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Agenda Item 7(a)

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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 OF SUBSTANCES USED AS PROCESSING AIDS

Prepared by Indonesia with the assistance of Belgium, China, France, India, Japan, Malaysia, New Zealand, Philippines, Thailand, United Kingdom, United States of America, Association of Manufactures of Fermentation Enzyme Product (AMFEP), Confederation of the Food and Drink Industries of the EU (CIAA), European Animal Protein Association (EAPA), Enzyme Technical Association (ETA), International Chewing Gum Association (ICGA) and International Dairy Federation (IDF)

BACKGROUND

1. The 38th Session of the Codex Committee on Food Additives and Contaminant (CCFAC) agreed that there was a need for guidance on the use of processing aids. For this purpose, it was agreed to establish an electronic Working Group, led by Indonesia, with the assistance of New Zealand, Russia, United States of America, Association of Manufactures of Fermentation Enzyme Product (AMFEP), Enzyme Technical Association (ETA), International Food Additives Council (IFAC), International Dairy Federation (IDF) and Institute of Food Technologists (IFT), to develop a discussion paper on guidelines and principles 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.
2. At the 39th of the Codex Committee on Food Additives (CCFA), the Committee agreed not to consider the document CX/FA 07/39/13 in detail but to focus the discussion on the recommendations, which highlighted the need for these guidelines to assist governments in developing national regulations on processing aids in order to control at post market level.
3. Some of the processing aids that currently used processing aids might either have a history of safe use or have been reviewed by JECFA. Focus should be directed on the processing aids which are not included yet. In addition, more focus on the real risk of processing aids should be conducted.
4. Some countries supported to start new work, as they were of the opinion that it was necessary to have some guidance to ensure the safe use of these compounds.
5. The Committee did not reach a conclusion as to this new work and agreed to establish an electronic working group, led by Indonesia, working in English, to revise the discussion paper in order to clarify the scope of the new work, for further consideration at its next session (ALINORM 07/30/12 Rev., para. 130).

6. Electronic working group was established to revise the discussion paper in order to clarify the scope of the new work for further consideration at the next session of the Codex Committee on Food Additives. The participants are Belgium, China, France, India, Japan, Malaysia, New Zealand, Philippines, Thailand, United Kingdom, United States of America, Association of Manufactures of Fermentation Enzyme Product (AMFEP), Confederation of the Food and Drink Industries of The EU (CIAA), European Animal Protein Association (EAPA), Enzyme Technical Association (ETA), International Chewing Gum Association and (ICGA), International Dairy Federation (IDF).

7. The current discussion paper has been already formulated by accommodate all the proposals and recommendations from among member of Electronic Working Group (EWG) to improve the project document and draft guidelines.

INTRODUCTION

8. Processing aids should have technological purpose during the treatment or processing of a food. The Codex Inventory of Substances Used as Processing Aids should serve as the reference document for specific processing aids, while guidelines and principles document will address broad recommended use practice for processing aids.

PURPOSE

9. Discussion paper contains, as Appendix I, a proposed project document that addresses the nine elements listed in the Codex Alimentarius Commission Procedural Manual, 16th Ed., pp. 21-22, that must accompany any proposals to the Commission to undertake new work.

10. Discussion paper as Appendix II also contains a Proposed Draft - Guidelines and Principles of Substances Used as Processing Aids with the following main elements:

- i. Scope
- ii. Description
- iii. The Criteria of Substances Used as Processing Aids,
- iv. General Principles for the Safe Use of Processing Aids
- v. Technical Categories of Processing Aids
- vi. Labelling
- vii. References

Appendix I**PROJECT DOCUMENT- PROPOSAL FOR NEW WORK ON THE ELABORATION OF GUIDELINES AND PRINCIPLES OF SUBSTANCES USED AS PROCESSING AIDS****1. Purpose and Scope of the Proposed New Work**

To develop guidelines and principles of substances used as processing aids that establishes safe conditions of use with the purpose of assisting Governments in developing national regulations on processing aids in order to control at post market level.

2. Its Relevance and Timeliness:

Processing aids has an important role in the food processing as well as food additives. Development of guidelines will provide a tool for Codex to offer information on the safety requirement and criteria of substances used as processing aids. Currently the Inventory of Substances Used as Processing Aids is updated by New Zealand.

3. Main Aspects to be Covered

Several aspects which will be covered including:

- All processing aids will be used under conditions of good manufacturing practice, which include the following:
 - the quantity of the processing aid added to the food being processed shall be the lowest possible amount necessary to accomplish its desired effect;
 - the quantity of the processing aid that become a component of food as a result of its use in the manufacturing, processing or packaging of the food and which is not intended to accomplish any physical, nutritional or other technical effect in the food itself, is reduced to the greatest extent reasonably possible; and
 - the processing aid is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.
- Any residues remaining in the processed food as consumed should not present any health risk.
- The Inventory of Processing Aids serves as a valuable reference document, but is not intended to be a complete or positive list of permitted substances used as processing aids.

4. An assessment against the Criteria for the Establishment of Work priorities

This proposal is consistent with the criteria applicable to general subjects:

a. Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade.

These guidelines will aim to protect consumers and ensure fair practices in the food trade by establishing a general principle of safety in the choice and conditions of use of processing aids. The Codex Inventory of Processing Aids will allow a monitoring of available processing aids in the Codex Member States. So far, it is not realistic to list only processing aids which have been approved by a Codex Member State as a limited number of countries have an approval procedure in place.

b. Diversification of national legislation and apparent resultant or potential impediments to international trade.

The absence of a Codex Guidelines and Principles for Substances Used as Processing Aids contributes to inconsistencies in the regulation of substances used as processing aids among different countries, although so far only a few countries have fully regulated the use of those substances in food processing. The proposed work could assist in establishing a common understanding of the principles which should rule the use of processing aids in the different Codex member countries and minimize potential impediment to international food trade.

c. Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

Safety assessments of food additives are often conducted by JECFA but does not address all substances used as processing aids. A number of Codex member countries also conduct their own safety assessment of food additives and processing aids. The Inventory of Substances Used as Processing Aids is periodically updated by New Zealand, is intended to capture as reviewed by JECFA or by competent authorities in Codex member states.

5. Relevance to codex strategic objectives.

The proposal is consistent with

- Objective 6 : Promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents

The proposal relates to the Inventory of Processing Aids (CAC/MISC 3), Codex General Standard for the 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. Identification of any requirement for and availability of expert scientific advice

Yes, food additives, food processing, food toxicological, international trade and government experts are needed to provide the education and scientific expertise needed to develop this Codex guideline and principles document

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for.

Yes, see item # 7 above, Any organization with this kind of expertise will be invited to assist in the development of project document and this guideline.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

The timeline for completing work on the proposed guidelines is four years. Therefore, if the new work is approved by the Commission in 2008, a proposed draft guideline could be considered at step 3 by the next session of Codex Committee on Food Additives in 2009, and adopted by the Commission at step 5 and step 8 in 2010 and in 2011, respectively.

Appendix II**PROPOSED DRAFT - GUIDELINES AND PRINCIPLES OF SUBSTANCES USED AS PROCESSING AIDS****1.0 SCOPE**

These guidelines set out criteria and basic principles for substances used as processing aids into the Codex Inventory of Substances Used as Processing Aids. The guidelines are composed of the following sections: Description, the Criteria of Substances Used as Processing Aids, General Principles for the Safe Use of Processing Aids, Technical Categories of Processing Aids and Labelling.

2.0 DESCRIPTION

2.1 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.

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

- Foods, including water,
- Food additives, and/or
- Substances used as processing aids that is not used as foods or food additives.

3.0 THE CRITERIA OF SUBSTANCES USED AS PROCESSING AIDS

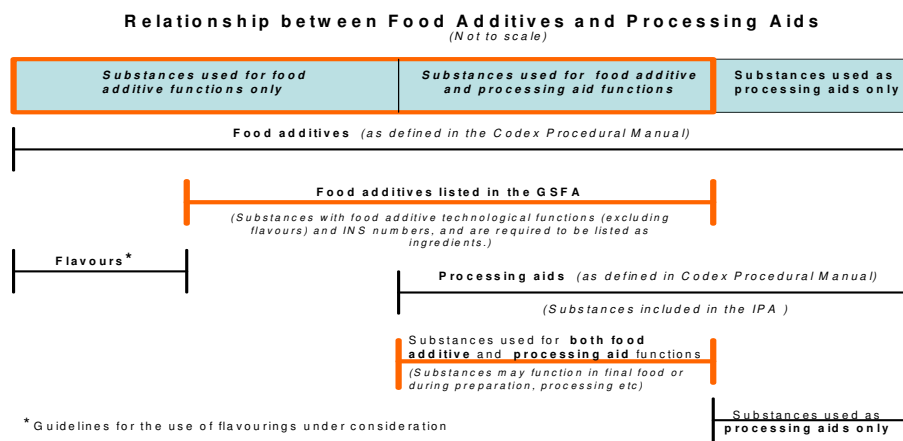
3.1 In terms of the Codex definition the key criteria for the use of a substance as a processing aid are:

- they are not consumed as a food ingredient by itself; and
- 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 present of the substance or any derivative or residue of the substance must be non intentional or unavoidable as well as must not present any health risk.

3.2 Substances used as processing aids that is used as foods or food additives should be in accordance with the requirement of food or food additives.

3.3 Substances are only used as processing aids as defined under section 2.1 in a food and it is not functioned as a food additive or as a food, the specific provisions should be established to ensure that the substances is fit and safe for human consumption.

3.4 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 additive* 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.



April 2007

4.0 GENERAL PRINCIPLES FOR THE SAFE USE OF PROCESSING AIDS

4.1 Processing aids are substances used as part of a manufacturing process but which may be removed from the food before the end of the process. They should not be present in the final food at levels that would pose an unacceptable risk to health. The removal step should not be a prerequisite to the use of processing aids, as this technical operation is often not possible nor applicable.

4.2 The safety of each substance should be demonstrated by the manufacturer of processing aids, before the products are put in market. This demonstration may include information on long history of safe use coupled with some analytical demonstrations of the presence of harmless and technically unavoidable traces of residuals.

4.3 When a Codex member reviews the safety of use of a processing aid in food manufacture, it should take appropriate measures in order to assess that the unintended or technically unavoidable presence of residues or denatured parts of that processing aid does not cause any unacceptable harm to the health of the consumer. The level of use of a processing aid should be adopted to ensure that the level of residues of the processing aids is below any level of toxicological concerns.

4.4 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.

4.5 All processing aids 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.

5.0 TECHNICAL CATEGORIES OF PROCESSING AIDS

5.1 Processing aids have many technological functions in food processing. The use of processing aids is justified only when such use has an advantage, does not present an unacceptable health risk to consumers and assists in the treatment or processing of food. The presence of the substance or any derivative or residue of the substance must be non-intentional or unavoidable, it must be at the lowest of the low level.

5.2 According to Inventory Substances Used as Processing Aids, the technical categories of processing aids include:

- 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 supports;
- 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

6.0 LABELLING

6.1 Labelling of processing aids should be in accordance with the requirement of the Codex General Standard for the 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 (Rev.1-1991)).

6.2 Labelling of processing aids shall be consistent with requirement in the country of sale.

REFERENCES

Codex Alimentarius Commission, Inventory of Substances Used as Processing Aids. Updated List. April 2008. CX/FA 08/40/10. China.

Codex Alimentarius Commission. Report of the 39th Session of The Codex Committee on Food Additives and Contaminants. April 2007. Alinorm 07/30/12. China.

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

Codex Alimentarius Commission. Procedural Manual. Sixteenth edition.

Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991)).

Codex General Standard for the Labelling of Food Additives When Sold as Such (CODEX STAN 107-1981).