

# codex alimentarius commission E



FOOD AND AGRICULTURE  
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Agenda Item 6(a)

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Forty-first Session

Shanghai, China, 16-20 March 2009

### PROPOSED DRAFT GUIDELINES AND PRINCIPLES FOR SUBSTANCES USED AS PROCESSING AIDS

(N14-2008)

(At Step 3)

(prepared by Indonesia, with the assistance of Australia, Belgium, Brazil, China, Dominican Rep, European Commission, Germany, Ireland, Japan, Malaysia, Mexico, New Zealand, Norway, Switzerland, Sweden, UK, USA, AMFEP, CEFIC, CEFS, ETA, IADSA, ICBA, ICGA, ICGMA, IDF, IFAC, and IOFI)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the attached proposed draft Guidelines and Principles are invited to do so **no later than 31 January 2009** 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*).

## INTRODUCTION

1. The 40<sup>th</sup> session of the Codex Committee on Food Additives agreed to establish an electronic Working Group, led by Indonesia and open to all interested members and observers, which would prepare proposed draft Guidelines and Principles for Substances Used as Processing Aids for circulation at step 3, subject to approval by the 31<sup>st</sup> Session of the Commission.

2. The 31<sup>st</sup> Session of the Codex Alimentarius Commission approved Guidelines and Principles for Substances used as Processing Aids as new work.

## PURPOSE

3. These Guidelines are intended to provide information on the criteria to identify processing aids, their safe use, and general use categories and to assist Governments to develop relevant national policies. The list of substances used as processing aids can be found in the Inventory of Substances Used as Processing Aids (CAC/MISC 3, updated annually by the Codex Committee on Food Additives). It is not intended to be a complete or positive list of permitted substances used as processing aids, but an international reference document to reduce trade conflicts. 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.

4. This paper contains, as Appendix I, a proposed draft Guidelines and Principles for [the use of] Substances used as Processing Aids with the following main elements:

1. Introduction
2. Objective and Scope

3. Definition
4. Principles for Use of Substances Used as Processing Aids Under Conditions of Good Manufacturing Practices (GMP)
5. General Principles for the Safe Use of Substances Used as Processing aids and the Safety of Their Residues in Food
6. Technological Purposes of Substances Used as Processing Aids
7. Labelling
8. Hygiene
9. Role of Inventory of Substances Used as Processing Aids (IPA)

## **RECOMMENDATIONS AND REQUEST FOR COMMENT**

5. Indonesia as the the lead country for the working group made twice circulations on the proposed draft and received a lot of comments and proposals from members of the working group. The first draft was circulated on June 23, 2008 and after the first circulation the working group agreed to add section for Hygiene in the draft guidelines. The second draft was circulated on November 05, 2008 and after the second circulation the working group agreed to add section Introduction so that the reader of the draft guideline can quickly understand the purpose and value of the document. Although Indonesia had tried to accomodate all comments and proposals but several proposals were very difficult to be decided, therefore some sections were put in the square brackets so that the committee could make decision on these parts.

6. One member of the working group considered that the background information in Section 9. Role of inventory of substances used as processing aids used (IPA) which can be found in Appendix I contains information that is not typically found in Codex Guidelines and suggested that the background information be removed from the draft guidelines and incorporated into the discussion document. Decision cannot be made on this part since the background information were proposed by other member of the working group to be included in the draft guidelines.

7. In addition Codex members are encouraged to provide comments and additional information on the attached proposed draft Codex Guidelines and Principles for the Use of Substances used as Processing Aids (Appendix I) for consideration by the Committee. In particular comments and specific information are requested relating to:

- (i) the appropriate title for the proposed draft guidelines.
- (ii) the correct definition of processing aids.
- (iii) decision to be made whether the definition of substances used as processing aids need to be defined.
- (iv) the overall structure and completeness of the guideline.
- (v) the appropriate section for the background of the IPA.

**Appendix I****PROPOSED DRAFT GUIDELINES AND PRINCIPLES FOR [THE USE OF] SUBSTANCES USED AS PROCESSING AIDS****(N14-2008)****(At Step 3)****1.0 [INTRODUCTION]**

1.1 Processing aids have an important role in food processing. The Inventory of Substances Used as Processing Aids (CAC/MISC 3, updated annually by the Codex Committee on Food Additives) is a compilation of substances used as processing aids from national authorities. It is not intended to be a complete or positive list of permitted substances used as processing aids, but an international reference document to reduce trade conflicts.

1.2 These guidelines and principles, built on existing definitions for “food additives” and “processing aids” found in the Codex Procedure Manual, are intended to provide information on the criteria to identify processing aids, their safe use, and general use categories. 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. ]

**2.0 OBJECTIVES AND SCOPE****2.1 Objectives**

These guidelines aim to provide principles for the safe use of substances used as processing aids and assist Governments to develop national policies and also to explain the role of the Inventory of Substances Used as Processing Aids (IPA).

**2.2 Scope**

The scope of the guideline are composed of the following sections: definition, principles for use of substances used as processing aids under condition of Good Manufacturing Practices (GMP), general principles for the safe use of substance used as processing aids and the safety of their residues in food, technological purposes of substances used as processing aids, labelling, hygiene, and the role of inventory of substances used as processing aids used (IPA).

**3.0 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 fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivative in the final product.]

Or

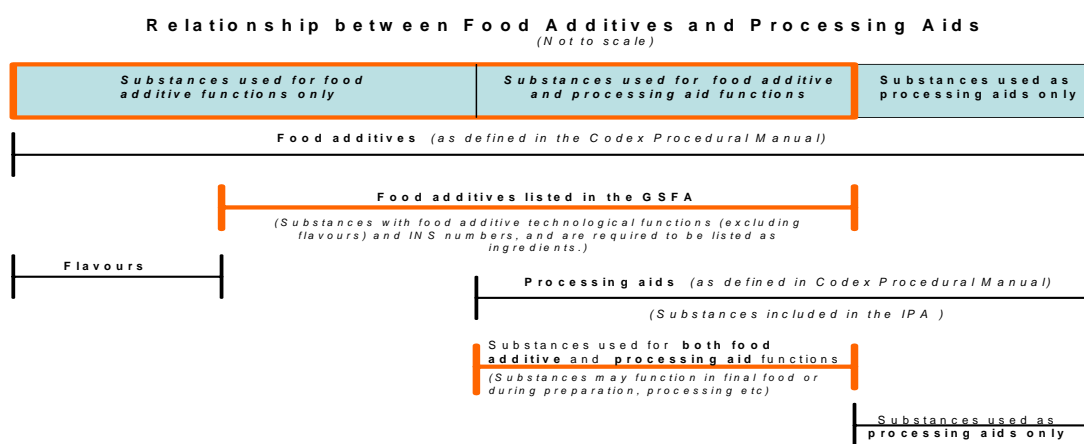
[A Processing Aid means any substance, not including apparatus or utensils and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients to fulfill a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.]

**4.0 PRINCIPLES FOR USE OF SUBSTANCES USED AS PROCESSING AIDS UNDER CONDITIONS OF GOOD MANUFACTURING PRACTICES (GMP)**

4.1 The diagram below shows the relationship between food additives and 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. It is important to note that the term *food additives* as defined in the *Codex Procedural Manual*, includes substances used as processing aids, and that the GSFA

does not include flavours or substances used only as processing aids [or any processing aids functions of listed food additives].

4.2 Although processing aids fall within the Codex definition of food additives, the food additive provisions in the General Standard for Food Additives (GSFA) (CODEX STAN 192-1995) do not include listings for the use of substances as processing aids. Substances that are used as processing aids have technological purposes in food during its treatment or processing but, unlike the additive uses they are not expected to be present at levels that would provide any technological effect in the finished food. The Inventory of Processing Aids (IPA) associates substances that are used as processing aids with their processing aid technological functions. Most substances listed in the IPA have not been assigned an acceptable daily intake (ADI), or otherwise reviewed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Some food additives listed in the GSFA for technological purposes in finished food are also listed in the IPA for technological purposes corresponding to their use as processing aids. This guideline covers substances used as processing aids rather than referring to just processing aids as defined above, to recognize that some foods and food additives may also be used to perform a technological purpose in the processing of food, for example water and fats or oils which can be found listed in the IPA.



4.2.1 Refers to section 4.1, It should be clear that substances used as processing aids include:

- substances which may also be used as food additives, and/or
- substances other than food additives used as processing aids
- foods, inclusive of water, although not meeting the definition of processing aid, can be used for the same technological purpose as processing aids.

4.2.2 Therefore, substances used as processing aids are:

- intentionally used in the processing of raw material, foods or its ingredients;
- used to fulfill a technological purpose during treatment or processing food;
- [generally not consumed as a food ingredient by itself but may include substances that may also function as food additives or be consumed as food;
- may result in the unintentional but unavoidable presence of residues or derivatives in the final product, provided that these residues do not present any health risk;
- do not perform a technological function in the final food.]

4.3 Substances used as processing aids shall be used under conditions of GMP which includes the following:

4.3.1 The quantity used shall be limited to the lowest level necessary to accomplish its desired technological purpose;

4.3.2 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 level and present no health risk;

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.

## **5.0 GENERAL PRINCIPLES FOR THE SAFE USE OF SUBSTANCES USED AS PROCESSING AIDS AND THE SAFETY OF THEIR RESIDUES IN FOOD**

5.1 The use of a processing aid is justified when such use performs one or more technological purpose as listed in the IPA, and only where other means are not economically or technologically practical.

5.2 Substances used as processing aids should meet established specifications on chemical identity and purity, suitable for use in food. Unavoidable impurities should not be present in the finished food at levels that would pose an unacceptable risk to health. Substances used as processing aids should be of appropriate food grade quality by conforming with the applicable Specification of Identity and Purity recognized by the Codex Alimentarius Commission or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies.

5.3 Substances used as processing aids should not lead to unsafe levels of the substance or its derivatives in final food.

5.4 The safety of each substance used as processing aid should be able to be demonstrated by the supplier of the substance, before the substance is placed on the market. This may include reference to a JECFA evaluation including an Acceptable Daily Intake (ADI) and specification where applicable or information on long history of safe use coupled with suitable analytical results showing the absence of residues, or presence of harmless and technically unavoidable residues.

5.5 The demonstration of safety of use of a processing aid should include appropriate assessment of any unintended or unavoidable residues of substances used as processing aids under conditions of GMP to ensure these do not cause any unacceptable harm to the health of the consumer.

5.6 The level of use of a substance used as a processing aid should ensure that the level of residues of the substances used is below any level of toxicological concerns.

5.7 Substances used as processing aids that are also used as food additives should meet a food additive specification.

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

Substances used as processing aids may have different technological purposes in food processing. According to the Inventory of Substances Used as Processing Aids, the technological purposes of processing aids include among others:

- (i) Antifoam agents
- (ii) Boiler water additives
- (iii) Catalysts
- (iv) Clarifying agents/filtration aids
- (v) Contact freezing and cooling agents
- (vi) Desiccating agents/anticaking agents
- (vii) Detergents/wetting agents
- (viii) Enzyme immobilization agents and supports
- (ix) Enzyme preparations including immobilized enzymes
- (x) Flocculating agents
- (xi) Ion exchange resins, membranes and molecular sieves (include counter ions for resins)
- (xii) Lubricants, release and anti stick agents, moulding aids
- (xiii) Microorganism control agents
- (xiv) Propellant and packaging gases

- (xv) Solvents, extraction and processing
- (xvi) Washing and peeling agents
- (xvii) [Corrosion inhibitors (oxygen consuming substances e.g. sulphites)]
- (xviii) [Precipitation agents (removing alkaline earth metals e.g. calcium from brine by precipitation with carbonates)]
- (xix) [pH regulators (use of alkaline substances e.g. caustic soda to increase the pH in brine, from which the salt is crystallized)]
- (xx) [Anti-scaling agents (use of substances which prevent metallic surfaces e.g. heat exchangers from the formation of incrustations)]
- (xxi) [Colour stabilizer]
- (xxii) Other processing aids

## **7.0 LABELLING**

7.1 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 Foods (CODEX STAN 1-1985).

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

## **8.0 [ HYGIENE**

8.1 It is recommended that processing aids covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), and other relevant Codex texts such as Codes of Hygiene Practices and Codes of Practices.

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

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

9.1 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. The range of substances included in the IPA is shown in the diagram in section 4. It covers substances used as processing aids rather than referring to just processing aids as defined above, to recognize that some foods and food additives may also be used to perform a technological purpose in the processing of food.

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/MICS 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.

### **9.3 Background to the IPA**

9.3.1 The IPA includes all substances listed in the original IPA CAC/MICS 3 and additions agreed to by CCFA meetings. The original IPA CAC/MICS 3 is a collection of information submitted by national authorities to provide a list of those substances whose sole function is that of processing aid. The 21<sup>st</sup> session in 1989, Codex Committee on Food Additives and Contaminants (CCFAC) agreed that the IPA be submitted to the CAC for adoption as a Codex advisory text. It was first published as a Codex advisory in 1991 and included amendments agreed to at the CCFAC meetings in 1990 and 1991. The 1995 Codex publication (volume 1A, section 5.8) is the same as that published in 1991.

9.3.2 On initiation of the list, CCFAC's primary purposes for the IPA were to develop information on substances used as processing aids and to determine priorities for the review of processing aids by JECFA.

9.3.3 The CCFAC agreed that the IPA was not intended to be a positive list of permitted processing aids to be used, for example, by reference in Codex Commodity Standards. Further, CCFAC or subsequently CCFA has not considered any risk assessment of any of substances on the inventory.

9.3.4 The 36<sup>th</sup> Session of the CCFAC recognized that the development of a positive list of processing aids was not a realistic approach at the present time due to a lack of resources. However, the value of the Inventory of Processing Aids or as it has since been renamed Inventory of Substances Used as Processing Aids (IPA) itself, as a useful reference tool has been recognized and the Committee agreed to maintain the IPA for the time being and decided that an updated version of the IPA would be prepared for consideration at subsequent session of the committee.

[9.3.5 CCFA may consider the need to retain the old CAC/MISC 3 Inventory of Processing Aids document and decided whether this should be deleted]