

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 6(a)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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COMMENTS ON PROPOSED DRAFT GUIDELINES AND PRINCIPLES FOR SUBSTANCES USED AS PROCESSING AIDS

The following comments have been received from the following Codex members and observers:

Chile, India, Malaysia, Switzerland and United States of America

Chile

Se hacen observaciones a los siguientes puntos:

- En el punto 3.0 DEFINICIÓN se opta por la indicada en el primer párrafo.
- [Por coadyuvante de elaboración se entiende toda sustancia o materia, excluidos aparatos y utensilios, que en cuanto tal no se utiliza como ingrediente alimentario y que se emplea intencionalmente en la elaboración de materias primas, alimentos o sus ingredientes, para lograr alguna finalidad tecnológica durante el tratamiento o la elaboración, pudiendo dar lugar a la presencia no intencional, pero inevitable, de residuos o derivados en el producto final.]
- En el punto 4.0 PRINCIPIOS PARA EL USO DE SUSTANCIAS UTILIZADAS COMO COADYUVANTES DE ELABORACIÓN SEGÚN CONDICIONES DE BUENAS PRÁCTICAS DE FABRICACIÓN (BPF), específicamente en el punto 4.2.2 solo considerar los dos primeros párrafos de los cinco indicados.
- En el punto 6.0 FINES TECNOLÓGICOS DE LAS SUSTANCIAS UTILIZADAS COMO COADYUVANTES DE ELABORACIÓN, no considerar (xxi) [Estabilizadores del color]

India

(i) The appropriate title for the proposed draft guidelines.

The proposed title for the draft Guidelines appears to be appropriate and hence the square brackets should be removed.

(ii) The correct definition of processing aids, and

SECTION 3.0 DEFINITION

The definition of the processing aids provided in the first paragraph of Section 3.0, which is the same as provided in the Codex Procedural Manual (17th Edition), is appropriate and acceptable.

(iii) Decision to be made whether the definition of substances used as processing aids need to be defined.

While we believe that substances used as processing aids are covered by the definition of processing aid and a separate definition may not be required as long as the proposed guidelines explains the term 'substances used as processing aid' distinctly with respect to the term processing aid. Therefore it should be specifically

emphasized in SECTION 2.2 SCOPE that, **“ it is the ‘use’ of a processing aid or substances used as processing aids in the product that determines whether it should be classified as processing aid or not”**.

With the above-proposed insertion, it would automatically follow that the very same substance, when used in another way, could also be classified as an additive.

(iv) The overall structure and completeness of the guideline.

The guidelines appear to be complete and appropriate in structure. However, the reference to the ‘Inventory of Substances Used as Processing Aids (IPA)’ in Sections 1.2, 4.2 (the portions ‘The Inventory of Processing Aids (IPA) associatesuse as processing aids.’ and ‘which can be found listed in the IPA.’) and 6.0 (second sentence) are irrelevant and inappropriate. These references therefore need to be deleted.

SECTION 1.0 INTRODUCTION, SUBSECTION 1.2

The last line should be editorially corrected as follows:

*“The IPA includes both substances only used as processing aids and those that can be both processing aids and food additives, depending on their use, processing methods and the food **they where are use where they are used.**”*

SUBSECTION 4.2.2.

We propose deletion of this SUBSECTION 4.2.2 and shifting the fifth bullet “• do not perform a technological function in the final food.” from SECTION 4.2.2 to SECTION 4.2 appropriately.

SECTION 5.2

Section 5.2, in its last sentence, mentions that in the absence of Codex recognized specifications of identity and purity for the substances used as processing aids, appropriate specifications developed by responsible national bodies may be complied with. This amounts to blanket endorsement of the specifications developed by any national bodies by the CCFA without having discussed them. This is not appropriate and is unacceptable from scientific point of view. Such an arrangement should be left to the importing and exporting countries’ authorities for a decision. Therefore, the text should be amended as follows:

*“Substances used as health. Substances used as ..., in the absence of such specifications, with appropriate specifications developed by responsible **national or international bodies.**”*

SUBSECTION 5.3 AND 5.6

Both convey the same meaning and section 5.6 may be deleted.

SUBSECTION 5.4

The safety of substance used as processing aids is a concern for manufacturers and not for the suppliers due to fact that it is the manufacturer who processes the food product and takes concern of the safety of food in relation to risk to consumers. Therefore, the text should be amended as follows:

*‘The safety of each substance used as processing aid should be **able to be demonstrated by the supplier manufacturer** of the substance, before the substance is placed on the market’*

SECTION 6.0

We propose the addition of adsorbents and fining agents to the list of processing aids.

(v) The appropriate section for the background of the IPA

SECTION 9.0 ROLE OF INVENTORY OF SUBSTANCES USED AS PROCESSING AIDS (IPA)

The Inventory of Substances Used as Processing Aids (IPA) lists substances under categories of technological purpose and provides information where this has been made available on use, residue levels, interaction with food, JECFA evaluations and ADI’s. We Support the IPA, since its value as a useful reference tool has been recognized for drawing up country positions. Hence, CCFA may consider the retention of the CAC/MISC 3 Inventory of Processing Aids document. Further, Section 9.3.5, which is in [], asking CCFA whether the old IPA document be retained or deleted (revoked), may be deleted. The CAC had endorsed that the IPA text was a Codex Advisory Text keeping in mind that additions to the inventory would be always possible. Hence the IPA list can be up-dated (which is not a Codex standard) any time.

Malaysia

Malaysia is of the view that the following be considered for clarity:

- To remove section 9.3 *Background to the IPA* from section 9.0 ROLE OF INVENTORY OF SUBSTANCES USED AS PROCESSING AIDS (IPA).
- To transfer section 9.3.1 and section 9.3.4 to section 1.0 INTRODUCTION and rearrange this section accordingly.
- To transfer section 9.3.2 and section 9.3.3 to section 9.0 and rearrange with existing sections 9.1 and 9.2
- To transfer section 9.3.5 to section titled "RECOMMENDATIONS AND REQUEST FOR COMMENT" in the document CX/FA 09/41/7.

Switzerland

INTRODUCTION

Switzerland would like to congratulate the E-Working Group led by Indonesia for the work they accomplished and for the results achieved on this complex issue. We acknowledge that significant progress has been made. Nonetheless, we are of the view that some issues might still require further discussion and clarification. We therefore sincerely appreciate the opportunity to contribute to the discussion as follows:

SPECIFIC COMMENTS

The Inventory of Processing Aids (IPA) was adopted by the Codex Alimentarius Commission at its 18th session in 1989 as a Codex advisory text and its **correct reference is CAC/MISC 3** and not MICS.

The document should be a general Guideline to Codex members and possibly to the private sector on how to ensure a safe use of processing aids using a risk-based approach. In our view, it should therefore be a *Guideline* without any intention to regulate processing aids on the international level using e.g. a positive list approach, for the time being. Thus, the Inventory of Processing Aids should maintain the status of a regularly updated document and not an exhaustive list.

In **Section 2.2 Scope**, we propose to introduce the scope with the following introductory sentence:

These Guidelines set out basic criteria for the safe use of substances used as processing aids in the preparation of foods and food ingredients that are subject to the Codex Alimentarius. The Scope of the guideline ...

We suggest that Section 3: Definition should be divided into two paragraphs. One paragraph that repeats the Processing aids definition as stated in the Codex Procedural Manual and the another one that lists conditions that provide further limitations that are, however, not essential to the technological definition of a processing aid.

The first paragraph under 3.1 is taken from the second option which is given in Draft Guidelines; the second one 3.2 is re-proposed by Switzerland. We consider it to be very important to state that these Guidelines do not apply to foods used as processing aids and to the manufacturing of food additives and flavourings. Section 3 would then read as follows:

Section 3.0 Definitions

New 3.1 Definition

Processing aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non intentional but unavoidable presence of residues or derivatives in the final product.

New 3.2 Conditions

Possible residues of processing aids shall not present any unacceptable health risk and shall not have any technological effect in the finished product. Food and food ingredients including water can be used for the same technological purpose as processing aids; such use does not turn them into processing aids falling under the definition above. Substances used in the manufacturing of food additives (including

flavourings) are not addressed by these Guidelines.

We propose the deletion of Section 4.2.2 which is simply a repetition of Section 3.0 on Definitions.

Under Section 4.3.2., we suggest to insert the word "possible" between "lowest level" as follows:

*The quantity of unintentional but unavoidable residues or derivatives of the substance remaining in food as a result of its use, should be reduced to the lowest **possible** level and present no health risk.*

In Section 4.3.3, we consider it to be sufficient that the substance used as a processing aid is "of appropriate food grade quality". Paragraph 4.3 refers initially to GMP which includes for food e.g. the HACCP approach and which therefore provides sufficient general guidance on how processing aids (like any other ingredient or apparatus used in a food premise needs to be controlled). We therefore suggest deleting the second part whose language is too vague.

The sentence would thus read as follows:

4.3.3 The substance is of appropriate food grade quality. as well as prepared and handled in a similar manner to other food ingredients or food additives.

Subsections 5.3 and 5.6 have the same meaning. We therefore suggest simplifying the text by using one sentence that replaces current 5.3; Section 5.6 would thus be deleted. Furthermore, it may be helpful to clarify the relation between a maximum level of use for a food additive and the acceptable residue level for a processing aid in the same food.

5.3 Amended as follows:

5.3 Processing aids should be used in foods at levels that ensure that any residues of the substance or its derivatives are below levels of toxicological concern. It is understood that for a substance for which a maximum level of use for a food additive is set, this level would also apply to any residues resulting from its use as a processing aid.

5.6 Deleted

We note that there are some technological functions missing in Section 6.0 Technological Purposes of Substances Used as Processing Aids. These are *decolourants, adsorbent agents, carriers, diluents, bleaching, enzymes (specifically of animal, plant and microbial origin), microbial nutrients & microbial nutrient adjuncts*. However, we wonder whether it is really necessary to have Section 6.0 as an exhaustive list of functions or whether such uses would be covered by (xxii) Other processing aids propose.

Under Section 8.2. it would be useful to clarify that processing aids should comply with any *applicable* microbiological criteria:

*8.2 Processing aids should comply with any **applicable** microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).*

We propose the deletion of the last two sentences in 9.2 since, in our view, it is not appropriate to mention in the current draft document, future work which could possibly be undertaken by Codex in the absence of any clearly defined work programme in this respect.

Therefore, 9.2 would read as follows:

*9.2 The IPA is a working document for the Codex Committee on Food Additives (CCFA) but it may also be used by others. Its role is to collect information by updating the original 1989 IPA CAC/MISC 3. **The IPA is likely to be updated at following meetings of CCFA until such time that CCFA considers the development of a standard for substances used as processing aids. This would involve a substantial review and relevant risk assessment.***

We sincerely appreciate the opportunity to submit our comments on this important Agenda item on Processing Aids and we look forward to an interesting exchange of views at the forthcoming session of the Codex Committee on Food Additives.

United States of America

This responds to CX/FA 09/41/7 (December 2008) which requests comments for additional revisions to the *Proposed Draft Guidelines and Principles for Substances Used as Processing Aids*. The United States appreciates the opportunity to provide the following comments for consideration at the forthcoming 41st Session of the Codex Committee on Food Additives (CCFA).

Responding to the request for an appropriate title for the proposed draft guidelines, the United States suggests that the title be revised to read: “*Proposed Draft Guideline for the Use of Substances as Processing Aids*.” Since the articulation of principles of safe use is one of the main purposes of Codex guidelines, we think it may be unnecessary to include the word “Principles” in the title.

With respect to the proposed definitions for the term “processing aid,” the United States notes that the Codex Alimentarius Commission (CAC) has adopted a definition for the term processing aid (Procedural Manual, 17th Ed., p. 41). We suggest that the proposed draft guideline use the definition already adopted by the CAC.

Paragraphs 4.1 and 4.2 of the proposed draft guideline describe the relationship between food additives and processing aids, and provides a useful chart to illustrate that relationship. This information will be helpful to users of this guideline. However, paragraph 4.2.1 appears to restate that which was described in paragraphs 4.1 and 4.2. In addition, paragraph 4.2.2 appears to be a restatement of the Codex definition of a processing aid (Section 3.0), with some additional conditions applied. These additional conditions may lead to potential confusion regarding the application of the Codex definition of processing aid in the future. The United States therefore suggests the following: (i) revising the header to Section 4.0 to read: “*The Relationship between Food Additives and Processing Aids*;” (ii) eliminating paragraphs 4.2.1 and 4.2.2; and (iii) moving paragraphs 4.3 and 4.3.1 through 4.3.3 under paragraph 5.0. If this suggestion is agreeable, then all principles for safe use of substances as processing aids would be listed under a single heading (Section 5.0). It is not clear to us why the proposed draft guideline currently has two sections describing principles of safe use.

The United States proposes that the final phrase at the end of paragraph 5.2 (“*with appropriate specifications developed by responsible national or international bodies*”) be deleted. This requirement is implicit in all Codex guidelines, and its explicit inclusion here may attribute more significance than is intended. For the same reason, we suggest the elimination of paragraph 7.2.

The United States recommends that the list of technological purposes in Section 6.0 (*Technological Purposes of Substances Used as Processing Aids*) be deleted, and a reference to the Inventory of Processing Aids (IPA) only be made. The IPA currently contains a list of technological functions. Since the IPA will be used together with the proposed draft guideline, the United States believes that it is unnecessary to duplicate the list in the proposed draft guideline. We note that, if the list of technological purposes were to be included in the proposed draft guideline, the list would need to be updated, as additional technological purposes for substances used as processing aids are identified. Eliminating the list of technological purposes in the proposed draft guideline, and referring to the IPA only, would eliminate the need for any future revisions to the list.

The United States also suggests moving the information in paragraphs 9.1 and 9.2 to the beginning of the proposed draft guideline under the heading *Introduction* (Section 1.0). An understanding of the relationship between this proposed draft guideline and the IPA, as well as the role of the IPA in Codex, provides necessary context for understanding the remainder of the proposed draft guideline.

Finally, the United States notes that the information under paragraph 9.3 (*Background to the IPA*), is of a type that does not normally appear in a Codex guideline. We suggest moving this information to the discussion paper accompanying the proposed draft guideline.