of Undisclosed Information - Article 39, and makes every effort to encourage the willingness of sponsors to provide data for JECFA assessment.

3.1.3 Establishment of a Preliminary Risk Profile

15. Member(s) request(s) the inclusion of a veterinary drug on the priority list. The available information for evaluating the request shall be provided either directly by the Member(s) or by the sponsor. A preliminary risk profile shall be developed by the Member(s) making the request, using the template presented in the Annex.

16. The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list.

3.1.4 Ranking of the Hazard for Risk Assessment and Risk Management Priority

17. The CCRVDF establishes an ad-hoc Working Group open to all its Members and observers, to make recommendations on the veterinary drugs to include into (or to remove from) the priority list of veterinary drugs for the JECFA assessment. The CCRVDF considers these recommendations before agreeing on the priority list, taking into account pending issues such as temporary Acceptable Daily Intakes (ADIs) and/or MRLs. In its report, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

18. Prior to development of MRLs for new veterinary drugs not previously evaluated by JECFA, a proposal for this work shall be sent to the Codex Alimentarius Commission with a request for approval as new work in accordance with the *Procedures for the Elaboration of Codex Standards and Related Texts*.

3.1.5 Commissioning of the Risk Assessment

19. After approval by the Codex Alimentarius Commission of the priority list of veterinary drugs as new work, the CCRVDF forwards it to JECFA with the qualitative preliminary risk profile as well as specific guidance on the CCRVDF risk assessment request. JECFA, WHO and FAO experts then proceed with the assessment of risks related to these veterinary drugs, based on the dossier provided and/or all other available scientific information.

3.1.6 Consideration of the Result of the Risk Assessment

20. When the JECFA risk assessment is completed, a detailed report is prepared for the subsequent session of the CCRVDF for consideration. This report shall clearly indicate the choices made during the risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided.

21. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations[7]. If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a timeframe in which data should be submitted, in order to allow Members to make an appropriate risk management decision.

22. The JECFA assessment reports related to the concerned veterinary drugs should be made available in sufficient time prior to a CCRVDF meeting to allow for careful consideration by Members. If this is, in exceptional cases, not possible, a provisional report should be made available.

23. JECFA should, if necessary, propose different risk management options. In consequence, JECFA should present, in its report, different risk management options for the CCRVDF to consider. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options.

24. The CCRVDF may ask JECFA any additional explanation.

25. Reasons, discussions and conclusions (or the absence thereof) on risk assessment should be clearly documented, in JECFA reports, for each option reviewed. The risk management decision taken by the CCRVDF (or the absence thereof) should also be fully documented.

3.2 Evaluation of Risk Management Options

26. The CCRVDF shall proceed with a critical evaluation of the JECFA proposals on MRLs and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. According to the 2nd statement of principle, the criteria for the consideration of other factors should be taken into account. These other legitimate factors are those agreed during the 12th session of the CCRVDF[8] and subsequent amendments made by this Committee.

27. The CCRVDF either recommends the MRLs as proposed by JECFA, modifies them in consideration of other legitimate factors, considers other measures or asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question.

28. Particular attention should be given to availability of analytical methods used for residue detection.

3.3 Monitoring and Review of the Decisions Taken

29. Members may ask for the review of decisions taken by the Codex Alimentarius Commission. To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary if they pose difficulties in the application of the *Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993).

30. The CCRVDF may request JECFA to review any new scientific knowledge and other information relevant to risk assessment and concerning decisions already taken, including the established MRLs.

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7 Definition of "Codex maximum limit for residues of veterinary drugs", Codex Procedural Manual.

8 ALINORM 01/31 paragraph 11.

31. The risk assessment policy for MRL shall be reconsidered based on new issues and experience with the risk analysis of veterinary drugs. To this end, interaction with JECFA is essential. A review may be undertaken of the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRL has been recommended.

SECTION 4. RISK COMMUNICATION IN THE CONTEXT OF RISK MANAGEMENT

32. In accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCRVDF, in cooperation with JECFA, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

33. In order to ensure the transparency of the assessment process in JECFA, the CCRVDF provides comments on the guidelines related to assessment procedures being drafted or published by JECFA.

ANNEX: TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Administrative information

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names
5. Names and addresses of basic producers

Purpose, scope and rationale

6. Identification of the food safety issue (residue hazard)
7. Assessment against the criteria for the inclusion on the priority list

Risk profile elements

8. Justification for use
9. Veterinary use pattern
10. Commodities for which Codex MRLs are required

Risk assessment needs and questions for the risk assessors

11. Identify the feasibility that such an evaluation can be carried out in a reasonable framework
12. Specific request to risk assessors

Available information[9]

13. Countries where the veterinary drugs is registered
14. National/Regional MRLs or any other applicable tolerances
15. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

Timetable

16. Date when data could be submitted to JECFA

[9] When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.

RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR RESIDUES OF VETERINARY DRUGS IN FOODS

[for inclusion in Section III]

Role of JECFA

1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on veterinary drug residues in food.

2. This annex applies to the work of JECFA in the context of Codex and in particular as it relates to advice requests from the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

(a) JECFA provides CCRVDF with science-based risk assessments conducted in accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and incorporating the four steps of risk assessment. JECFA should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and proposing Maximum Residues Limits (MRLs).

(b) JECFA should take into account all available scientific data to establish its risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.

(c) Constraints, uncertainties and assumptions that have an impact on the risk assessment need be clearly communicated by JECFA.

(d) JECFA should provide CCRVDF with information on the applicability, public health consequences and any constraints of the risk assessment to the general population and to particular sub-populations and, as far as possible, should identify potential risks to specific group of populations of potentially enhanced vulnerability (e.g. children).

(e) Risk assessment should be based on realistic exposure scenarios.

(f) When the veterinary drug is used both in veterinary medicine and as a pesticide, a harmonised approach between JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should be followed.

(g) MRLs, that are compatible with the ADI, should be set for all species based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.

Data Protection

3. Considering the importance of intellectual property in the context of data submission for scientific evaluation, JECFA has established procedures to cover the confidentiality of certain data submitted. These procedures enable the sponsor to declare which data is to be considered as confidential. The procedure includes a formal consultation with the sponsor.

Expression of Risk Assessment Results in terms of MRLs

4. MRLs have to be established for target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice.

5. However, if residue levels in various target tissues are very different, JECFA is requested to consider MRLs for a minimum of two. In this case, the establishment of MRLs for muscle or fat is preferred to enable the control of the safety of carcasses moving in international trade.

6. When the calculation of MRLs to be compatible with the ADI may be associated with a lengthy withdrawal period, JECFA should clearly describe the situation in its report.

AMENDMENTS TO THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS ~~CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS~~

SECTION 1. SCOPE

1) This document addresses the respective applications of risk analysis principles by the ~~Codex Committee on Food Additives and Contaminants (CCFAC)~~ Codex Committee on Food Additives (CCFA) and the Codex Committee on Contaminants in Foods (CCCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters which cannot be addressed by JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.

2) This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

SECTION 2. ~~CCFAC~~ CCFA/CCCF and JECFA

3) ~~CCFAC~~ CCFA/CCCF and JECFA recognize that communication between risk assessors and risk managers is critical to the success of their risk analysis activities.

4) ~~CCFAC~~ CCFA/CCCF and JECFA should continue to develop procedures to enhance communication between the two committees.

5) ~~CCFAC~~ CCFA/CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.

6) JECFA, in consultation with ~~CCFAC~~ CCFA/CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by ~~CCFAC~~ CCFA/CCCF in preparing ~~its~~ their Priority List for JECFA. The JECFA Secretariat should consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

SECTION 3. ~~CCFAC~~ CCFA/CCCF

7) ~~CCFAC~~ CCFA/CCCF ~~is~~ are primarily responsible for recommending risk management proposals for adoption by the CAC.

8) ~~CCFAC~~ CCFA/CCCF shall base ~~its~~ their risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments[10], of food additives, naturally occurring toxicants, and contaminants in food.

9) In cases where JECFA has performed a safety assessment and ~~CCFAC~~ CCFA/CCCF or the CAC determines that additional scientific guidance is necessary, ~~CCFAC~~ CCFA/CCCF or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.

10) ~~CCFAC~~ CCFA's risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.

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[10] A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2) the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition is available).

11) ~~CCFAC~~ CCCF's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food.

12) ~~CCFAC~~ CCFA/CCCF's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.

13) ~~CCFAC~~ CCFA/CCCF's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described by JECFA.

14) ~~CCFAC~~ CCFA shall endorse maximum use levels only for those additives for which 1) JECFA has established specifications of identity and purity and 2) JECFA has completed a safety assessment or has performed a quantitative risk assessment.

15) ~~CCFAC~~ CCCF shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. ~~CCFAC~~ CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

16) ~~CCFAC~~ CCFA/CCCF shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food.

17) Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, ~~CCFAC~~ CCCF shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to ~~CCFAC~~ CCCF.

18) When establishing its standards, codes of practice, and guidelines, ~~CCFAC~~ CCFA/CCCF shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.

19) ~~CCFAC~~ CCFA/CCCF's risk communication with JECFA includes prioritising substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum levels or codes of practice for contaminants and naturally occurring toxicants in food.

20) ~~CCFAC~~ CCFA/CCCF shall consider the following when preparing their priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- ~~CCFAC~~ CCFA/CCCF's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan , its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e., magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,

– Work already undertaken by other international organizations;

21) When referring substances to JECFA, ~~CCFAC~~ CCFA/CCCF shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation;

22) ~~CCFAC~~ CCFA/CCCF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.

23) ~~CCFAC~~ /CCFACCCF requests JECFA to review any methods and guidelines being considered by ~~CCFAC~~ CCFA/CCCF for assessing maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants. ~~CCFAC~~ CCFA/CCCF makes any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for ~~CCFAC~~ CCFA/CCCF's work.

SECTION 4. JECFA

24) JECFA is primarily responsible for performing the risk assessments upon which ~~CCFAC~~ CCFA/CCCF and ultimately the CAC base their risk management decisions.

25) JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.

26) JECFA should strive to provide ~~CCFAC~~ CCFA/CCCF with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for ~~CCFAC~~ CCFA/CCCF's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA should determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this may be possible in only a few cases for the foreseeable future. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.

27) JECFA should strive to provide ~~CCFAC~~ CCFA/CCCF with science-based quantitative risk assessments and safety assessments for food additives, contaminants, and naturally occurring toxicants in a transparent manner.

28) JECFA should provide ~~CCFAC~~ CCFA/CCCF with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g., children, women of child-bearing age, the elderly).

29) JECFA should also strive to provide ~~CCFAC~~ CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.

30) JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.

31) JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants.

32) When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA should take into account regional differences in food consumption patterns.

33) JECFA should provide to ~~CCFAC~~ CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of ~~CCFAC~~ CCCF.

34) JECFA should communicate to ~~CCFAC~~ CCFA/CCCF the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide ~~CCFAC~~ CCFA/CCCF with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

35) JECFA should communicate to ~~CCFAC~~ CCFA/CCCF the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

36) JECFA's risk assessment output to ~~CCFAC~~ CCFA/CCCF is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius and Risk Analysis Principles applied by the ~~Codex Committee on Food Additives and Contaminants~~ Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods.

37) When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with ~~CCFAC~~ CCFA/CCCF to ensure that ~~CCFAC~~ CCFA/CCCF's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated. With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat should give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.

38) When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

AMENDMENTS TO THE CCFAC POLICY FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

~~CCFAC~~ POLICY OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

SECTION 1. INTRODUCTION

1. Maximum Levels ~~Limits~~ (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The Preamble of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF) states in Section 1.3.2 that "maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected". Setting standards for foods that contribute little to dietary exposure would mandate enforcement activities that do not contribute significantly to health outcomes.

2. Exposure assessment is one of the four components of risk assessment within the risk analysis framework adopted by Codex as the basis for all standard-setting processes. The estimated contribution of specific foods or food groups to the total dietary exposure to a contaminant as it relates to a quantitative health hazard endpoint (e.g. PMTDI, PTWI) provides further information needed for the setting of priorities for the risk management of specific foods/food groups. Exposure assessments must be guided by clearly articulated policies elaborated by Codex with the aim of increasing the transparency of risk management decisions.

3. The purpose of this Annex is to outline steps in contaminant data selection and analysis undertaken by JECFA when requested by ~~CCFAC~~ the Codex Committee on Contaminants in Foods (CCCF) to conduct a dietary exposure assessment.

4. The following components highlight aspects of JECFA's exposure assessment of contaminants and toxins that contribute to ensuring transparency and consistency of science-based risk assessments. Exposure assessments of contaminants and toxins in foods are performed by JECFA at the request of ~~CCFAC~~CCCF. ~~CCFAC~~CCCF will take this information into account when considering risk management options and making recommendations regarding contaminants and toxins in foods.

SECTION 2. ESTIMATION OF TOTAL DIETARY EXPOSURE TO A CONTAMINANT OR TOXIN FROM FOODS/FOOD GROUPS

5. JECFA uses available data from member countries and from GEMS/Food Operating Program for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g. PTDI, PTWI, or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake combined with data on carcinogenic potency to estimate potential population risks.

6. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the ~~GEMS/Food Regional diets~~GEMS/Food Consumption Cluster Diets to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the ~~GEMS/Food Regional diets~~GEMS/Food Consumption Cluster Diets are likely to approach or exceed the tolerable intake.

7. In some cases, available national contaminant and/or individual food consumption data may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children.

8. JECFA performs exposure assessments if requested by ~~CCFAC~~ CCCF using the ~~GEMS/Food Regional diets~~GEMS/Food Consumption Cluster Diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform ~~CCFAC~~ CCCF about these risk management options.

SECTION 3. IDENTIFICATION OF FOODS/FOOD GROUPS THAT CONTRIBUTE SIGNIFICANTLY TO TOTAL DIETARY EXPOSURE OF THE CONTAMINANT OR TOXIN

9. From dietary exposure estimates JECFA identifies foods/food groups that contribute significantly to the exposure according to ~~CCFAC's~~CCCF's criteria for selecting food groups that contribute to exposure.

10. The ~~CCFAC~~CCCF determines criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. These criteria are based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the ~~GEMS/Food Regional diets~~GEMS/Food Consumption Cluster Diets) for which dietary exposures exceed that percentage.

11. The criteria are as follows:

    a) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10%[11] or more of the tolerable intake (or similar health hazard endpoint) in one of the ~~GEMS/Food Regional diets~~GEMS/Food Consumption Cluster Diets;

    or,

    b) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5%[1] or more of the tolerable intake (or similar health hazard endpoint) in two or more of the ~~GEMS/Food Regional diets~~GEMS/Food Consumption Cluster Diets;

    or,

    c) Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the ~~GEMS/Food Regional diets~~GEMS/Food Consumption Cluster Diets. These would be considered on a case-by-case basis.

SECTION 4. GENERATION OF DISTRIBUTION CURVES FOR CONCENTRATIONS OF THE CONTAMINANT IN SPECIFIC FOODS/FOOD GROUPS (CONCURRENT WITH SECTION 2, OR SUBSEQUENT STEP)

12. If requested by ~~CCFAC~~CCCF, JECFA uses available analytical data on contaminant or toxin levels in foods/food groups identified as significant contributors to dietary exposure to generate distribution curves of contaminant concentrations in individual foods. ~~CCFAC~~CCCF will take this information into account when considering risk management options and, if appropriate, for proposing the lowest achievable levels for contaminants/toxins in food on a global basis.

13. Ideally, individual data from composite samples or aggregated analytical data would be used by JECFA to construct the distribution curves. When such data are not available, aggregated data would be used (for example mean and geometric standard deviation). However, methods to construct distribution curves using aggregated data would need to be validated by JECFA.

14. In presenting the distribution curves to ~~CCFAC~~CCCF, JECFA should, to the extent possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both the maximum and outlier values) and of the proportion of foods/food groups that contain contaminants/toxins at those levels.

SECTION 5. ASSESSMENT OF THE IMPACT OF AGRICULTURAL AND PRODUCTION PRACTICES ON CONTAMINANT LEVELS IN FOODS/FOOD GROUPS (CONCURRENT WITH SECTION 2, OR SUBSEQUENT STEP)

15. If requested by ~~CCFAC~~CCCF, JECFA assesses the potential impact of different agricultural and production practices on contaminant levels in foods to the extent that scientific data are available to support such assessments. ~~CCFAC~~CCCF takes this information into account when considering risk management options and for proposing Codes of Practice.

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[11] Rounded to the nearest 1/10th of a percent.

16. Taking this information into account, ~~CCFAC~~CCCF proposes risk management decisions. To refine them, ~~CCFAC~~CCCF may request JECFA to undertake a second assessment to consider specific exposure scenarios based on proposed risk management options. The methodology for assessing potential contaminant exposure in relation to proposed risk management options needs to be further developed by JECFA.