



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON FOOD ADDITIVES**  
**Forty Fifth Session**  
**Beijing, China, 18 – 22 March 2013**

**DATABASE ON PROCESSING AIDS - CRITERIA FOR ENTRY INTO THE DATABASE**

Prepared by an electronic Working Group (eWG) led by New Zealand and co-chaired by China with the assistance of Australia, Belgium, European Union, Iran, Malaysia, United Kingdom, United States of America, AMFEP, ELC and ICGMA.

**1. INTRODUCTION**

1. The 44<sup>th</sup> Session of the Codex Committee on Food Additives (CCFA) held in Hangzhou, China in March 2012, agreed to establish an electronic Working Group, led by New Zealand and co-chaired by China, to develop criteria for the entry of substances into the Database for processing aids, for discussion at the next Session.
2. In developing entry criteria it will be useful to consider the *Codex Guidelines on Substances used as Processing Aids CAC/GL 75-2010* (the Guidelines) and relevant sections of the discussion paper on the structure and content of the Database that was presented to the 43<sup>rd</sup> Session of the Codex Committee on Food Additives<sup>1</sup>. The 43<sup>rd</sup> session agreed to the development of a prototype database to collect information on substances used as processing aids, but made no decision on the detail of the structure or entry criteria.
3. As noted in the discussion paper, the content of the Database will largely depend on how it is intended to be used. It was suggested that the Database may be used to provide information:
  - On substances permitted for use as processing aids under Codex Standards;
  - On decisions by CCFA about substances used as processing aids;
  - On substances that are safe and acceptable for use as a processing aid subject to any stated conditions;
  - On substances that are permitted for use by one or more Codex Members; and
  - To identify data gaps, including priorities for safety evaluations of substances used as processing aids for use in the future development of a Codex processing aid standard.
4. The paper noted that a wide range of data could be collected if the aim of the Database was to include substances permitted for use as processing aids by one or more Codex Members. A larger database will be more useful to identify data gaps including priorities for safety evaluations and specifications.
5. Appendix 1 contains sections of the discussion paper that are relevant to the development of criteria for entry, including possible intended uses of the Database, different users, and the scope of substances (the four options).

**2. SCOPE OF THE DATABASE**

6. The scope of the Database will affect how the principles for safe use in the Guidelines will be implemented to set criteria for entry into the Database.
7. It is useful to note the following points when considering a database for substances used as processing aids:
  - The Database will be of the most use if it identifies all substances that meet the principles for safe use of substances used as processing aids as described in Section 3 of the Guidelines.

<sup>1</sup> CX/FA 11/43/20 [ftp://ftp.fao.org/codex/Meetings/CCFA/ccfa43/fa43\\_20e.pdf](ftp://ftp.fao.org/codex/Meetings/CCFA/ccfa43/fa43_20e.pdf)

- Consumer exposure to most substances used as processing aids is low, as the intended effect is during treatment or processing and under the Guidelines any residues remaining in the food should not perform a technological function in the final food and should be reduced to the extent reasonably achievable.
- The Database is not intended to be a Codex standard but is intended to be a source of information on substances used as processing aids and supporting safety information.
- Codex Members that choose to regulate the use of processing aids would be able to determine if the information available is sufficient to allow safe use.

8. The eWG has previously considered various Options that describe the different classes of substances to be included in the Database based upon various potential uses (scope) of the Database and the principles for safe use listed in Section 3 of the Guidelines. For completeness, these Options are presented in Appendix 1. The eWG has previously recommended that Option 3 (substances used by one or more Codex Members) best reflects the aim of the Database to include all substances that meet the criteria set by the Guidelines. Option 3 recognizes that uses or specific permissions by Codex Members are based on considerations of safe use and technological justification, and therefore meet the principles for safe use of processing aids as described in Section 3 of the Guidelines.<sup>1, 2</sup>

### 3. CONSIDERATION OF CRITERIA FOR THE ENTRY AND UPDATE OF THE DATABASE

9. The task of the current eWG is to develop criteria for the entry of substances into the Database<sup>3</sup>. This task is based upon recommendations in the working document on the prototype database presented to the 44<sup>th</sup> CCFA<sup>4</sup>. The document summarized previous recommendations for the criteria for entry of substances contained in the discussion paper presented to the 43<sup>rd</sup> CCFA<sup>5</sup> that:

- 1) Section 3 of the Guidelines be used to provide general criteria for entry; and
- 2) The Database includes all substances used as processing aids by one or more Codex Members (this is termed "Option 3" in Appendix 1).

10. Table 1, below, lists proposed entry criteria. Criterion 1 (Definition) and Criterion 2 (Safe Use) paraphrase the Guidelines. These criteria are consistent with including a broader range of substances under Option 3 in Appendix 1. Additional criteria, for example procedural criteria discussed in CX/FA 11/43/20, but not directly mentioned in the Guidelines, are included under Criterion 3 (Other criteria).

11. While some eWG members preferred safety related criteria that would limit the number of substances, others supported criteria that would allow a larger database, noting that the Database could identify which entry criteria are met by substances. Being an electronic database would allow users to select substances that meet selected criteria.

#### Further discussion

##### "Acceptable Use"

12. The eWG noted that the Database is not intended to be a Codex standard; and therefore it is not appropriate to refer to these substances as being "accepted." Furthermore, the term "acceptable use" does not appear in the Guidelines, but is taken from the discussion paper presented by the eWG to the 43<sup>rd</sup> CCFA<sup>6</sup>, which defines acceptable use as "based on the criteria in Section 3 of the Guidelines..." Therefore, the term "acceptable use" has been replaced with the phrase "meet the principles for safe use of processing aids as described in Section 3 of the Guidelines."

##### Safety Criterion 2.2.1.2 - substances used in a Codex Member country and not otherwise prohibited.

13. While there was general agreement on substances specifically approved as a processing aid by regulation, the eWG expressed differing views on substances used and not otherwise prohibited. Views differed on whether this provided sufficient evidence of safety to meet criteria in Section 3 of the Guidelines. One suggestion was to move 2.2.1.2 to a new heading "Other criterion" and that this could also include substances listed in the Updated IPA.

<sup>2</sup> CX/FA 12/44/18

<sup>3</sup> ALINORM REP 12/FA, para. 184.

<sup>4</sup> CX/FA 12/44/18.

<sup>5</sup> CX/FA 11/43/20

<sup>6</sup> CX/FA 11/43/20, paragraph 16.

14. Criterion 2.2.1.2 may be accepted as a safety criterion by requiring a Codex Member to propose a substance for inclusion in the Database and confirm that the substance is used in their country to support the view that it is safe, technologically justified, and meets the principles in Section 3 of the Guidelines. While inclusion in the Database implies that the principles for safe use in the Guidelines have been met, users will be able to identify whether additional safety criteria have been met and act accordingly when considering safe use of a particular substance.

15. Acceptance of this criterion will ensure the Database contains a wide range of information. As noted in the Table, not every Codex Member regulates the use of processing aids, and there is the possibility that if a regulatory listing is required, various processing aids that are used to manufacture products currently in international trade will not be included in the Database.

### **Criterion 3.1 - Entry of substances listed in the Updated IPA**

16. The eWG expressed differing views regarding criterion 3.1 "Entry of substances listed in the Updated IPA". If all substances currently listed in the updated IPA are required to be nominated for entry into the Database, a large amount of work will have to be addressed either by an eWG or another mechanism. To require the nomination of substances already in the Updated IPA (and review of such nominations) may not be a prudent use of the Committee's resources, considering that the:

- (i) Database is not intended to be a Codex Standard;
- (ii) Database will be relatively empty during the nomination process;
- (iii) Exposure to the majority of these substances from their use as processing aids can be expected to be low; and
- (iv) Majority of these substances have a history of safe use.

17. Further discussion may be required on how substances currently listed in the Updated IPA would be considered for entry in the Database if criterion 3.1 is not accepted. It is likely that these substances will meet one or more criteria under section 2.2. It may be possible consider whether substances meeting criterion 3.1, to confirm that they also meet one or more of the safety criteria in 2.2.

### **Proposal to amend the Guidelines**

18. The Guidelines state that residues or derivatives of processing aids in food "*should not pose any health risk*". The eWG noted that "*any health risk*" implies there should be an absolute zero risk. More appropriate language to describe the application of risk assessment to processing aids would be that commonly used by JECFA, such as "*should not pose a health concern*". The eWG proposes that CCFA considers a corresponding editorial change to the Guidelines.

## **RECOMMENDATIONS**

### **Recommendation 1**

19. That the Database will be of most value if it identifies all substances that that meet the principles for safe use of processing aids as described in Section 3 of the Guidelines (Option 3 in Appendix 1).

### **Recommendation 2**

20. That the criteria set out in Table 1 be considered for the entry of substances into the Database.

(Note that since the Database is electronic, it should be possible to select substances on the basis of any of the criteria as desired.)

### **Recommendation 3**

21. That CCFA considers an editorial change to the Guidelines so that the wording "should not pose any health risk", be replaced with "should not pose a health concern" which is consistent with language used by JECFA when evaluating safety of substances.

**Table 1 Database Entry Criteria**

	Criteria for consideration	Reference	Comment
<b>1.Meets definition of processing aid</b>			
1.1	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.	CAC/GL 75-2010 Procedural Manual	Other substances including foods, water, and food additives may also function as processing aids.
1.2	Performs one or more of the technological functions/specified categories for processing aids. Any residues of a processing aid remaining in the food after processing should not perform a technological function in the final food.	Updated IPA-information document CAC/GL 75-2010	Further work is needed to revise and define the categories.
<b>2. Safe Use</b>			
<b>2.1 GMP</b>	Substances used as processing aids shall be used under conditions of good manufacturing practices (GMP) which includes the following:	CAC/GL 75-2010	
2.1.1	Quantity of the substance used is limited to the lowest achievable level necessary to accomplish its desired technological function.	CAC/GL 75-2010	
2.1.2	Residues remaining in food are reduced to the extent reasonably achievable.	CAC/GL 75-2010	Where applicable include a reference to a method for detecting residues and /or derivatives.
2.1.3	The processing aid is prepared and handled in the same way as a food ingredient.	CAC/GL 75-2010	
<b>2.2. Safety</b>	Safety of the substance is demonstrated by the supplier or user of the substance by meeting <b>one or more</b> of the following criteria. (Note that the criteria that are met by a substance may be identified in the Database.):	CAC/GL 75-2010	Relevant information that demonstrates compliance with the Guidelines should be provided. Where possible, this could, reference an appropriate safety evaluation.
2.2.1	The substance is permitted for use by one or more Codex Member countries, which means the substance is:	Discussion paper CX/FA 11/43/20	This criterion acknowledges that the safety of the substance has been considered by those members and that use may be sufficient to establish a history of safe use.
	2.2.1.1. specifically approved as a processing aid by regulation; or		This may be considered sufficient evidence that the use of the substance meets the principles for safe use of processing aids as described in Section 3 of the Guidelines.
	2.2.1.2. used in a Codex Member country and not otherwise prohibited. (Note further discussion above.)		Not every Codex Member regulates the use of processing aids, and there is the possibility that if a regulatory listing is required as criteria for entry into the Database, various processing aids that are used to manufacture products currently in international trade will not be included.

	<b>Criteria for consideration</b>	<b>Reference</b>	<b>Comment</b>
2.2.2	An appropriate risk assessment or an assessment of unintended and unavoidable residues confirms that use of the substance does not pose a health concern.	Discussion paper CX/FA 11/43/20	
2.2.3	The substance has been classified as a processing aid by CCFA.		For example the substance is listed as a processing aid in a Commodity Standard, or where CCFA has agreed to addition of substances to the IPA.
2.2.4	The substance has been evaluated as safe by JECFA for use as a processing aid and is covered under a JECFA specification monograph.		
<b>2.3 Specifications</b>	The substance is of food grade quality An appropriate specification of identity and purity is available.	CAC/GL 75-2010	
<b>2.4. Specific to category or substance</b>	The substance meets any criteria specified for the substance or category of processing aids.		For example, specific criteria for enzymes may be considered.
<b>3. Other Criteria</b>			
3.1 Entry of substances listed in the Updated IPA:	The substance is listed in the Updated IPA and there are no health concerns or other reasons to exclude the substance. (Note further discussion above.)	Discussion paper CX/FA 11/43/20	In the absence of any identified health concern, include substances used as processing aids currently listed in the IPA, noting this is officially a working document for information. There may also be other reasons eg GMP for excluding a substance. NB It will be possible to identify entry criteria met by a substance including those from the IPA.
3.2 Entry of a new substance	The Database procedural requirements are met. For example: A Codex Member has nominated the substance to be added to the Database. NGOs may make proposals that are supported by a Codex Member.	Procedures for elaborating the GSFA Discussion paper CX/FA 11/43/20	Procedures relating to development and maintenance of the Database have yet to be considered.

## APPENDIX 1 INFORMATION ON INTENDED USERS, AND OPTIONS FOR SCOPE OF SUBSTANCES (FROM CX/FA 11/43/20).

### Users of the Database may include:

- Codex Alimentarius Members and Non-governmental Observers (NGOs)
- Industry (eg food additive manufacturers or suppliers, food processors)
- Codex Committees (e.g. CCFA, commodity committees) and CAC
- Any interested person or organization.

### Scope of substances in the Database

**Option 1 (Codex uses)** Include only those substances that:

- The use of which has been classified as a processing aid by CCFA; or
- The use of which is permitted as a processing aid under a Codex Commodity Standard; or
- Are evaluated by JECFA for use as a processing aid and are covered under a JECFA specification monograph that has been recommended by the CAC; and
- Meet any applicable microbiological criteria under CAC/GL 21 1997.

**Option 2 (Acceptable uses)** To list all of the substances under Option 1 plus any substances that are permitted for use by one or more Codex Members, provided that:

- A justified technological need exists under conditions of GMP as required under Section 3.2 of the Guidelines and
- Safety of the substance used as a processing aid is demonstrated as in Section 3.3 of the Guidelines; and
- Food grade quality is demonstrated as in Sections 3.4 and 3.5 of the Guidelines.

**Option 3 (All reported uses)** Include substances under Options 1 and 2 plus any substances used by one or more Codex Member Countries.

**Option 4 (All uses including potential uses)** include substances under Options 1, 2 and 3 plus any substances with proposed or potential uses (or existing substances with new proposed or potential uses) by Codex Members, suppliers or NGOs.

Option 1 Limits the Database to those substances permitted as processing aids in the Codex System and includes the need for a JECFA evaluation. The advantage of Option 1 is that the criteria are well defined. However, only a small number of substances would be included and hence the value of the Database will be limited. Such a database will not accurately reflect usage by Codex Members.

Option 2 is a list of acceptable uses of substances as processing aids based on the principles of safe use contained in Section 3 of the Guidelines. This will provide a useful reference. However, under this option further discussion or guidance will be needed on what is meant by *appropriate assessments* of residues and *appropriate specifications*. It requires a reference to an appropriate safety assessment and specification which requires further consideration of how appropriate is defined.

Option 3 [is the **preferred option** as it] is most consistent with the aim of providing a database of substances used as processing aids. It will provide information on the acceptable use of processing aids on the basis of use by one or more Codex Members and will identify those processing aids already considered within Codex. Option 3 acknowledges that where a substance is used as a processing aid by one or more Members, the safety of such uses will have been considered by those Members. Furthermore, existing uses may establish a history of use.

Option 4 includes potential uses and would further extend the Database. However, potential uses do not meet the criteria for safe use as outlined in the Guidelines. As the Database considered under Option 3 is likely to be widely inclusive of current processing aid usage, Option 4 is not recommended at this time.

Option 3 or Option 4 are able to provide significant information for future processing aid work by Codex or other regulatory agencies, including identifying data gaps such as appropriate safety assessments and specifications of identity and purity.

**APPENDIX 2 -PROCESSING AIDS CATEGORIES BASED ON THE IPA WITH SUGGESTED REVISIONS IN BOLD (FROM CX/FA 11/43/20)**

Processing aids perform one or more of the following technological functions listed as categories of processing aids:

Antifoam agents

**Bleaching agents,**

Boiler water additives

**Carriers**

Catalysts

Clarifying agents/ filtration aids/ decolourants/ adsorbent agents

Contact freezing & cooling agents

Desiccating agent/anti-caking agents

Detergents (wetting agents)

Enzyme immobilization agents & supports

Flocculating agents (**could delete if included in clarifying agents**)

Ion exchange resins, membranes, and molecular sieves

Lubricants, release and anti stick agents, moulding aids

Microbial nutrients and microbial nutrient adjuncts

Micro-organism control agents

Packaging gases

**Processing aids used in packaged water and in water used as an ingredient in other foods**

Solvents, extraction & processing

Washing and Peeling agents

Other processing aids

**Food Enzymes** (including immobilized enzymes)

Further work is needed to define the categories and explain the overlap with food additive functional classes (e.g. carriers and antifoaming agents), noting that these are important functions during food processing as well as in some final foods.