codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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DISCUSSION PAPER ON GUIDELINES AND PRINCIPLES ON THE USE OF PROCESSING AIDS

(Prepared by Indonesia with the assistance of New Zealand, Russia and United State of America (USA), Association of Manufactures of Fermentation Enzyme Products (AMFEP), Enzyme Technical Association (ETA), International Dairy Federation (IDF), International Food Additives Council (IFAC) and Institute of Food Technologists (IFT)

BACKGROUND

1. The main purpose of Codex Alimentarius Commission (CAC) in developing internationally adopted food standards is to protect consumer health and ensure fair practices in food trade.

2. The presence of processing aids in the final food product may pose a health hazard. There is a risk that not all substances listed in Inventory of Processing Aids (IPA) Codex have been reviewed by JECFA.

3. The delegation of New Zealand prepared the first discussion paper on processing aids which was then presented to the 33rd session of the Codex Committee on Food Additives and Contaminants (CCFAC) in 2001 for review. This discussion paper contains sections concerning processing aids, current Codex definitions for food additives and processing aids and several options concerning the future consideration of processing aids, including the option of including processing aids in the Codex General Standard for Food Additives. After reviewing the discussion paper, the Committee decided that a drafting group led by New Zealand would prepare another (second) discussion paper on the consideration of processing aids in the context of the GSFA

4. The second discussion paper (CX/FAC 02/9) on processing aids and carriers highlighted the following issues: definitions of processing aids, consideration of a horizontal approach to processing aids and the role of the existing IPA. Several other options on how processing aids should be handled by CCFAC were further presented in this discussion paper. One of the options was that of a horizontal approach to the regulation of processing aids. This horizontal approach proposed the inclusion of processing aids in the Codex General Standard for Food Additives (GSFA) (CX STAN 192).

5. The 35th session of CCFAC decided not to consider the inclusion of processing aids into the GSFA for the time being. In view of the difficulty in incorporating processing aids into the Codex General Standard for Food Additives and the potential related delays in finalizing the text.

6. The 36th session of the CCFAC recognized that the development of a positive list of processing aids was not a realistic approach to resolving the issue. The committee acknowledged that provisions for processing aids were already included in commodity standards. It agreed to consider the need for developing guidelines, for Governments to address various aspects such as principles for the use of processing aids and their control; advice on Good Manufacturing Practice (GMP); information on handling; etc. However, the committee could not identify a delegation willing to prepare a document dealing with these issues.

7. The Committee accepted the offer of the Delegation of New Zealand to prepare a further updated version of the IPA which would also include the proposals made at the current meeting for consideration at the next session of the Committee. It further agreed that an introductory text with an explanation of changes, suggestions on the use of the IPA and possible future work would be included in this document.

8. During its 38th session, which was held from April 24 to 28, 2006, in the Hague, the CCFAC agreed to establish an electronic working group led by Indonesia with the assistance of New Zealand and Russia, Association of Manufactures of Fermentation Enzyme Products (AMFEP), Enzyme Technical Association (ETA), International Dairy Federation (IDF), International Food Additives Council (IFAC) and Institute of Food Technologists (IFT) in order to prepare a discussion paper on guidelines and principle on the use of processing aids which would address: technological justification; safe use and suitable controls on processing aids; the relationship between processing aids and food additives; and other issues related to processing aids.

9. A few countries have regulations covering processing aids such as Australia-New Zealand, Japan, Philippines, United State of America (USA), Canada and Malaysia (Malaysia's definition of food conditioner includes processing aids and certain food additives).

GENERAL OVERVIEW OF COMMENTS RECEIVED

10. The electronic working group discussion had developed the first proposed draft guidelines and circulated for comments in December 2006. As a lead country, Indonesia received some comments from New Zealand, AMFEP, ETA and IFT. Surprisingly, the USA gave some constructive comments even though in the last meeting the USA did not offer to be one of the members of electronic working group discussion. The working group discussion appreciated the attention of USA in improving the discussion paper.

11. According to the comments received from the member of electronic working group discussion, the discussion was emphasized on the relationship of processing aids and food additives, general principles and labelling.

12. On the basis of the comments received and took into account the concern of discussion above, the Government of Indonesia tried to formulate the final discussion paper on guidelines and principles on the use of processing aids.

INTRODUCTION

13. Several countries have varying definitions of processing aid. Some of these are given below in Attachment 1. There is presently no consensus among Codex members on a definition of processing aid, as illustrated by the attached list. If its desired to establish criteria for inclusion of a compound in the IPA, agreement on a Codex definition will be needed.

14. The other issues raised by the 38th CCFAC in paragraph 8 above are addressed herein.

RELATIONSHIP BETWEEN FOOD ADDITIVES AND PROCESSING AIDS

15. Some confusion exists over when a substance is used as a processing aid and when it is used as a food additive. Under Codex, food additives means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food result, or may be reasonably expected to result, (directly or indirectly) in it or its by products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities. Meanwhile, processing aids 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.

16. Confusion is possible due to the complex definition of food additives and processing aids provided in the Codex Procedural Manual. A comparison of the two codex definition is provided in the table below:

Food Additives	Processing Aids
Any substance	Any substance or material, not including apparatus or utensils
Not normally consumed as a food by itself and not normally used as a typical ingredient of the food	And not consumed as a food ingredient by it self
Whether or not it has nutritive value	
The intentional addition of which to food	Intentionally used in the processing of raw materials, foods or its ingredients,
For a technological purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food	To fulfill a certain technological purpose during treatment or processing and
Result, or may be reasonably expected to result, (directly or indirectly) in it or by-product becoming a component of	Which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product
Or otherwise affecting the characteristic of such foods	

17. In terms of the Codex definitions the key distinguishing features of processing aids from other food additives are:

- they must be intentionally used during the processing of raw materials, foods or ingredient; and
- they are used to fulfill a technological purpose during treatment or processing and not a function in the final food; and
- the presence of any residue of the substance must be non intentional and unavoidable

18. It should be clear that substances used as processing aids include:

- Foods, including water
- Food additives, and/or
- Other substances used to as a processing aid that are also not used as food or a food additive.

19. According to CAC/MISC/3 the classification of substance used as processing is divided into two Appendices as follow :

a) Appendix A is all substances that are annotated according to the following system:

- Group 1: indicates a processing aid that clearly fits the definition of "processing aid" above
- Group 2: indicates those materials that are both food additives and processing aids (i.e. the substance functions as a processing aid in one food but may have a different function in another food).
- Group 3: indicates those compounds that because of carry-over residues, would seem to usually be considered only as food additives.
- Group 4: indicates those materials that might actually have simultaneous function as processing aids and functionality in the finished food.

b) Appendix B is a list of the Microbial Enzyme Preparation

20. According to the New Zealand updated version of IPA (April 2006), the classification of substance used as processing aids consists of two parts as follow:

(1) The main inventory includes processing aids that clearly fits the definition of "processing aid" (group 1) and microbial enzymes preparation

(2) Appendix A includes:

- materials that are both food additives and processing aids (i.e. the substance functions as processing aid in one food but may have a different function in another food) (group 2),
- compounds that because of carry-over residues, would seem to usually be considered only as food additives (group 3),
- materials that might actually have simultaneous function as processing aids and functionality in the finished food (group 4).

21. The differences between substance which is used only for processing aids and food additives should be regulated precisely.

22. There are several matters which are not included in the definition of processing aids and these need to be considered:

a. Processing aids which are included in group 1, 2 and 3 do not perform any technological function in the finished product.

b. Processing aids which are included in group 4 may perform technological function in the finished product.

c. Processing aids are substances use as part of a manufacturing process but which may be removed from the food before the end of the process. They may however leave residues in the food, in most cases processing aids are of low toxicity and the residue is likely to be of only limited concern. The residues do not present any health risk.

GENERAL PRINCIPLES ON THE USE OF PROCESSING AIDS

A. Safety Concern of Processing aids

- Since processing aids are added to food and may be present in the final food they should be subject controls on their use and be subject to risk assessment. This may indicate the need for specified maximum residue levels.

- The safety and suitability of processing aids for their proposed use should be established by appropriate means analogous to those used to establish the safety and suitability of food additives. The IPA was intended to be a list of processing aids used somewhere in Codex countries. Accordingly, the safety of each compound used must be presumed to already have been determined by its user.
- For food additives, listing in the GSFA must be requested by a delegation whose country has already approved it. Such approval predisposed that its safety for such use has been established.
- For processing aids a similar procedure should be followed. Items in the IPA are presumed safe by virtue of having been nominated for listing by a member country delegation or non-voting Codex NGO selling the product in a country in which the product is already approved or has been reviewed for safety. The product would not have been used if it were unsafe or ineffective. Furthermore, it would not likely be used at levels greater that needed to achieve the intended effect because such use would be more costly than necessary.
- The quantity of the processing aids that remains in the final food product as a result of food processing should not present any health risk and should not present any health risk and should not have any technological function in the final product

B. Justification for the use of Processing aids

The use of processing aids is justified only when:

a. such use has an advantage;

b. does not present an appreciable health risk to consumers; and

c. assists in the treatment or processing of food.

C. Good Manufacturing Practices (GMPs)

All processing aid shall be used under conditions of GMPs which include the following:

a) the quantity of the processing aids used in food processing shall be limited to the lowest possible level necessary to accomplish its desired effect;

b) the quantity of the processing aids that becomes residue as a result of food processing and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,

c) the processing aid is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

D. Specifications for the Identity and Purity of Processing Aids

Processing aids should be appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies. In terms of safety, food grade quality is achieved by conformance of processing aids to their specifications as a whole (not merely with individual criteria) and through their production, storage, transport, and handling in accordance with GMPs.

TECHNOLOGICAL CATEGORIES/CLASSES

23. The technological categories of processing aids listed in the IPA are:

- Antifoam agents;
- Boiler water additives;
- Catalysts;

- Clarifying agents)/filtration aids
- Contact freezing and cooling agents;
- Desiccating agents/anticaking agents;
- Detergents/wetting agents;
- Enzyme immobilization agents and support;
- Enzyme preparation include immobilized enzymes;
- Flocculating agents;
- Ion exchange resins, membranes and molecular sieves (include counter ions for resins;
- Lubricants, release and anti stick agents, moulding aids;
- Microorganism control agents;
- Propellant and packaging gases;
- Solvents, extraction and processing;
- Washing and peeling agents;
- Other processing aids

LABELLING

24. Processing aids that do not perform a technological function in the final food and are either absent or present in trace amounts are not be required to be declared on labels. The maximum limit for the presence of processing aids in the final product shall be established for labeling purposes

CONCLUSION AND RECOMMENDATION

25. A guideline is needed to assist member countries in developing national regulations on processing aids in their own countries.

26. All processing aids should be evaluated by JECFA (*Joint FAO/WHO Expert Committee on Food Additives*). Processing aids which have sole function as a processing aid (group 1); its safety should be evaluated separately.

27. It is recommended to develop a guideline on the use of processing aids to accompany the IPA.

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Codex Alimentarius Commission. Report of The 38th Session Of The Codex Committee on Food Additives and Contaminants. May 2006. Alinorm 06/29/12. The Hague

Japan External Trade Organization (JETRO). Specifications and Standards For Foods, Food Additives Under The Food Sanitation. General Standards for Use of Food Additives. 2004. Japan

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Attachment 1

Definition of processing aids in many countries were :

- Codex : 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 (Codex Alimentarius Commission Procedural Manual).
- CFR Title 21 (USA) : substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, floculents, filter aids, and crystallization inhibitors, etc.
- FSANZ (Australia-New Zealand) : the substance is used in the processing of raw materials, foods or ingredient to fulfill a technological purpose relating to treatment or processing but does not perform a technological function in the final food; and the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, or respective of any maximum permitted level specified.
- Adm. Order no.88-a s 1984 (BFAD Phillippines) : additives that are used in the processing of food to achieve a specified technological purpose and which may or may not result in the presence of residues or derivatives in the final product.
- Food conditioner (Malaysia) : any substances that is added to food for a technological purpose to obtain the desired food and include emulsifiers, antifoaming agents, stabilizers, thickeners, modified starches, gelling agents, acidity regulators, enzymes, solvents and anticaking agents, but shall not include preservative, colouring substances, flavoring substances, flavour enhancer and antioxidants.