CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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DISCUSSION PAPER ON DEVELOPMENT OF A DATABASE ON PROCESSING AIDS

Prepared by an electronic Working Group (eWG) led by New Zealand with the assistance of Australia, Austria, Belgium, European Union, France, Indonesia, Hungary, Thailand, Malaysia, Norway, USA, AMFEP, CEFIC, CIAA, ETA, IADSA, IDF, IFAC, IOFI, ISA, ISDFI, and ISDI.

1. BACKGROUND

1. The 42nd Session of the Codex Committee on Food Additives (CCFA; Beijing, China 15-19 March 2010) agreed to consider the development of a database to collect information on substances used as processing aids[1]. In order to start the development of this database, the Committee agreed to establish an electronic working group, led by New Zealand, to prepare a discussion paper on:

- Structure and content of the database, and
- Criteria for the entry and update of the database.

The Committee further agreed to maintain the current updated Inventory of Processing (IPA) until the completion of the database.

2. The discussion paper outlines the two issues and makes recommendations. The paper uses principles contained in the *Codex Guidelines on Substances Used as Processing Aids* (hereinafter referred to as "the Guidelines"; ALINORM 10/33/12, Appendix VIII) that was adopted by the 33rd Session of the Codex Alimentarius Commission (CAC; ALINORM 10/33/REP, Appendix III, Part 2).

2. STRUCTURE AND CONTENT

3. The structure and content of the database will largely depend on how the database is intended to be used. For example, the database could aim to list substances that are safe and acceptable for use as processing aids, based on supporting information from the Guidelines. This could provide helpful guidance to Codex Members on substances that could be used in their country.

4. A wider 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.

2.1 Intended uses of the database

5. The database may be used to provide information:

- On substances permitted for use as processing aids under Codex Commodity 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 Members; and

[1] ALINORM 10/33/REP Appendix III

- 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.

2.2 Intended users

6. Users of the database may include:

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

2.3 Possible structure of the database

7. The database could be divided into the following sections:

Introduction and background to the database

(How the database came to be established, what the database contains, who it is intended for, intended uses, and how it is maintained and updated.)

Scope and purpose

Information on the safe and technologically justified use of substances used as processing aids

(Include reference to the Guidelines)

Definition of terms

Information about substances (main section):

8. Substances could be listed under technological function (as in the IPA), and alphabetically by name (as in the General Standard for Food Additives (GSFA)). Substances may be identified by name and by International Numbering System (INS) number, or Chemical Abstract Service (CAS) Registry Number; or in the case of enzymes, by their unique Number and Accepted Name according to the International Union of Biochemistry and Molecular Biology.

2.4 Type of information in the main table (column headings)

9. The database will need to record information to identify the substance, its technological function, its use as a processing aid, and safety-related information, such as references to specifications and safety evaluations.

2.5 RECOMMENDATIONS – on database structure and content

10. The eWG proposes using the existing structure of the Inventory of Substances Used as Processing Aids (IPA), where processing aids are grouped in alphabetical order by technical function. Structuring the database in this manner is straightforward and has worked well with the IPA. For consistency in identifying substances in the database, the eWG also proposes that, in the absence of a Codex specification of identity and purity, substances used as processing aids be identified by their Chemical Abstract Service (CAS) Registry Number and Systematic Name; or in the case of enzymes, by their unique Number and Accepted Name according to the International Union of Biochemistry and Molecular Biology (IUBMB).

11. The information listed for a specific substance will vary according to the type of substance and whether the information is available or not. The information included in the main table of substances may include the following:

- Substance name, description, code number;
- Technological function (category);
- Area of use (or examples of use that do not limit further uses which are technologically justified);

- Any conditions of use including any maximum permitted levels in the final food and or maximum level of use;
- Reference to an appropriate specification of identity and purity,
- Reference to an appropriate safety evaluation, or demonstration of safety, including appropriate assessment of any unintended or unavoidable residues resulting from its use as a processing aid under conditions of good manufacturing practice (GMP);
- Any further information specific to certain substances (e.g. for enzymes from microbial origin: the source organism, the donor organism (if genetically modified (GM), etc.);
- Reference to the date or CCFA meeting at which the entry or update was agreed; and the name of the Member proposing the entry or update; and
- Any other comments.

12. Further consideration may be needed when recording the area of use so that it is clear whether the listed use is an example of the use or if it is a limitation of use (e.g., the use is limited to the listed process or food category). In most cases the appropriate area will not be limited to specified foods. For example, antifoam agents could be suitable for use in any food where this function is needed. Listing all cases would be impractical and unnecessary.

Options for technological functions or categories of substances:

2.5 Option 1 List substances under the technological function categories used in the IPA

2.5 Option 2 revise the IPA categories, with recommended revisions in bold:

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)

13. The eWG noted that further work should be done 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.

14. The database is likely to be available in electronic form. Therefore, the main table of substances may be arranged in several ways including by technological function, by code number, or alphabetically by name.

3. CRITERIA FOR THE ENTRY AND UPDATE OF THE DATABASE

15. The intent of the database is to identify substances that are acceptable for use as processing aids. This can be achieved by providing information on substances used as processing aids that meet the criteria for safe use as outlined in the Guidelines.

16. ***Acceptable use*** based on the criteria in Section 3 of the Guidelines includes: a technological function that is needed under conditions of GMP, that any residues or derivatives remaining in the food should not pose any health risk, and the availability of an appropriate safety evaluation and specification of identity and purity.

17. However, CCFA may wish to consider "use by one or more Codex Members" as being sufficient for a substance to be included in the database. Such use will normally be based on consideration of safe use.

3.1 RECOMMENDATIONS – on criteria for the entry of a substance used as processing aid to the database

18. The eWG recommends that the *Principles for the safe use of substances used as processing aids* contained in Section 3 of the Guidelines are used to provide general criteria for ***acceptable use*** of a processing aid

3.2 RECOMMENDATIONS – on the range of substances included in the database using criteria for entry

Several options for deciding on entry of substances into the database and subsequent updates can be developed using the criteria in Section 3 of the Guidelines.

3.2 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.

3.2 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.

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

3.2 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

3.3 Further RECOMMENDATIONS –on managing entry and update of the database

24. It may be useful to build the database one technological functional category at a time, or by groups of categories to help ensure orderly development.

25. Another approach, in the absence of any identified safety concerns, is to include in the proposed database all substances used as processing aids currently listed in the IPA. The use of these substances as processing aids should conform to the principles in the Guidelines.

26. The Committee may consider whether only Codex Members should be able to nominate processing aids to be added to the database, as well as to propose modifications to, or the deletion of, existing entries in the database. The nomination, modification, or deletion of the listing of a processing aid from the database should require that the interested Codex Members provide information on the use and safety of the processing aid as specified in the Guidelines. This would be consistent the current procedures for elaborating the GSFA that allow NGOs to provide comments on GSFA provisions, but NGOs may only propose new provisions for, or modifications to, the GSFA if the NGO's proposals are supported by a Codex Member. This procedural model has worked well with the GSFA and is likely to also be effective when applied to the proposed processing aids database.

27. If a database is developed, the Committee may wish to consider establishing an on-going electronic working group to consider new entries and updates to the database and to make recommendations each year to CCFA to update the database.