

# codex alimentarius commission

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FOOD AND AGRICULTURE  
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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6 (a)

CX/FA 10/42/10  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

Forty-second Session

Beijing, China, 15-19 March 2010

### PROPOSED DRAFT GUIDELINES AND PRINCIPLES FOR SUBSTANCES USED AS PROCESSING AIDS (N14-2008)

Prepared by the electronic Working Group led by Indonesia with the assistance of Armenia, Australia, Belgium, Brazil, European Community, France, Germany, Japan, Malaysia, New Zealand, South Africa, Switzerland, United Kingdom, United States of America, AMFEP, CEFS, CEFIC, ETA, IADSA, ICGMA, IDF, IFAC, IFT, IOFI and IOV.

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the document are invited to do so **no later than 31 January 2010** as follows: Secretariat, Codex Committee on Food Additives, National Institute of Nutrition and Food Safety, China CDC, 7 Panjiayuan Nanli, Chaoyang District, Beijing 100021, China (Telefax: + 86 10 67711813, E-mail: [secretariat@ccfa.cc](mailto:secretariat@ccfa.cc) *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39 06 5705 4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org) - *preferably*).

#### BACKGROUND

1. At the 41<sup>st</sup> Session of Codex Committee on Food Additives, in view of the extensive comments received and time constraints, the Committee agreed not to consider the proposed draft Guidelines at this session and to consider a further revision at its next session. The Committee agreed to return the proposed draft Guidelines and Principles to Step 2 for redrafting by an electronic Working Group hosted by Indonesia, which would prepare revised proposed draft Guidelines. The Committee noted that many comments had been submitted and that there were still several unresolved issues, such as the title and scope of the document, the need for a definition of substances used as processing aids and the function of the IPA.

#### PROCEEDING OF THE ELECTRONIC WORKING GROUP

2. In June 2009, Indonesia invited all member countries interested in participating in the e-WG to provide contact information by June 30, 2009. The expressions of interest in participating were received from 25 members.

3. EWG members were invited to provide comments to the entire section of the proposed draft guidelines. The eWG made two circulations on the proposed draft guidelines. On the first circulation 12 members of the eWG forwarded their comments and on the second circulation 10 members forwarded their comments.

4. In particular the following comments were made:

**Title**

5. One member of the eWG proposed to change the title to be “PROPOSED DRAFT GUIDELINES FOR THE USE OF SUBSTANCES USED AS PROCESSING AIDS” because it is more accurate and reflects the title agreed in Alinorm 08/31/12. But most of members of the eWG agreed to simplify the title because it is more describe the content of the Guidelines. The Committee may further discuss this item at this current meeting.

**Objective and Scope**

6. Some members of the eWG proposed to delete the example of food used as processing aids (water and fats or oils) because those products are explicitly excluded from the definition of processing aids in the CAC Procedural Manual. But the coordinator and other members of the eWG considered that it is more informative to mention examples of food used as processing aids. This information is more describe the scope of substances used as processing aids and important, especially for developing countries which have not regulate the use of processing aids.

**Definition**

7. Some members of the eWG supported the definition of processing aids to be consistent with the definition in the CAC Procedural Manual. Other members of eWG proposed to modify the definition of Processing Aids recognizing that some foods can be used as processing aids. The Committee may further discuss this matter or established other eWG to consider the revision of the definition of processing aids.

**Principles for the Safe Use of Substances Used as Processing Aids**

8. Many comments and recommendations received regarding to this section with the result that this section became more comprehensive. The points of this section clarify:

- Point 1. It stated that residues left after removing the processing aid from the food should not perform a technological function in the final product.
- Point 2. Good Manufacturing Practices Principles.
- Point 3. Safety assessment
- Point 4. Specification of substances which have food additive and processing aid functions
- Point 5. Compliance with any applicable microbiological criteria

**Technological Purposes of Substances Used as Processing Aids**

9. It is agreed to refer the technological purposes of processing aids to the Inventory of Substances Used as Processing Aids (IPA) since the technological purposes of processing aids of IPA is being developed continuously.

**Annex : The Range of Substances Used as Processing Aids**

10. As suggested by one member of the eWG, The coordinator tried to modify the diagram to clarify the range of substances used as processing aids. The diagram takes into account the *Codex Procedural Manual* definitions and the scope of the *General Standard for Food Additives (GSFA)* and the IPA

**RECOMMENDATIONS TO THE COMMITTEE**

11. The Proposed Draft Guidelines on Substances Used as Processing Aids is presented in Appendix 1.
12. The Committee may wish to consider the content of Appendix 1, with the view of forwarding this for adoption at step 5 to the Codex Alimentarius Commission.

**Appendix 1****PROPOSED DRAFT GUIDELINES ON SUBSTANCES USED AS PROCESSING AIDS**

(N14-2008)

(At Step 3)

**1.0 OBJECTIVES AND SCOPE**

1.1 The Guidelines aim to provide information for the safe use of substances used as processing aids in the preparation of foods and food ingredients.

1.2 The Guidelines cover all substances used as processing aids, recognizing that some foods (for example water and fats or oils) and food additives may also be used as processing aids to perform a technological function in the processing of food.

**2.0 DEFINITION**

2.1 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 fulfil a certain technological function during treatment or processing and which may result in the unintentional but unavoidable presence of residues or derivatives in the final product.<sup>1</sup>

2.2 The Annex includes a diagram to help clarify the range of substances used as processing aids.

**3.0 PRINCIPLES FOR THE SAFE USE OF SUBSTANCES USED AS PROCESSING AIDS**

3.1 The use of a substance as a processing aid is justified when such use performs one or more technological functions during treatment or processing of raw materials, foods, or ingredients. The residues left after removing the processing aid from the food should not perform a technological function in the final product.

3.2 Substances used as processing aids shall be used under conditions of good manufacturing practices (GMP) which includes the following:

- The quantity of the substance used shall be limited to the lowest possible level necessary to accomplish its desired technological function;
- Residues or derivatives of the substance remaining in food should not pose any health risk;
- The substance is prepared and handled in the same way as a food ingredient.

3.3 The safety of a substance used as a processing aid should be demonstrated by the supplier or the user of the substance. The demonstration of safety should include appropriate assessment of any unintended or unavoidable residues when the substance is used as a processing aid under conditions of GMP. Examples of the type of information considered to be adequate to demonstrate safety may include:

- Reference to an evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), including an acceptable daily intake (ADI) and specification, where applicable.
- Data demonstrating a long history of safe use as a processing aid.

3.4 Substances used as processing aids should be of food grade quality. This can be demonstrated by conforming to the applicable specifications of identity and purity recommended by the Codex Alimentarius Commission or, in the absence of such a specification, with an appropriate specification developed by responsible national or international bodies or suppliers. Substances used as processing aids that are also used as food additives should meet the appropriate food additive specifications (e.g., JECFA Combined Compendium of Food Additive Specifications).

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<sup>1</sup> Codex Procedural Manual, "Section I : Definitions for the purpose of the Codex Alimentarius"

3.5 Substances used as 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).

#### **4.0 TECHNOLOGICAL PURPOSES OF SUBSTANCES USED AS PROCESSING AIDS**

4.1 Substances may have a variety of technological purposes when used as processing aids. These technological purposes are categorized in the Inventory of Substances Used as Processing Aids (IPA).

#### **5.0 LABELLING**

5.1 Labelling of substances used as processing aids should be in accordance with the requirement of the Codex General Standard for Labelling of Food Additives When Sold as Such (CODEX STAN 107-1981) and the Codex General Standard for the Labelling of Prepackaged Food (CODEX STAN 1-1985).

5.2 Labelling of products containing substances used as processing aids shall be consistent with requirement in the country of sale.

#### **6.0 ROLE OF THE INVENTORY OF SUBSTANCES USED AS PROCESSING AIDS (IPA)**

6.1 The IPA lists substances under categories of technological function and provides information, where available, on use, residue levels, interaction with food, and JECFA evaluations and ADIs.

6.2 The original IPA (CAC/MISC 3), which was made available in 1989, consisted of a list of substances used as processing aids compiled from national authorities, and was forwarded to the Commission for adoption as an advisory text. Subsequent updates of the IPA collected information on the current uses of processing aids, and served as an information document for the Codex Committee on Food additives (CCFA) and other Committees. As such, the IPA and this guideline provide valuable guidance on principles of safe use of substances used as processing aids in order to reduce trade conflicts and assist governments in the development of national policies pertaining to processing aids.

6.3 The role of the IPA is only to provide information on substances currently used as processing aids. Due to its ad hoc development, the IPA is not a complete list and is not intended as a positive list of permitted substances to be used as processing aids. The information contained in the IPA has neither been reviewed as a whole, nor have specific risk assessments for the substances in the IPA been performed for their use as processing aids. As such, the IPA is not intended for use as a Codex standard, and updates to the IPA are not forwarded to the Commission for adoption.

**ANNEX: THE RANGE OF SUBSTANCES USED AS PROCESSING AIDS**

The diagram below shows the range of substances used as processing aids. The diagram takes into account the definitions for these substances in the Codex Procedural Manual and the scope of the General Standard for Food Additives (GSFA; CODEX STAN 192-1995) and the IPA. The diagram is intended to include all substances used as processing aids and recognizes that some foods and food additives may also be used to perform a technological function in the processing of food. It is important to note that the term food additives includes substances used as processing aids, and that the GSFA does not include flavourings or substances used only as processing aids nor the processing aid functions of listed food additives.

**The Range of Substances Used as Processing Aids**

