codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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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:

Brazil, European Community, AMFEP, CEFIC, CEFS, CIAA, ICBA, ICGMA, IDF

Brazil

Brazil would like to make the following comments on this document, considering its RECOMMENDATIONS AND REQUEST FOR COMMENT.

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

Taking into account the understanding that "guidelines" and "principles" do not apply to the substances but to their use, Brazil considers that the appropriate title, which reflects the content of the document, is: **PROPOSED DRAFT GUIDELINES AND PRINCIPLES FOR THE USE OF SUBSTANCES USED AS PROCESSING AIDS**.

Moreover, this title would be consistent with that one approved by the CCFA for the **"Guidelines for the Use of Flavourings"** (ALINORM 08/31/12).

(ii) The correct definition of processing aids and **(iii) Decision to be made whether the definition of substances used as processing aids need to be defined.**

Brazil considers that "processing aids" should be defined in the document and agrees with the second definition proposed, since it makes clearer that residues must not present health risk and not have technological effect on the product:

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.

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

Item 1 – Brazil considers that only the first paragraph should be maintained in the document. However, we think that it is more appropriated to include it in the item 9 – ROLE OF INVENTORY OF SUBSTANCES USED AS PROCESSING AIDS (IPA). The content of the second paragraph is already contemplated in other parts of the document, as items 2 and 9.

Item 6.0 – Brazil agrees that the list of technological purposes should be replaced with a reference to the technological functions listed in the IPA.

Item 7.0 – Brazil suggests excluding the item 7.2 *Labelling of products containing substances used as processing aids shall be consistent with requirement in the country of sale*. This statement is applied not only to processing aids, but also to any foodstuff, ingredient, additive etc. and because of that it is not necessary to be included in this kind of document.

Besides, the reference to the CODEX STAN 1-1985 should be updated, considering its last revision (1991)

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

As the United States, Brazil also believes that the intent of the background is to clarify the role of the IPA in the Codex system. This information is important to countries that use the document as a reference. Therefore, Brazil recommends that this section be incorporated into a discussion document, in witch the Draft Guideline would be included as an Annex.

European Community (EC)

The EC and its Member States (ECMS) thank the delegation of Indonesia and the participants of the electronic working group for the draft Guidelines and Principles for the use of substances used as Processing aids. The ECMS would like to make the following suggestions:

As a general comment the ECMS note that although food ingredients (e.g. water or fats/ oils) can be used in a similar way to processing aids, such ingredients are specifically excluded from the Codex definition. For this reason and because the use of such substances would generally be insignificant when compared to the normal use as food the ECMS consider that these guidelines need not be applicable to food ingredients. Therefore the guidelines should be kept as simple as possible and not refer to food ingredients which are not covered by the existing definition of processing aids.

With regard to the title

The title should maintain the wording "Proposed draft guidelines and principles for the use of substances used as processing aids" in accordance with the wording specified in Alinorm 08/31/12 (Annex XI).

With regard to the section 2.1:

It is suggested to amend the section 2.1 as follows: "These guidelines aim to provide principles for the safe use of substances used as processing aids and the safety of their residues in food and assist Governments to develop national policies. They will also provide a description of categories of processing aids and ~~to~~ explain the role of the Inventory of Substances Used as Processing Aids (IPA)."

With regard to the section 2.2:

As said before, it should be clarified in section 2.2 that the scope of the guidelines is to set the principles for the safe use of substances used as processing aids including substances which are in other cases used as food additives but excluding food ingredients used in a similar manner as processing aids.

With regard to section 3:

No mandate has been set to modify the definition of processing aids. Therefore, the ECMS can support the first definition on processing aids as this definition is already agreed upon by the Codex Alimentarius Commission and contained in the procedural Manual as well as in the General Standard for the Labelling of prepacked food.

Nevertheless, the ECMS are of the opinion that two crucial criteria from the second definition should be emphasised in the guidelines, e.g. at the top of section 4.2.2., i.e.

(i) the residues should not present any health risks and

(ii) the residues should not have any technological functions in the final product"

With regard to the sections 4.1. and 4.2:

Sections 4.1 and 4.2, except sections 4.2.1 and 4.2.2, should be deleted.

Sections 4.2.1 and 4.2.2 should be moved to section 2.2 (scope).

With regard to the section 4.2.1:

It is suggested to delete the last indent referring to foods as explained initially

With regard to section 4.2.2

The brackets should be removed in the last indents and the section reformulated in order to emphasise that the residues do not present any health risk and do not have any technological effect in the final product.

With regard to the section 5.1:

The section 5.1 should be moved under 6.0 as this section relates to the technological purposes of processing aids. In addition, the reference to the IPA should be deleted, bearing in mind that the IPA list is not a text adopted by the Codex Alimentarius Commission.

With regard to the section 5.2:

The second sentence of section 5.2 should be merged with 5.3 as follows: Unavoidable impurities of substances used as processing aids or its derivatives should not be present in the final food at levels that would pose an unacceptable risk to health.

With regard to the section 5.3:

Section 5.3 should be deleted

With regard to the section 6.0:

Bearing in mind that the IPA is not adopted by the codex Alimentarius Commission, the ECMS question the need to refer to the IPA list.

The ECMS note the proposal to include some additional categories in the list of technological purposes of substances used as processing aids. The ECMS consider that the additional categories should be considered carefully before being included in the list and in particular questions whether the category of "colour stabiliser" would in fact be a food additive functional class rather than a processing aid use.

Furthermore, definitions of Categories should be elaborated.

With regard to the section 9.3:

The ECMS consider the background information as very useful for clarifying the role of IPA.

AMFEP (Association of Manufacturers and Formulators of Enzyme Products)/ETA(Enzyme Technical Association)

Amfep and ETA would like to thank Indonesia for preparing the new proposed draft guidelines for substances used as processing aids, which has been improved considerably when compared to the previous one.

As a member of the electronic Working Group, Amfep and ETA have given some comments which unfortunately have not been taken fully into account. Therefore, we herewith would like to repeat those comments that are of main importance for us. Moreover, Amfep and ETA would like to react to the specific request for comments.

Specific request for comments

(i) the appropriate title for the proposed draft guidelines

Amfep and ETA believe that there are two options, of which the second is preferred:

1) Guidelines and principles for the use of substances as processing aids

2) Guidelines and principles for substances used as processing aids

(ii) the correct definition of processing aids

As the definition of processing aids was not part of the assignment, Amfep and ETA believe that the present Codex definition should stay as it is. If the CCFA feels that there is a need to discuss the current definition, a separate Working Group could be installed.

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

Substances used as processing aids are covered by the definition of processing aid. Therefore, there is no need for another definition (see point (ii) above). However, the guidelines should explain why the term 'substances used as…' is used, namely to emphasize that it is not the substance, but its use that determines whether it should be classified as processing aid or not. Then, it automatically follows 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

Amfep and ETA are of the opinion that the proposed draft guidelines are quite complete. As a matter of fact, we think it contains several issues that should be removed as they are not part of the assignment.

Amfep and ETA feel that the overall structure could be improved by grouping the issues in a more logical way, by less duplication and by better emphasis of the most important criteria. This will result in a shorter, more readable paper.

As most important criteria we see:

1) The production should be according to GMP (i.e. food grade raw materials, etc)

2) The substance used as processing aid should comply with certain purity specifications

3) The dosage should not be more than necessary (i.e. *quantum satis* principle)

4) Residues should be below any level of toxicological concern based on scientific principles

5) Residues should have no technological function in final food

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

The assignment said that the guidelines should cover: An explanation of the role of the IPA and its status. Therefore, the background can be deleted, making the guidelines shorter and more readable. The background should be part of the IPA itself.

Main comments to the draft guidelines

1.0 Introduction

As this section (apart from the last sentence) is new, Amfep and ETA have not as yet been able to give comments to it. We do not agree, as is stated in paragraph 1.2 that the guidelines are intended to provide information on the criteria to identify processing aids. It is not the substance itself, but its use that determines whether it is to be classified as a processing aid or not. This part of the sentence should therefore be deleted or rephrased. We suggest:

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 safe use of processing aids and their general use categories. The IPA includes both…

3.0 Definition

As food additives are referred to several times, Amfep and ETA believe that the Codex definition of food additive should also be included.

4.2

As this section is new, Amfep and ETA have not as yet been able to give comments to it. We feel that it is not clear which message Sections 4.1. and 4.2 is trying to give. The text is, in our opinion, very confusing. The draft guidelines mention correctly that the Codex definition of the term 'additive' covers the word 'processing aid'. However, if the term 'additive' is used in such a broad sense, it is not possible to consider substances used as additives and processing aids as separate categories as is done in these guidelines. Therefore, it should be made clear that in (Codex) practice – including in these guidelines - the term 'additive' is used in a narrower sense, namely excluding substances used processing aids. Only then is it justified to compare substances used as additives with those used as processing aids.

The above has nothing to do with the fact that some substances can be used as additives (in the narrow sense) as well as processing aids. Therefore, the last sentence of section 4.2 does not belong there. It merely adds to the confusion.

In summary, it is our opinion that sections 4.1 and 4.2 should be deleted.

4.2.1 and 4.2.2

These sections are quite superfluous, as the content is already covered by the definition of the term processing aid. The fact that it is not the substance itself, but its use which determines whether it is to be classified as a processing aid or additive should be included under section 3.0 to explain the term 'substances used as processing aid'. From such explanation it logically follows that some substances can be used as additives (in the narrow sense) as well as processing aids.

4.3.2

Amfep and ETA **strongly object** to the requirement that the residues of substances used as processing aids should be reduced to the lowest level. This is an undefined, arbitrary, uncontrollable and thus unworkable criterion. As mentioned before, the only criteria of importance are: 1) the levels should be such that there is no toxicological concern, and 2) the levels should be such that there is no technological function in final food. As 'reduction to the lowest level' is fully dependent on technical developments as well as the food matrix in question, it gives no guarantee that these criteria are met. On the other hand, it is possible that these criteria are already met without further reduction of the level of the residues. If 4.3.2 remains, it should be re-written to:

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 present no health risk;

5.1

Amfep and ETA are of the opinion that this section should be deleted. The justification requirement has nothing to do with safety and is out of the scope of these guidelines. Moreover, the IPA list might not be exhaustive.

5.4

Regarding the last part of this paragraph, it should be noted that there is no such thing as total absence and that it is very

much dependent on the detection methods available whether something can be detected. We therefore propose that the last part is deleted, so that the paragraph ends with ...*long history of safe use*.

6.0 Technological purpose of substances used as processing aid

As suggested before, it might be more practical to include a link to the IPA, instead of listing the categories mentioned in the IPA. Otherwise, this list has to be updated each time the one in the IPA is updated.

Furthermore, we propose to change the word 'purposes' into 'categories' in both the title and the subsequent paragraph.

7.0 Labelling

Labelling is not within the scope of the original project document proposal. The proposal merely mentions 'Information on the relation between the proposal and other existing Codex documents', such as the Codex General Standard for the Labelling of Food Additives When Sold as Such and the Codex General Standard for the Labelling of Prepackaged Foods.

Amfep and ETA find it confusing if these guidelines merely make reference to the above Codex documents without mentioning that on basis of these documents, labelling is not required for substances used as processing aids.

Section 7.2 should be deleted, as these guidelines do not concern local labelling requirements. Alternatively, the whole section 7.0 can be deleted.

9.1

For the same reasons as mentioned under 4.2 above, the last sentence of this section is totally confusing and should therefore be deleted. The IPA presently covers all substances that can be used as processing aids, including those that are also used as additives. As far as we understand, these guidelines have the same scope. Therefore, no sentences should be included that suggest otherwise.

We sincerely hope that our comments will be taken into account and the draft revised to make it consistent with the assignment and as simple as possible,

CEFIC (the European Chemical Industry Council)

The European Chemical Industry Council (CEFIC) represents European-based and globally active manufacturers of chemicals of which a considerable number are also used in or with food. On behalf of the CEFIC Food Regulatory Panel comments and proposals are submitted in response to CX/FA 09/41/7 on the proposed draft guidelines and principles for substances used as processing aids.

Cefic Comments and proposals:

Definition:

Cefic suggests to keep the first definition on processing aids as this definition is already agreed upon by the codex Alimentarius Commission.

Point 4.3.2

Cefic objects to the requirement that the residues of substances used as processing aids should be reduced to the lowest level. This is an undefined, arbitrary, uncontrollable and thus unworkable criterion. As mentioned before, the only criteria of importance are: 1) the levels should be such that there is no toxicological concern, and 2) the levels should be such that there is no technological function in final food. As 'reduction to the lowest level' is fully dependent on technical developments as well as the food matrix in question, it gives no guarantee that these criteria are met. On the other hand, it is possible that these criteria are already met without further reduction of the level of the residues. If 4.3.2 remains, it should be re-written to:

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 present no health risk;*

Point 4.3.3

Cefic suggests deleting this point see comments related to the hygiene chapter.

Point 5.2

Cefic suggests deleting this point as it is already covered under the other points of section 5.0.

Point 5.4

Cefic comments: In addition to point 5.4, a substance could as well be accepted as a processing aid and be recognised as GRAS (for example) based on scientific principles.

Point 7.0 LABELLING

Labelling is not within the scope of the original project document proposal. The proposal merely mentions information on the relation between the proposal and other existing Codex documents, such as the Codex General Standard for the Labelling of Food Additives When Sold as Such and the Codex General Standard for the Labelling of Prepackaged Foods.

Cefic finds it confusing if these guidelines merely make reference to the above Codex documents without mentioning that on basis of these documents, labelling is not required for substances used as processing aids.

Point 7.2 should be deleted, as these guidelines do not concern local labelling requirements.

Alternatively, the whole section 7.0 can be deleted.

Point 8.0 HYGIENE

Cefic comments: The overall objective of food safety is to put food products on the market which are in compliance with strict hygiene requirements. It is the safety of the final foodstuff which is important. For some intermediates, including processing aids, strict rules with regard hygiene are not necessary. Example: washing of ingredients can be done with clean water. Clean water does not mean potable water. The ingredients are further processed and in the end there is for example a sterilisation process. The use of potable water would in this case does not make sense and would in some areas even be a waste of valuable resources. But that does not mean that food ingredients, including processing aids, derived from perishable raw material should not comply with strict food hygiene requirements (including microbiological criteria). For example ingredients derived from animal sources should follow strict hygiene rules. We therefore suggest to have the application of hygiene rules where needed and this is normally already covered under GMP. We therefore suggest deleting this chapter as it is already covered by point 5.5.

CEFS (Comité Européen des Fabricants de Sucre)

CEFS (Comité Européen des Fabricants de Sucre), on behalf of all sugar manufacturers in the EU and Switzerland, would like to present comments on the Proposed Draft Guidelines and Principles for Substances Used as processing Aids at Step 3 of the Codex procedure.

As a member of the electronic working group (eWG) that contributed to the development of these Proposed Draft Guidelines, CEFS would like to very much thank Indonesia for its work and efforts. We acknowledge that a number of positive changes were made to the very first draft that was circulated to the members of the eWG for their consideration; however we remain concerned with the overall lack of consistency of the paper now circulated at step 3. We would advise that this paper be checked against inconsistencies and redundant text deleted.

In addition to this general remark, we would like to make the following specific comments:

- Section 4.3. referring to good manufacturing practices should better be integrated somewhere into section 5 (General Principles for the Safe Use of Substances Used as Processing Aids and the Safety of their Residues in Food).

- Section 9 is ambiguous as regards the status of the IPA updates. Only the official IPA-document (CAC/MISC 3) should serve as a basis for further CCFA discussions, and not non-officially adopted updates, of which the drafting is simply an interim measure until CCFA is able to consider developing a standard for substances used as processing aids.

Finally, we would like to recall that Codex' work on the "Guidelines and Principles for Substances Used as Processing Aids" was primarily initiated with a view to avoid a more complex (*i.e. time- and resources-consuming*) GSFA-type Codex standard for processing aids. Consequently, any future Codex activities on these "Guidelines and Principles for Substances Used as Processing Aids" should comply with this overall objective.

CIAA(the Confederation of the Food and Drink manufacturing industries)

CIAA, the Confederation of the Food and Drink manufacturing industries of the EU, appreciates the opportunity to respond to the proposed draft Codex Guidelines and Principles on Substances used as Processing Aids - **(CX/FA 09/41/7)** and would like to offer the following comments

While acknowledging that a number of positive changes were made to the first draft circulated by Indonesia, we remain concerned with the overall lack of consistency of the paper now circulated at step 3. This paper would need to be checked against inconsistencies and redundant text should be deleted. It would also need to be checked for compliance with the guiding principles and conclusions laid down in the project document for new work approved by the 2008 Session of the Codex Alimentarius Commission (ALINORM 08/31/12, Appendix XI). In addition we would like to express our strong wishes to maintain the "*Guidelines*"-nature of this document. Codex' work on the "Guidelines and Principles for Substances Used as Processing Aids" was primarily initiated with the view to avoid a more complex GSFA-type Codex standard for processing aids. Therefore, the IPA list should maintain its non-exhaustive character, while avoiding that it becomes a binding positive list in future.

In addition to these general remarks, we would like to present the following specific comments.

Section 2.0

We consider **sections 2.1 and 2.2** to some extent repetitive. Therefore, we propose to merge both paragraphs into one, while completing the message provided in **section 2.2** by adding at the beginning the following sentence: "*These guidelines set out criteria and basics 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 guidelines…"*

Section 3.0: "Definition":

We support the second proposal. We suggest adding at the end of the definition the following: "*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 this definition. Substances used in the manufacturing of food additives (including flavourings) are not addressed by the present document."*

Section 4.0: "Principles for use of Substances used as processing aids under conditions of GMP":

- We propose to delete **section 4.2.2**, which is only a repetition of the Section 3.0 "Definitions".

- We suggest erasing **section 4.3.1**, as this requirement is taken from food additives GMP, but is not relevant for processing aids. **Section 4.3.2** should be accordingly amended by introducing "lowest possible level" for the unavoidable residues or derivatives of a processing aid, which may remain in a food**.**

Section 5.0: "Principles for use of Substances used as processing aids under conditions of GMP":

We believe that as sections 5 and 6 consider very similar information, both should be merged into one section. We suggest combining these statements into one sentence.

Section 6.0: "Technological Purposes of Substances Used as Processing Aids":

There seems to be a missing category covering: decolourants, adsorbent agents, carriers, diluents, bleaching, enzymes - specifically of animal, plant and microbial origin, microbial nutrients & microbial nutrient adjuncts. However, we assume that these are to be included under (xxii) "*Other processing aids*".

Section 8.0: "Hygiene":

In **section 8.2** it might be useful to clarify that processing aids should comply with any ***applicable*** microbiological criteria, by adding the term "*applicable*" in this sentence.

Section 9.0 "Role of inventory of substances used as processing aids (IPA)":

Section 9 is ambiguous as regards the status of the IPA updates. The IPA list should keep its non-exhaustive character, while avoiding that it becomes a binding positive list in the future. Only the official IPA-document (CAC/MISC 3) should serve as a basis for further discussions, and certainly not non-officially adopted updates, of which the drafting is simply an interim measure until CCFA is able to consider developing a standard for substances used as processing aids. Therefore we propose to redraft **section 9.2** as follows: "*The IPA is information on which substances are used as processing aids on a worldwide basis. Therefore, IPA is not intended to be regarded as a positive list of permitted processing aids*." Subsequently **section 9.3.4** should be adapted "*…However, the value of the Inventory of Processing Aids as a useful reference tool has been recognized and the Committee agreed to maintain the IPA for the time being.*"

ICBA (the International Council of Beverages Associations)

The International Council of Beverages Associations (ICBA) is a nongovernmental organization that represents the interests of the worldwide nonalcoholic beverage industry. The members of ICBA operate in more than 200 countries and produce, distribute, and sell a variety of nonalcoholic beverages, including sparkling and still beverages such as soft drinks, juice-containing drinks, bottled waters, and ready-to-drink coffees and teas. ICBA is pleased to provide the following comments in response to the Proposed Draft Guidelines and Principles for Substances Used as Processing Aids at Step 3.

ICBA participated in the e-working group and provided comments that time but wishes to provide additional suggestions for consideration of the Committee. In general, we continue to believe that the document could be greatly simplified and revised to avoid repetitive text without losing its essential content. With regard to the specific comments requested, we are pleased to provide the following suggestions:

(i) the appropriate title

While we understand that the title originates from the project document, we would support revising the title to make it simpler, such as "Guidelines and Principles for Substances Used as Processing Aids".

(ii) the correct definition of processing aid

(iii) Decision to be made whether the definition needs to be defined

We believe that the current Codex definition should be maintained because the Commission did not mandate revising it.

(iv) the overall structure and completeness of the guidelines

The proposed draft Guidelines could be simplified to only contain the essential elements. We note that during the e-working group, several suggestions were made to that extent. Our more specific comments are provided below.

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

While we can appreciate the information contained in Section 9 on the role of the Inventory of Substances Used as Processing Aids (IPA), we believe that the more appropriate place for it is in the IPA itself and the Guidelines should only contain a short description of the IPA.

Specific comments

Section 1 Introduction

We support maintaining the section but believe that **Section 1.2** should be revised. Our suggestion is to simply state the following

1.2 These guidelines and principles **are**~~,~~ built on existing definitions for "food additives" and "processing aids" found in the Codex Procedur**al** 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.~~

Section 2 Objectives and Scope

Concerning **Section 2.1** and following the typical format of the Codex guidelines, we suggest simply stating the following:

"These guidelines aim to provide principles for the safe use of substances used as processing aids and the safety of their residues in food."

We suggest deleting the rest of the sentence. We do not think it is necessary to state that the guidelines aim to assist governments to develop national policies since all Codex texts can be used for that purpose. If there is a need to maintain **Section 2.2**, it should be revised according to the agreed on sections in the draft Guidelines and Principles.

Section 3 Definition

Only the existing Codex definition should be included. There is no mandate to revise it.

Section 4 Principles for Use of Substances Used as Processing Aids under Conditions of Good Manufacturing Practices (GMP)

We believe that **Sections 4.1 and 4.2** are unnecessary and should be deleted. **Sections 4.2.1** (without the last indent) and **4.2.2** should be moved to Section 2 and combined to avoid repetition. We suggest that the remaining **Section 4.3** could be combined with Section 5. These suggested revisions would simplify the guidelines and avoid repetitive text.

Section 5 General Principles for the Safe Use of Substances Used as Processing Aids and the Safety of Their Residues

Section 5.1 should be deleted since it has nothing to do with the safe use of processing aids. We suggest replacing it with the slightly revised proposed draft Section 4.3.3 ("The substance should be used under the conditions of Good Manufacturing Practice (GMP), and to be of appropriate food grade quality as well as prepared and handled in a similar manner to other food ingredients or food additives.").

Section 5.2 should be revised to remove the requirement to meet the Codex specifications since not all processing aids have established Codex specifications. We suggest deleting the last sentence and adding "when available" so that the Section 5.2 would read:

"5.2 Substances used as processing aids should meet established specifications**, when available,** 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.~~

Section 5.3 and 4.3.2 are similar and could be combined and we suggest the following wording: "The quantity of unintentional but unavoidable residues or derivatives of the substance remaining in food as a result of its use, should not present a health risk."

Section 5.4 should be revised since it may lead to unintentional trade barriers. While JECFA has evaluated substances that are used both as food additives and processing aids and some enzymes, JECFA does not typically conduct evaluations of substances only used as processing aids. We suggest considering the need to maintain the second sentence. We suggest simply stating that "The safety of each substance used as processing aid should be able to be demonstrated by the supplier or the user of the substance." Suppliers do not always know how the users will use the substance so we suggest adding "or the user".

Section 5.5 should be deleted as unnecessary since there have been no demonstrated safety concerns as a result of use of processing aids listed in the IPA.

Section 6.0 Technological Purposes of Substances Used as Processing Aids

We suggest deleting the list of technological purposes and just providing a link to the IPA. If the list is maintained, it will be difficult to keep it current in view of future developments.

Section 7.0 Labelling

We suggest deleting **Section 7.2** since the reference to the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) is sufficient and in accordance with the Procedural Manual.

Section 8 Hygiene

We suggest deleting **Section 8.2**. We are questioning its applicability to processing aids.

Section 9 Role of the Inventory of Substances Used as Processing Aids

We believe that the section in its current form is somewhat unusual and does not correspond to other Codex guidelines. The section contains a description of discussions at CCFAC rather than explains what IPA is. We suggest that Section 9 should be revised and only a simple explanation of IPA should be provided with a web link how to find it from the Codex Alimentarius website.

ICGMA (The International Council of Grocery Manufacturers Associations)

The International Council of Grocery Manufacturers Associations (ICGMA) is a nongovernmental organization that represents foods and consumer packaged goods manufacturers globally. ICGMA promotes the harmonization of food standards and policies based on science and is a strong supporter of Codex Alimentarius. ICGMA also works to facilitate international trade of food products by eliminating or preventing artificial barriers to trade and believes that global harmonization of food additive standards is important to achieve that goal. ICGMA thanks the Indonesian delegation for its work on the proposed draft guidelines and principles for substances used as processing aids. ICGMA appreciates the opportunity to respond to and is pleased to provide the following comments on the proposed draft document CX/FA 09/41/7.

1) Section 2.1 - ICGMA notes that these Guidelines are intended to provide information on the criteria to identify processing aids, their safe use, and general use categories and to explain the role of inventory. All Codex texts are used to assist governments to develop relevant national policies. ICGMA recommends to delete the text "to develop relevant national policies" as it is unnecessary.

2) Section 5.2 - Section 5.2 refers to substances used as processing aids to meet established specifications on chemical identity and purity suitable for use in food. It goes on to state that, in the absence of applicable Specification of Identity and Purity recognized by the Codex Alimentarius Commission, conformance with appropriate specifications developed by responsible national or international bodies would suffice. ICGMA notes that specifications for processing aids are not solely developed by national and/or international bodies but may be prepared by the supplier for a specific customer and use. Thus, ICGMA recommends adding, "or by responsible manufacturers or customers of substances used as processing aids" to the end of Section 5.2.

3) Sections 5.4 and 5.5 – Sections 5.4 and 5.5 refer to a demonstration of safety of use of substances used as processing aids according to Good Manufacturing Practices (GMPs) and their unavoidable residues by the supplier. ICGMA agrees that food manufacturers are responsible for the safety of their products which should conform with GMPs. The

supplier does not always know the downstream use of a processing aid so it is not clear how this could be demonstrated. The safety in use of each substance should be verified by the downstream user. ICGMA suggests removing the text "before the substance is placed on the market."

4) Section 6.0 - The Inventory of Substances Used as Processing Aids lists technological functions for which substances used as processing aids may be used. This would make the list of categories presently under Section 6.0 unnecessary. This would also avoid the potential inconsistencies in future work between the technical categories of processing aids listed in this guideline and the Codex inventory.

5) Section 7.2 - Section 7.2 should be deleted in that the labeling reference should only refer to existing Codex text in 7.1. Any additional labeling text would require referral and approval by CCFL.

6) Section 8.2 - Finally, ICGMA deems Section 8.2 on Microbiological criteria redundant as existing Codex text on Hygiene is already being referred to in 8.1. Section 8.2 should be deleted.

It is important to keep in mind the reason behind the proposed draft Guidelines/Principles For Substances Used as Processing Aids. 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. 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.

IDF (the International Dairy Federation)

The International Dairy Federation recognizes the significant amount of work completed by the Indonesian eWG Chair to develop the Codex "Guidelines And Principles For The Use Of Substances Used As Processing Aids" and thanks them for their sincere efforts to complete this task. We believe this present version is an improvement in many areas from previous drafts; however, we do believe some additional simplification is needed and many of the points about "safe use" could be replaced with a reference to the existing Codex definition of "processing aids". Our specific comments are listed below with justification.

IDF Comments:

Title: IDF would support the title, "Guidelines and Principles for Substances Used as Processing Aids" as it is a simpler form of English and the Guideline is intended to focus on clarifying what are Processing Aids, not on guidelines regarding use.

1. Introduction: Add the following to section 1:

"1.3 This guideline applies to all substances used as processing aids according to the definition, even if they may have other functional classifications. Recognition of a substance as a processing aid is dependent upon meeting the definition for its use in the processing of a specific food."

Explanation: We recommend the addition of this paragraph in the "Introduction" in order to acknowledge that substances used as processing aids may have other functional attributes and this does not preclude its use as a processing aid if they meet the Codex definition of "Processing Aids".

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).

Explanation: The basis of the Codex system of standards and guideline is for adoption and use by national governments and therefore it is not necessary to repeat this in the objectives of this Guideline as it is implied for every Codex standard and guideline.

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 fulfill a certain technological purpose during treatment or processing and which may result in the nonintentional 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.]~~

Explanation: The existing Codex definition of Processing Aids should be referenced in this Guideline as we believe the scope of work to develop such a Guideline did not extend to modifying this widely accepted definition that is supporting international trade in food products.

Combine the bullets under Section 4.2.1 ("include") and Section 4.2.2 ("are") into Section 4.2.1 since the explanatory sentences for each Section are so similar that there is no need or benefit derived from keeping these sections separate. Combining them will simplify the document and remove some duplication created by having two Sections.

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

- 4.2.1.1 Substances which may also be used as food additives, and/or
- 4.2.1.2 Substances other than food additives used as processing aids, and/or
- 4.2.1.3 Intentionally used in the processing of raw material, foods or its ingredients; and/or
- 4.2.1.4 Used to fulfill a technological purpose during treatment or processing food; and/or
- 4.2.1.5 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; and/or
- 4.2.1.6 May result in their un-intentional but unavoidable presence of residues or derivatives in the final foodproduct. ~~provided that these residues do not present any health risk~~ do ~~not perform a technological function in the final food.~~

Explanation: It is universally understood that any food additive or ingredient in a food or its residues or derivatives cannot present any health risk. Also, by definition of a Processing Aid, its unavoidable presence in the final food is acceptable as long as it performs no technological function in the final food. Since the definition is stated earlier in the document, repeating this is duplication.

4.3.2 The quantity of non-intentional 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.~~.

Explanation: It is universally understood that any food additive or ingredient in a food or its residues or derivatives cannot present any health risk.

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~~.

Explanation: The current definition of processing aids does not limit their use to ". . . where other means are not economically or technologically practical." so it would not be appropriate to use this restrictive terminology in 5.1.

5.2 Substances used as processing aids should meet established specifications on chemical identity and purity, suitable for use in food. ~~Una~~Avoidable 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~~.

Explanation: We believe there is a minor typographical error at the beginning of the second sentence. In addition, there is no current Codex requirement to have Processing Aids reviewed by JECFA or anoy other qualified international body and this part of the sentence would require such a review when the safety of processing aids use in foods does not appear to be an international problem.

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~~.

Explanation: There is no current Codex requirement to have foods tested for the presence of Processing Aids and by definition, it is possible that some small amount or Processing Aids or their residues or derivatives could be present in the final food as long as there is no technological effect. Encouraging test of foods could possibly trigger a dispute between importing governments and food exporters as to whether detected levels of Processing Aids have a technological effect in the final food, creating a new barrier to international trade without any measurable benefit in the safety of the food.

~~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.~~

Deleting Section 5.5 is recommended as Processing Aids listed in the IPA have a long history of safe use and requiring a "demonstration of safe use" that "includes appropriate assessment of any unintended or unavoidable residues" without any evidence of such a problem in the current practice and use of 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 STAND 107-1981) and the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAND 1-1985 (Amended-2008)).

Explanation: The date for the most recent vesion of the GSLPF is in need of correction.

Delete Section 7.2: This is implied in all Codex guidelines and standards and as per our previous comment does not need to be stated in this guideline.

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

8.0 HYGIENE

Delete Section 8.2: The reference to the Principles for the Establishment and Application of Microbiological Criteria for Foods is unnecessary and not applicable to the purpose of a guideline on the use of Processing Aids food additives in general are intended to be microbiologically safe, but rarely have microbiological criteria associated with them.~~ 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)].~~