Discussion Committee on Food Additives

Discussion paper on the development of criteria for entry into the processing aids database - Draft 2.1 – 18 Oct 2012

1. INTRODUCTION

The 44th 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.

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 43rd Session of the Codex Committee on Food Additives. The 43rd 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.

As noted in the discussion paper, the content of the database will largely depend on how the database 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 used as a processing aid subject to any stated conditions;
- On substances that are permitted for use by one or more 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.

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.

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 database). 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.

2. SCOPE OF THE DATABASE

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. The database will be of the most use if it identifies all substances that are acceptable for use used as processing aids. The principles for safe use described in the Guidelines should be seen as a suitable basis for criteria for acceptability of use.

The eWG has previously considered various Options that describe the different classes of substances to be included in the database based on various potential uses (scope) of the database and the principles for safe use 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 Members are based on considerations of safe use and technological justification, and therefore should also be considered as sufficient evidence of acceptable for use.

Comment [1]: ICGMA thanks New Zealand and China for the work on the discussion papers on the development of criteria for database entry of substances used as processing aids. ICGMA welcomes this opportunity to offer the following comments in response to the second Draft. As suggested in the attached in Track Changes, the terminology in the latest discussion draft should be modified to reflect the fact that the CAC/GL 75-2010 GUIDELINES ON SUBSTANCES USED AS PROCESSING AIDS (ftp://ftp.fao.org/codex/Meetings/CCFA/ccfa43/fa43_20e.pdf) never refers to "acceptable", "permitted" or "allowed" uses or use levels of processing aids but rather provides principles for the safe use of substances used as processing aids. This database initiative was not intended to be a Codex Standard. Instead, it was to serve as a clearinghouse for substances used as processing aids that may not necessarily undergo review and acceptance by Codex. Thus, the database should not refer to these substances as being acceptable for use which would require review, but rather simply "used" in certain markets.

Additionally, of the options listed in the Appendix "Information on intended uses, and options for scope of substances", ICGMA would support Option 3 in which all reported uses including those used by one or more Codex Member Countries would be entered into the database.

IGCMA thanks you for taking these comments into consideration.

Comment [2]: The guideline CAC/GL 75-2010 on using substances as processing aids never refers to acceptable, permitted or allowed uses or use levels. This is not a Codex Standard but rather a database and without review and acceptance by Codex, should not refer to these substances as such.

Comment [3]: Does the eWG agree that a processing aid is "acceptable for use" if it meets the Guideline criteria?"
3. CONSIDERATION OF CRITERIA FOR THE ENTRY AND UPDATE OF THE DATABASE

The task of the current eWG is to develop criteria for the entry of substances into the database for processing aids. This task is based upon recommendations in the working document on the processing aids database prototype presented to the 44th CCFA. This working document summarized previous recommendations for the criteria for entry of a substance into the processing aids database from the discussion paper presented to the 43rd CCFA 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).

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 procedural criteria, discussed in CX/FA 11/43/20, but not directly discussed in the Guidelines, are included under Criteria 3 Procedural Criteria.

<table>
<thead>
<tr>
<th>Criteria for consideration</th>
<th>Reference</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>CAC/GL 75-2010 Procedural Manual</td>
<td>Other substances including foods, water, food additives may also function as processing aids</td>
</tr>
<tr>
<td>1.2 Performs one or more of the technological functions/specified categories for processing aids. Technological function occurs during the treatment or processing of a food.</td>
<td>Updated IPA information document</td>
<td>Further work is needed to revise and define the categories</td>
</tr>
<tr>
<td>2. Safe Use</td>
<td></td>
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<tr>
<td>2.1 GMP</td>
<td></td>
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<tr>
<td>Substances used as processing aids shall be used under conditions of good manufacturing practices (GMP) which includes the following:</td>
<td>CAC/GL 75-2010</td>
<td></td>
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<tr>
<td>2.1.1 Quantity of the substance used is limited to the lowest achievable level necessary to accomplish its desired technological function.</td>
<td>CAC/GL 75-2010</td>
<td></td>
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<tr>
<td>2.1.2 Residues remaining in food are reduced to the extent reasonably achievable.</td>
<td>CAC/GL 75-2010</td>
<td></td>
</tr>
<tr>
<td>2.1.3 The processing aid is prepared and handled in the same way as a food ingredient.</td>
<td>CAC/GL 75-2010</td>
<td></td>
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<td>2.2 Safety</td>
<td></td>
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<tr>
<td>Safety of the substance is demonstrated by the supplier or user of the substance by meeting one or more of the following:</td>
<td>CAC/GL 75-2010</td>
<td>This could reference an appropriate safety evaluation</td>
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<tr>
<td>2.2.1 The substance is permitted for use by one or more Codex Member countries, which means the substance:</td>
<td>Discussion paper</td>
<td>This criterion acknowledges that the safety of the substance</td>
</tr>
<tr>
<td>2.2.1.1 specifically listed as a processing aid by regulation; or</td>
<td>CFX/FA 11/43/20</td>
<td>has been considered by those members and that use may be sufficient to establish a history of safe use. This may be considered sufficient evidence of acceptable use.</td>
</tr>
<tr>
<td>2.2.1.2 used in the Codex Member country and not otherwise prohibited.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comment [v4]: As noted in the comments by the USA, Criteria 2.2.1.1 and 2.2.1.2 are two possibilities for defining the “use by a Codex Member.” The eWG may like to consider whether a history of safe use in a member country, even without a specific regulatory approval by that member country, may be considered sufficient evidence of acceptable use.

3 ALINORM REP 12/FA, para. 184.
4 CX/FA 12/44/18.
5 CX/FA 11/43/20
6 Acceptable use/ed is based on the criteria in Section 3 of the Guidelines includes that:
- the processing aid performs a technological function under conditions of GMP,
- any residues or derivatives remaining in the food should not pose a health concern,
- an appropriate safety evaluation and specification of identity and purity is available.

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| 2.3.2 | 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 |
| 2.3.3 | The substance has been classified as a processing aid by CCFA. |
| 2.3.4 | The substance is permitted as a processing aid under a Codex Standard. |
| 2.3.5 | The substance has been evaluated by JECFA for use as a processing aid and is covered under a JECFA specification monograph. |
| 2.4 Specifications | The processing aid is of food grade quality. An appropriate specification of identity and purity is available. | CAL/GL 75-2010 |
| 2.5. Specific to category or substance | Meets any criteria specified for a particular substance or category of processing aids. | For example, specific criteria for enzymes may be considered. |

### 3. Procedural Criteria

**3.1 Inclusion of substances already 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. | Discussion paper CX/FA 11/43/20 |

**3.2 Inclusion of new processing aids into database:**

| 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 |

**3.2.1 Inclusion of substances already in the Updated IPA:**

- In the absence of any identified health concern, include in 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 e.g. GMP for excluding a substance.

### Further points

The wording "should not pose a health concern" in reference 6 to explain acceptable use is based on the wording "should not pose any health risk" in the Guidelines. The eWG noted that "any health risk" implies there should be an absolute zero risk, which is impossible to demonstrate. 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 recommends the database criteria use language quoted above. Furthermore, the eWG proposes that CCFA considers a corresponding editorial change to the Guidelines.

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4. Recommendations

Recommendation 1

That the database will be of most value if it identifies all substances that are acceptable for use or have been used as processing aids (Option 3).

Recommendation 2

That the criteria to determine acceptability of use or addition to the list are taken from the Guidelines but applying wording that use of a processing aid "should not pose a health concern" rather the current wording "should not pose any health risk", which may imply there should be zero risk which is clearly not possible to demonstrate.

Recommendation 3

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

Recommendation 4

Taking in account Recommendation 2, CCFA considers a corresponding editorial change to the Guidelines so 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.
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

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
- Desiccating agent/anti-caking agents
- 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.