codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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DISCUSSION PAPER ON THE CONSIDERATION OF PROCESSING AIDS AND CARRIERS IN THE CONTEXT OF THE GENERAL STANDARD ON FOOD ADDITIVES (GFSA)

Secretariat Note: Due to time constraints, comments are not being requested on the attached Discussion Paper and therefore, comment summary paper CX/FAC 02/9-Add. 1 will not be issued.

INTRODUCTION

1. The 33rd Session of the CCFAC considered paper CX/FAC 01/10 on processing aids prepared by New Zealand and CX/FAC 01/9 *Comments submitted on the use of food additives as carriers.*

2. At the 33rd session, CCFAC:
- decided that carriers should be included in the Codex*General Standard for Food Additives* (GSFA);
- agreed that a drafting group led by New Zealand would prepare a discussion paper on the consideration of processing aids and carriers in the context of the GSFA. Drafting group members to assist New Zealand were Australia, Canada, Denmark, Italy, Japan, the Netherlands, the United Kingdom, Association of Manufacturers of Fermentation Enzyme Products (AMFEP), European Commission (EC), Federation of European Food Additives and Food Enzyme Industries (ELC), International Dairy Federation (IDF), Institute of Food Technologists (IFT), and International Federation of Fruit Juice Producers (IFU);
- agreed that comments be requested on CX/FAC 01/10 for consideration by the drafting group; and
- agreed that the document would include a discussion and proposed definition for carriers, the potential amendment to the Codex definition for processing aids, the way in which the substances are used in food processing and similarities and differences between them.[1]

3. This document revises CX/FAC 01/10 to reflect comments on the processing aids paper and CX/FAC 01/9 comments submitted on the use of food additives as carriers. Comments on CX/FAC 01/10 were received from Canada, Cuba, Malaysia, Mexico, the Netherlands, Spain, USA, AMFEP, Conseil Europeen de l'Industrie Chimique (CEFIC), ELC, and International Soft Drink Council (ISDC). ISDC also provided comments on processing aids in CX/FAC 01/9.

ISSUES

4. The key issues discussed in this paper, for consideration by the CCFAC, are:

[1] ALINORM 01/12A, paras 67 and 71.

- Whether the definitions of processing aids and food additives should be amended.
- Defining carriers and including food additives carriers in the GSFA.
- Whether processing aids should be covered under Codex commodity standards.
- Options for considering processing aids in the context of the GSFA including what should be done with the Inventory of Processing Aids (IPA).

SHOULD THE DEFINTIONS OF PROCESSING AIDS AND FOOD ADDITIVE BE AMENDED?

Definitions of terms

5. The following CAC definitions of **food additive** and **processing aid** have been in existence for many years. They have been adopted into many Codex member countries' national legislation, although some countries have adopted modified definitions.

6. **"Food additive** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities."[2]

7. **"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 fulfil 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."[3]

Preliminary discussion

8. Confusion exists over when a substance is a processing aid and when it is a food additive. Confusion is possible due to the complex definitions of **food additive** and **processing aid** provided in the Procedural Manual.

9. A comparison of the two definitions is most easily seen by the table below.

Food Additive	**Processing Aid**
any substance	any substance or material, not including apparatus or utensils,
not normally consumed as a food by itself and not normally used as a typical ingredient of the food,	and not consumed as a food ingredient by itself,
whether or not it has nutritive value,	
the intentional addition of which to food	intentionally used in the processing of raw materials, foods or its ingredients,
for a technological purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food	to fulfil a technological purpose during treatment or processing and
results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of	which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.
or otherwise affecting the characteristics of such foods.	

[2] Codex Alimentarius Procedural Manual, 11th edition, page 45, Rome 2000.
[3] Codex Alimentarius Procedural Manual, 11th edition, page 47, Rome 2000.

10. In terms of Codex definitions it appears that processing aids are intended to be a sub-set of food additives. This is supported by:

- the requirements of the Procedural Manual concerning endorsement and approval of food additives (including processing aids),
- the listing of processing aids in the food additive section of a number of commodity standards, and
- the note in section 6 of the GSFA that the tables do not include processing aids.

11. In terms of the two Codex definitions the key distinguishing features of processing aids from other food additives are:

- they must be intentionally used during the processing of raw materials, foods or ingredients; and
- they are used to fulfil a technological purpose during treatment or processing and not a function in the final food; and
- the presence of any residue of the substance must be non-intentional and unavoidable.

Comments received and further discussion

12. The Netherlands and ELC have highlighted that a key problem is the way that the term 'food additive' is often used, including by CCFAC. The formal definition is wide and refers to substances having a technological effect at any stage during the manufacture, processing etc. However, 'food additive' is often used in a narrower sense, to refer only to substances that have a technological effect in the finished food or food ingredient. However, we have no more specific term to cover this narrower sense.

13. USA and Canada proposed retaining the existing definitions of food additive and processing aid. Only one country (Mexico) proposed an amendment to the definition of 'food additive'. However the suggestion to shorten and modify the definition does not appear to assist in distinguishing between food additives and processing aids.

14. Three comments were received on changing the definition of 'processing aid'. The Netherlands proposed:

- defining 'processing aids' as a category on its own and adjusting the definition of 'food additive' in such a way that it does not include processing aids, and
- defining 'residue'.

Creating suitable wording to achieve this was not suggested and may create wider problems within Codex where the terms processing aid and food additive are used. (The issue of residues is further discussed in section 6, on handling processing aids in the context of the GSFA.)

15. CEFIC proposed that the addition of the requirement that "residues not present any health risk". This addition is superfluous, as the definition of food additive does not speak about the absence of a health risk. Under Codex, safety in use is essential and a requirement before CCFAC endorses proposed uses.

16. Mexico, as well as suggesting shortening the definition, also proposed the addition of a phrase at the end of the definition to make it clear that processing aids do not perform any technological function in the finished product. The suggestion from Mexico to add a definition for 'processing' to include activities in the distribution, handling storage and retailing of the product appears to conflict with the intent of the use of the term 'processing' in the definition of 'processing aid'.

17. ELC considered the current definitions cause confusion and suggested it should be clearer how to distinguish between processing aids and food additives. ELC does not regard it as generally accepted that processing aids are a subcategory of food additives. They consider that if it were true that processing aids are a sub-category of additives, an attempt to distinguish between the two would be comparable to an attempt to distinguish between a rose and a flower. ELC considered that the same rules applying to carryover of additives requiring the amount present in the final food to be safe and non-functional should also apply to processing aids. AMFEP supported the ELC comments.

18. The ELC and Mexico proposal to add to the definition that processing aids do not have any technological effect in the final food seems useful. The current definition allows for processing aid residues to exert a technological effect in the final food, provided the substance was initially used to assist processing. This

seems to provide a loophole, since current labelling rules would not alert consumers to the presence of the residue or its technological effect. For labelling purposes the *Codex General Standard for the Labelling of Prepackaged Food* (section 4.2.3) requires labelling of direct food additives and additives carried over into a food in a significant quantity or amount sufficient to perform a technological function in that food. Labelling is not required food additives carried over into foods at a level less than that required to achieve a technological purpose, or processing aids.

19. The greatest confusion internationally, regarding distinguishing processing aids from other food additives, is caused by some countries using different definitions to Codex in their national law. Some countries regard substances that fulfil a technological purpose during processing and leave a residue in the food to be food additives and regulate as for direct food additives. This has had consequences for the GSFA in that some processing aids will occur in the GSFA. While CCFAC states that processing aids are not listed in the standard it also accepts substances for inclusion in the GSFA that are regulated as food additives by the country initiating the request for inclusion.

CARRIERS

Background

20. Neither Codex nor JECFA have established a definition for a carrier. However, the Codex definitions of food additive and processing aid do not exclude substances that are used as carriers. The list of technological function classes for food additives used by Codex does not include carrier functions. CCFAC has however used the JECFA functional name "carrier solvent " in the GSFA[4]. JECFA also uses the terms "carrier"[5] and "carrier for flavour"[6] in more recent monographs for food additives.

21. In some food additive preparations, some food additives, (and foods) are used to function as solid carriers (e.g. sugar, salt, cyclodextrins, talc), carrier solvents (e.g. propylene glycol, ethyl acetate), diluents and encapsulating agents.

Examples of carriers

22. Below are examples of food additives as they function as carriers.

- Propylene glycol, used as a solvent to dissolve and disperse other food additives.
- Dioctyl sodium sulfosuccinate used to solubilise hydrophilic gums and colloids to prevent aggregation of the gum or colloid and to promote rapid hydration when added to water.
- Polysorbate 60 used as a surfactant or wetting agent for colours added to dry soft drink, gelatin dessert, and pudding mixes to enhance dispersion. Some natural and artificial colours are not readily soluble in water or in many foods.
- Cyclodextrins for use as an encapsulating agent for flavours added to water-based beverages, to extend the shelf life of flavours stored in a dry state and release flavour when added to a beverage.
- Carriers such as triglycerides used to coat granular aspartame to inhibit decomposition during baking. Such carriers melt near the end of the baking cycle releasing the aspartame.

Definition

23. A suggested Codex definition for carriers for consideration is:

"A carrier is a substance that is intended to serve as a vehicle for the introduction of, or to facilitate the delivery of another food additive, (or to stabilise another food additive), or to otherwise enhance the other food additive's intended functional effect in the final food[7]."

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[4] For example, CCFAC uses the functional class 'carrier solvent' for candelillia wax, carnauba wax, caster oil, and propylene glycol (Alinorm 01/2A App II, III and IV).

[5] For example, the monograph for gamma- cyclodextrin in Food and Nutrition Paper Number 52 Addendum 6 lists 'carrier' as a functional use. The monograph for beta-cyclodextrin in Food and Nutrition Paper Number 52 Addendum 3 lists 'encapsulation agent for food additives, flavourings and vitamins' as a functional use.

[6] For example, the monograph for Carnauba wax in Food and Nutrition Paper Number 52 Addendum 3 lists 'carrier for flavour' as a functional use.

[7] US comments in CX/FAC 01/9.

24. CCFAC should consider whether the phase in brackets in the proposed definition is needed. The functional class name stabiliser does not cover such functions. See para 22 for examples. Stabilisers make it possible to maintain a uniform dispersion of two or more immiscible substances in food.

25. The UK prefers the following definition, which is based on the EU definition of carrier:
"A carrier is a food additive that is intended to facilitate delivery of another food additive, by dissolving diluting, dispersing, or otherwise physically modifying it, but without exerting any technological effect itself."

26. The UK proposed definition is more constrained in scope than that proposed for use by CCFAC and would prevent the use of:
- carriers that stabilise another food additive (e.g. the stability of aspartame in the example in paragraph 22), and
- substances exerting some functional effect in the final food (such as the last four examples in para 22).

27. Sub-classes of carriers are solid carriers, carrier solvents, diluents and encapsulating agents. The definition and sub-classes could be added to the *Table of functional classes, definitions and technological functions for food additives* that is published by CAC and used for labelling purposes by the Codex Committee on Food Labelling.

Carriers as part of the GSFA

28. At its 33rd Session, CCFAC decided that carriers should be included in the GSFA.[8]

29. A specific category for preparations of food additives could be introduced into the GSFA Food Categorisation System. This would allow entries for food additive preparations to be made in Table 1 and Table 2. This would allow the substances used as carriers to be listed as well as providing permission to use food additives with a wider range of needed technological functions.

30. In addition to carriers, food additive preparations may contain food additives such as anti-caking agents, emulsifiers and preservatives that are used to stabilise or enhance their usability. These food additives are used to perform technological functions at similar levels as they would when used in foods.

31. A number of Codex advisory specifications (i.e. JECFA Monographs) contain provisions permitting subsidiary food additives (e.g.antioxidants)[9]. These tend to be permitted to ensure the stability of the additive as such rather than to assist their incorporation into food additive preparations or other foods. The format for JECFA monographs for flavours is different to other monographs. The monographs for flavours are for the individual chemicals used as flavours and do not provide for any subsidiary food additives such as carriers that may be needed when these chemicals are mixed to create flavour preparations.
Many food additives preparations, including flavour preparations would need permission to contain other food additives, in addition to those requiring the use of carriers.

32. CCFAC might consider establishing food categories for other minor ingredients such as vitamin preparations (sold as such or used as ingredients in food), which may need to use carriers.

SHOULD PROCESSING AIDS BE COVERED UNDER COMMODITY STANDARDS?

Procedures for handling processing aids

33. The Codex Procedural Manual prescribes how commodity committees and CCFAC should address food additives and contaminants,[10] including processing aids.

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[8] Alinorm 01/12A, para 67.
[9] For example, the monograph for carotenes (algae) permits the presence of tocopherols to retard oxidation of the pigment, the monographs for mineral oil (medium and low density) and petroleum jelly permit antioxidants for food use, and the monographs for carthamus red and carthamus yellow permit the use of food grade materials such as dextrin to be added as carriers for manufacturing the dry powdered items of commerce.
[10] Codex Alimentarius Procedural Manual, 11th edition, pages 93-95, Rome 2000.

34. Codex commodity committees are required to "*prepare a section on food additives in each draft commodity standard and this section should contain all the provisions in the standard relating to food additives. The section should include the names of those additives which are considered to be technologically necessary or which are widely permitted in the food within maximum levels where appropriate*". (Note that there is no reference to processing aids in this first paragraph, unlike the subsequent paragraphs, which may cause some confusion.)

35. The Procedural Manual requires that "*All provisions in respect of food additives (including processing aids) and contaminants contained in Codex commodity standards should be referred to the CCFAC…"* and *"All provisions in respect of food additives will require to be endorsed by the CCFAC…"*.

36. In preparing working papers for the CCFAC, the Secretariat should prepare a report concerning the endorsement of provisions on food additives (including processing aids) on the basis of the General Principles for the Use of Food Additives. The general principles are now included in the Preamble to the General Standard for Food Additives (GSFA) (Codex Stan 192-1995).

37. Conflicting decisions by the CCFAC have resulted in confusion among Codex commodity committees over whether processing aids should be listed in commodity standards and, if listed, whether they are subject to endorsement by the CCFAC. For example, the CCFAC agreed[11] that the listing of processing aids did not need to be endorsed in commodity standards when discussing the vegetable protein products (1989) and soy protein products (1989) standards. The Codex Alimentarius Commission (CAC) subsequently adopted these standards containing reference to the IPA[12]. CCFAC however has endorsed provisions for processing aids in the food additive section of twelve commodity standards (including several fruit juice standards).

The need for Codex provisions on processing aids

38. The CAC's primary purpose in developing internationally adopted food standards is to protect consumers' health and ensure fair practices in food trade. The CAC has a medium term objective to integrate risk analysis principles into Codex procedures. However within Codex processing aids have not been subject to the same risk analysis principles as other food additives.

39. Ensuring fair practices in food trade is another aim of Codex standards. Codex standards and related texts have status as reference documents in international trade with regard to the World Trade Organisation (WTO) Agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Technical Barriers to Trade (TBT Agreement).

40. Codex member countries treat processing aids in different manners, which could result in trade restrictions or barriers. The absence of provisions for processing aids such as a list of processing aids in a Codex standard or related text could lead to processing aids being used as sanitary (due to safety concerns) or technical barriers to trade. As many commodity standards are silent on processing aids, they are not comprehensive with respect to all risks for the foods that they cover. This could have a negative impact on international trade.

Options for dealing with processing aids in commodity standards

41. The following options available to the CAC for handling processing aids have been identified.

Option 1 – Continue to include processing aids in commodity standards

42. The current requirement to include processing aid provisions in commodity standards (where appropriate) ensures a consistent approach to listing substances that may be permitted in food. Permitted food additives and nutritive substances and maximum permissible levels of contaminants are all positively listed in standards.

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[11] Alinorm 98/12A, para 99.

[12] These standards permit a list of functional classes of processing aids, as compiled in the advisory inventory of the CAC.

43. Commodity committees have the best knowledge about the technological need and types of substances used in foods regulated by a commodity standard. They would be responsible for deciding on and preparing the justification for inclusion of processing aids in the relevant commodity standards.

44. To make this option work, the Codex Secretariat would have to provide guidance to commodity committees on what information is required to propose use of processing aids, reinforce the requirement to include processing aid provisions where applicable in new commodity standards, and recommend revision of existing standards.

45. One drawback of this approach is that only a small percentage of foods are regulated by Codex commodity standards. There is no international guidance for those foods that are not regulated by commodity standards and have a technological need for processing aids. This has both food safety and trade implications for those foods.

Option 2 – Remove processing aids from commodity standards

46. If processing aids continue to be of concern to the CAC, they could be handled other than by inclusion in commodity standards. For example, a positive list of safe and suitable processing aids, specifying maximum residue limits, could be developed.

Comments received

47. Canada considers processing aids should appear in Codex standards and be referred to CCFAC for endorsement only if the processing aids leave residues. Mexico regards locating processing aids in commodity standards as the least desirable option and prefers a horizontal approach to processing aids (see section 6). USA suggests that processing aids should continue to be listed in a subsection under the food additive section of commodity standards. But permission should be for a technological function (e.g. antifoaming agents) not listing specific names of processing aids.

Further discussion

48. The USA proposal has considerable merit. Currently, of the twelve commodity standards that include permission for processing aids, eight list the functional classes of processing aids permitted (e. g. by referring to 'clarifying agents and filtering agents approved by the CAC' or listing the class names 'as compiled in the advisory inventory of the CAC') without listing the specific substances permitted in those classes. A prerequisite for the USA proposed approach is a positive list of safe and suitable processing aids listed by functional class. No such list currently exists. If CCFAC decides to develop a horizontal standard on processing aids CCFAC should consider the USA proposal to list only functional classes of processing aids permitted in commodity standards.

49. As processing aids are food additives they should be handled the same way as other food additives. The discussion and decision of CCFAC under agenda item 7 (b) *Discussion Paper on the Relationship Between Codex Commodity Standards and the Codex General Standard for Food Additives, including Consideration of the Food Category System'* will further assist CCFAC consideration of how to deal with processing aids in commodity standards.

OPTIONS FOR A CONSISTENT HORIZONTAL APPROACH TO PROCESSING AIDS AND WHAT SHOULD BE DONE WITH THE INVENTORY OF PROCESSING AIDS (IPA)

Inventory of Processing Aids

50. The primary focus of the CCFAC's discussions on processing aids relates to the development of the IPA.[13] The IPA is a collection of information submitted by national authorities. CCFAC has not conducted

[13] Alinorm 89/12A, Appendix VIII.

its own risk assessment of the substances on the inventory, whose purpose is simply to provide a list of those substances whose sole function is as a processing aid.[14]

51. The CCFAC's primary purposes for the IPA were to:
- develop information on substances used as processing aids; and
- determine priorities for the review of processing aids by JECFA.

52. The Introduction to the IPA indicates that "the character of the Inventory is not intended to be complete or a *positive list* of permitted aids".[15] For example, it was not intended to be used by reference in Codex commodity standards. However, despite the introductory statement, it is often viewed as an approved list of processing aids. The IPA's status as a published Codex advisory text and the reference to the advisory inventory in the processing aid section of several Codex commodity standards contributes to the misperception.

53. The second main problem with the existing IPA is that it has not been kept current. Although the CCFAC appeared to commence work on processing aids in 1979, it was not until 1989 that a comprehensive list of processing aids was presented for discussion by the CCFAC. No agreed update by the CCFAC has been appended to any report of the CCFAC, nor submitted to the CAC for adoption, since then. A proposed revision (prepared by Germany and in an abridged form) was discussed by the CCFAC in 1996. As this revision was not agreed to be satisfactory, however, resubmission was requested, but this has not occurred.

54. New Zealand has prepared a draft updated IPA[16] that could be used by the CCFAC. It includes all clearly stated decisions by the CCFAC for amendments since 1989, and other relevant information. New Zealand has also prepared a list of substances proposed at previous sessions of CCFAC for inclusion in the IPA but on which CCFAC has made no decision to date on whether to include in the IPA[17].

Options for a horizontal approach to processing aids

Option 2a – Include processing aids in the GSFA

55. There are benefits to the horizontal approach adopted by Codex for food additives. The inclusion of processing aids as a section of the GSFA would reinforce that processing aids are a sub-category of food additives. Also, including processing aids in the GSFA would enable the CCFAC to build on the General Principles for the Use of Food Additives, on other requirements within the Preamble to the GSFA, and on procedures used to develop other parts of the GSFA. As a sub-category of food additives, processing aids interface with some of the provisions in the GSFA. Much of the Preamble to the GSFA is applicable to processing aids, with specified exceptions (Tables 1, 2, and 3).

56. The functional classes of food additives are listed in relation to each substance listed in Table 1 of the GSFA but not for generally permitted additives in Table 3. The IPA also lists processing by functional class, although the functional classes are generally different from those for food additives[18]. The GSFA addresses food additives in all foods rather than a narrow range of foods for which Codex commodity standards have been developed. The use of functional categories across all foods could be appropriate for processing aids.

Option 2b – Develop a horizontal standard for processing aids

57. Many of the current problems around the IPA would be solved by the development of a Codex standard listing safe and suitable processing aids that could be approved by the CAC. This would be consistent with the CAC approach to other issues that transcend individual commodity standards, e.g. food additives, contaminants, and labelling. As for food additives, a horizontal standard for processing aids would apply to

[14] However, the IPA does contain substances that can function as direct food additives (i.e. have a function in the final food). Also, Appendix A of the IPA contains food and food additives that can also function as processing aids.
[15] Codex Alimentarius, Volume 1A, Section 5.9, pages 219-220.
[16] This list is not appended, but is available on request from the NZ delegation.
[17] This list is not appended, but is available on request from the NZ delegation.
[18] The only functional class in common between the two lists is for antifoaming agents and propellants.

all foods and not just those foods standardised by a Codex commodity standard. This would provide greater flexibility to address evolving food consumption trends and trade patterns among countries.

Issues relevant to both options

58. Development of a standard for processing aids would ensure a consistent risk management and risk assessment approach for all substances that are present in a food, even at very low levels. In line with the GSFA, only those substances that have been evaluated as safe by JECFA would be listed in the standard. This would eliminate the confusion around the safety status of processing aids listed in the current IPA. It would remove the problems associated with some commodity standards being silent on processing aids and other commodity standards misleading the user to believe that Codex has approved the permitted processing aids and that they are therefore safe for use in food.

59. This approach would also remove potential trade issues, as the SPS Agreement does not distinguish among Codex texts: it recognises all of "the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives…".[19]

60. One problem with these options is the limited data in the IPA on residues, interactions with food and toxicology. Perhaps this indicates that such data is not available. It has impacted on the ability of CCFAC to decide priorities relating to JECFA assessments for processing aids.

61. On the positive side, approximately half of the substances listed in the IPA have been evaluated by JECFA. Some have been evaluated for direct food additive functions, not specifically as processing aids, The large number of substances that have not yet been evaluated by JECFA could place increased demand on JECFA resources. Alternatively, CCFAC will need to prioritise the evaluation of processing aids, food additives, contaminants and other substances for which a risk assessment is required.

62. However, if a new approach to JECFA advice is sought a standard covering processing aids may be able to be developed quickly. For example CCFAC could seek JECFA's advice on a risk management approach based on variants of a GMP listing. Instead of seeking JECFA assessment of individual substances, some scenarios could be put to JECFA for an assessment of whether the risks are insignificant. For example, whether JECFA could consider:

- for those substances in the IPA already evaluated as direct food additive, (whether given a numerical ADI or ADI "not specified") and which also have processing aid functions, and based on the data available in the IPA on likely residues whether any additional intake would be insignificant compared to direct additive use such that they can be generally permitted as processing aids for the functions listed in the IPA.
- if a threshold of residues of no toxicological concern could be applied to many processing aids not yet evaluated by JECFA and what such a threshold might be. Substances with residues below the threshold, together with the threshold or default level in food, could then be listed in the Codex standard.
- what situations might warrant a more prescriptive approach such that it is necessary to list the food types in which the substance can be used as a processing aid and specify the maximum residue permitted in the final food.

63. Significant CCFAC resources are currently being directed towards the development of the GSFA, which is expected to take several more years to complete. CCFAC resources are unlikely to be available to actively develop a positive list of processing aids until the work on food additives is substantially complete.

Comments received

64. Canada suggesting including processing aids in the GSFA but only those substances that leave residues in food should be listed. For substances not leaving residues (and for those that do) Canada believes that these should be listed in the IPA. Cuba believes processing aids should be included in the GSFA. USA gives in principle support for inclusion of provisions for processing aids in the GSFA, but recommends that the IPA be first updated and elaborated independently. Malaysia supports a horizontal approach to the

[19] SPS Agreement, Annex A, "Definitions", section 3(a).

control of processing aids. Mexico considers the horizontal standard and GSFA standard options merits further discussion. Spain proposes a horizontal standard so as not to obstruct further progress with the general standard. ISDC also supports the GSFA covering all additives including processing aids. ISDC asks:

- If there is a single list of processing aids and food additives, how would processing aids be defined by functional class?
- If processing aids are appended as a separate list to the GSFA, how would the standard deal with substances that are a direct additive in some situations but a processing aid function in other situations?

Further assessment of options

65. One simplified approach would be to disregard those processing aids that leave no residues in foods and to include in the GSFA (or a separate general standard for processing aids) only those that leave residues. An acceptable cut-off for residues to be regarded as non-detectable would need to be defined and accepted by JECFA as of no toxicological significance. However, listing only substances that leave residues is likely cause confusion over the status of substances not listed in the standard. If a substance is not listed, is this because it is not safe, or because it does not leave a detectable residue?

66. A more global and transparent approach is a standard that lists substances whether they leave residues or not. The standard for processing aids in section 1.3.3 of the joint Australia New Zealand Food Standards Code (available on the ANZFA website: www.anzfa.gov.au) provides an example of a general standard on processing aids. In this standard permission is based on functional use. Many substances are permitted for use in foods generally at GMP; other substances have maximum residue limits set and/or are limited to use in certain foods.

67. ISDC's questions could be resolved by

- Developing a table of widely permitted processing aids that are limited only by GMP; and where necessary, including particular substances provided residues are below a suitable threshold level. (This could be part of or attached to Table 3 of the GSFA); and
- Substances with very specific food uses, or a need to limit use to specific residues in certain foods would form part of Table 1 and Table 2 of the GSFA.

What should be done with the IPA?

Options

68. Changes to the existing IPA should be given serious consideration, given the problems noted earlier: primarily, lack of currency and the misperception that is a list of approved substances.

Option 1 – Update and maintain the IPA as an advisory list

69. In the short term, the CCFAC should consider amending the title of the IPA to ensure its purpose is unambiguous. The aim is to ensure that readers are not misled into believing that the IPA is a Codex "positive" or "approved list". A possible title is: "Register (or Inventory) of Substances reported to be used as Processing Aids", followed by a statement such as: "This is NOT a positive list of approved processing aids. Before using or proposing permission for the use of any substance, a safety evaluation must be conducted."

70. Retaining the IPA as an advisory text provides some openness about substances that are used or sold as processing aids in member countries, particularly if it was revised to a listing of national processing aid provisions. However, currently it does not give any indication either as to which member countries permit a substance or to any maximum residue levels that may be prescribed in national legislation.

71. If the IPA is regularly updated, it may be a useful reference document for CCFAC when assessing requests for endorsement of processing aids in commodity standards or assessing the need for a risk assessment of substances. The IPA also highlights shortcomings in the CCFAC's knowledge about the use, residues and toxicological evaluation of listed substances.

72. However, retaining the current IPA is contrary to Codex objectives with respect to protecting consumers' health and ensuring fair practices in trade. Codex advisory texts have no different status to standards or guidelines in the SPS Agreement. Even with a new title for the IPA, substances in the list could be interpreted as being assessed as safe for use in food. Individual member countries will have to decide how they will apply these texts.

73. The current IPA advisory text is also contrary to the statement in the Procedural Manual that food standards, guidelines and other recommendations of CAC should be based on the principles of sound scientific analysis and evidence and the requirement to integrate risk management principles into Codex procedures.

Option 2 – Update and maintain the IPA as an in-house document (from which to develop a general standard covering processing aids)

74. Another option is to retain a current, updated version of the IPA, to be used as an in-house reference tool by the CCFAC. Using the IPA in this way in the short to medium term could assist the CCFAC in the development of a Codex standard.

75. In this scenario, the CCFAC would still need to continue to gather information to keep the IPA up to date. As the CCFAC would not refer the IPA to the CAC for approval, this option reduces accessibility to the information contained in the Inventory, as it would not be published or included in the CAC web site. The CAC's approval to remove the IPA as an advisory document would be required.

76. Changing the status of the IPA to an in-house document reduces the potential for confusion over the list being an approved list of permitted processing aids. Possible concerns about the safety of residues of processing aids in foods remains, but the IPA is removed from any questions or disputes concerning the safety of food.

Option 3 – Withdraw the IPA

77. The IPA could be viewed as a redundant document if processing aids are handled through either commodity standards or a horizontal standard. Similarly, the CCFAC could simply provide general guidance to commodity committees, for example, in the Procedural Manual or GSFA. This could outline such general requirements as ensuring that processing aids are safe for human consumption and that they leave minimum residues in the final food product, toxicological evaluation, and so on.

78. Alternatively, the CCFAC could agree that it is not necessary for the CAC to address processing aids if it considers that the risks from any residues are not of toxicological concern. In these scenarios, the CCFAC could agree to withdraw the IPA and seek approval from the CAC to delete it as an advisory text.

79. Retention of the IPA has to be questioned because CCFAC has not met its objective of prioritising substances for review by JECFA since approving the first version (ALINORM 89/12A, Appendix VIII). However, it does provide some openness concerning the use of processing aids and this would be lost if it were withdrawn.

Comments received

80. Canada suggests maintaining the IPA as an advisory list, to list all processing aids whether they leave residues or not. Canada does not propose assigning priority to such work. Cuba wants the IPA updated and used as an internal reference document by CCFAC. Spain proposes updating and maintaining the inventory as a consultative list. USA proposes updating the IPA and then using it to develop processing aid provisions in the GSFA. CEFIC questions the need for the IPA (if its suggestion on definition change for processing aid is adopted) and proposes the IPA be abandoned. ISDC suggests that, if CCFAC decides to include processing aids in the GSFA, the IPA should be withdrawn.

Further assessment

81. There is little support for retaining the IPA as an advisory document. The use of the IPA as a starting point to develop a horizontal standard seems more appropriate.

RECOMMENDATIONS

Definitions of food additive and processing aid

82. CCFAC should consider:
1. Retaining the current definition of food additive and amending slightly the definition of processing aid by adding the phrase 'which have no technological effect in the final product' at the end of the definition.
2. Establishing guidelines on how to interpret the definitions of food additive and processing aid, with an emphasis on how to distinguish between the two terms.

Definition of carrier and inclusion of carriers in the GSFA.

83. CCFAC should agree to:
1. Define a carrier as "*A carrier is a substance that is intended to serve as a vehicle for the introduction of, or to facilitate the delivery of another food additive, or to stabilise another food additive, or to otherwise enhance the other food additive's intended functional effect in the final food"*.
2. The following sub-classes for carriers: solid carrier, carrier solvent and encapsulating agent.
3. Propose to CCFL the inclusion of the above definition and sub-classes in the *Table of functional classes, definitions and technological functions for food additives* published by the CAC.
4. Include a category for "food additive preparations" in the food categorisation system used in the GSFA
5. Consider including a category for "vitamin preparations" and other minor ingredients and permitting the use of carriers in these categories.
6. Seek information from member countries and international organisations on the carriers (and other food additives such as preservatives, anticaking agents) that should be considered for inclusion in food additive preparations.

Processing aids in commodity standards

84. CCFAC should agree that:
1. If the GSFA (or a companion standard on processing aids) lists processing aids by functional class, then wherever possible, commodity standards should list just the functional classes of processing aids permitted in the commodity standard. The permission should appear as a subcategory of the food additive provisions in the commodity standard (but clearly delineated under the heading 'processing aids').
2. In the interim, Commodity Committees should be reminded of the Procedural Manual requirements and that processing aids should appear as a subsection of the food additive section of a commodity standard.
3. CAC agreement should be sought to a modification to the Procedural Manual concerning endorsements by putting processing aids in brackets after the use of the term food additive wherever it is used in p95 and 96. Such a requirement would remain until a general standard covering processing aids is developed.

Horizontal approaches to processing aids?

85. CCFAC should consider:
1. Expanding the GSFA to include processing aids whether they leave residues or not, noting that of the options for a horizontal approach to processing aids, expanding the GSFA has the least problems.

2. Wherever appropriate the GSFA expanded to include processing aids should provide:

- general permissions for specific processing aids according to functional class limited by GMP, and where necessary, include particular substances provided residues are below a suitable threshold level; and
- specifying numerical limits or specific food uses for substances only where necessary for public safety.

3. Seeking CAC agreement to including processing aids in the GSFA.

JECFA advice

86. CCFAC should:
    1. Consider different approaches when seeking JECFA advice on processing aids, such as asking JECFA if it possible to set a threshold of no concern, rather than asking JECFA to consider substance by substance.
    2. Note that a significant number of substances could be readily assessed for inclusion in the GSFA as about half of the substances in the New Zealand update of the IPA already have JECFA numerical ADIs or ADI "not specified". Some of these assessments are for direct food additive use. Therefore JECFA advice may be needed on whether additional intake through use as processing aids would be insignificant. CCFAC would be responsible for assessing the residue situation. If there are no residues, the matter need not be referred to JECFA.

What should be done with the IPA?

87. CCFAC should:
    1. Seek CAC agreement to withdrawing the IPA as an advisory document and agree that the IPA should be used as an in house document, intended for use only by CCFAC, updated and used to develop provisions for processing aids in the GSFA.
    2. Circulate the updated IPA proposed by New Zealand, along with the list of substances proposed for inclusion in the IPA but on which CCFAC has made no decision at previous sessions with a view to agreeing an updated IPA for in house use.
    3. Circulate the updated IPA (with amended title to make clear it is not a positive or approved list) and seek further information on proposed uses to make it more complete. Such information should include area of use (food category), how it is used and include any available information on residues, interactions with food and existing JECFA evaluation.
    4. Seek requests for further substances for inclusion in the list (supported with the information listed above) with a view to consideration of substances in the IPA for inclusion in the GSFA as permitted processing aids.
    5. Use the updated IPA as a worksheet from which to develop provisions for processing aids in the GSFA.