CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 8 **CX/FA 18/50/13 Rev.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

DISCUSSION PAPER ON "FUTURE STRATEGIES FOR CCFA"[1]

Background

1. The 70th Session of the Executive Committee of the Codex Alimentarius Commission (CCEXEC 70) recommended that all Committees consider the need to develop an approach for the management of their work similar to that used by the Codex Committee on Food Hygiene (CCFH).[2] In response to the request from the CCEXEC, the 48th session of the Codex Committee on Food Additives (CCFA48) agreed to develop a discussion paper defining broader strategies on how CCFA could prioritise its future work.

2. CCFA49, held on 20-24 March 2017 in Macao SAR of China, considered the Discussion Paper on the Management of CCFA Work[3] prepared by China and the United States of America, with assistance of Australia. The Committee generally supported the Chair's proposal of a "one CCFA approach" and further agreed that the Chairs of the four Working Groups (WGs; i.e. WGs on: General Standard for Food Additives (GSFA); Alignment of Food Additive Provisions in Commodity Standards and GSFA (Alignment); International Numbering System (INS), and Priority List for Joint Expert Committee on Food Additives (JECFA) Evaluation) working with China (host of CCFA), would develop a discussion paper on "Future Strategies for CCFA", which analyzes the major challenges and barriers hindering the advancement of CCFA work.[4]

3. A pre-consultation was undertaken in May 2017 in which an e-mail was sent to all the CCFA49 delegations to ask for their comments and suggestions on CCFA's future strategy. Fifteen replies[5] were received containing a total of 47 individual comments. These comments and recommendations, together with those raised at CCFA49 were summarised into the following major areas:

I. General Standard for Food Additives (GSFA)

- Principle and Procedure of Reviewing Provisions Currently in the Step Process;
- Colour and Sweetener Provisions/ Provisions with Note 161.

II. Alignment of Food Additive Provisions in Commodity Standards and GSFA

- The role of the Commodity Committees;
- Management of the workload and the backlog.

III. International Numbering System (INS)

IV. JECFA Evaluation and Re-evaluation of Food Additives

- Prioritisation of requests to JECFA;
- Requests for substances that are not to be included in the GSFA;
- Information supporting the requests;
- Maintenance re-evaluations of additives in the GSFA.

V. Processing Aids

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[1] Comments on the document are requested through CL2017/92-FA by 15 February 2018.
[2] CCFH Information Document.
[3] CX/FA 17/49/14.
[4] REP 17/FA, para. 141.
[5] Replies received from: European Union, New Zealand, Iran, Russian Federation, AMFEP, CCC, IACM, ICA, ICBA, ICGA, ICGMA, IFAC, IOFI and NATCOL.

VI. Prioritisation of CCFA future work

4. Between May and September 2017 the four WG Chairs and China, in consultation with the Codex and the JECFA Secretariats, held several teleconferences and worked electronically to evaluate the issues and prepare options/recommendations for the committee to consider.

I. General Standard for Food Additives (GSFA)

Principles and Procedures for Reviewing the Provisions Currently in the Step Process.

Analysis of key issues

5. In response to the pre-WG consultation, several participants expressed concern that many draft and proposed draft provisions have been held at their current Step for a long period of time. These comments also asserted that the long delay resulted in a loss of information that would be useful to the Committee when determining if the provision met the GFSA adoption criteria.

6. As noted in the "Discussion Paper on the Management of CCFA Work" (CX/FA 17/49/14), it is expected that CCFA can complete its work on the remaining historical provisions for which no "outstanding issues" have been identified by its 52nd session (2020). The Committee will then be able to circulate provisions for comment soon after a provision enters the Step Process. The proposed new process is presented below:

(i) Once an additive has a JECFA acceptable daily intake (ADI) and specifications, and INS number and functional class, provisions for the additive can be submitted in response to the Circular Letter (CL) for new provisions/revision of adopted provisions;

(ii) Proposals submitted in response to the CL are discussed in the physical Working Group (PWG) at the following session of CCFA. Based upon consensus, the PWG provides recommendations to the Plenary of CCFA on entry of the proposed draft standard into the Step Process at Step 2. The Plenary determines if the provisions are entered into Step Process at step 2;

(iii) If the CCFA Plenary enters the provisions into the Step Process the provisions will be circulated for comment at Step 3 by the subsequent GSFA electronic Working Group (EWG). The GSFA EWG formulates proposals for those provisions (adopt, discontinue, discuss further, etc.) based upon EWG member comments;

(iv) The PWG at next CCFA session discusses the GSFA EWG proposals and sends recommendations to the Plenary (adopt, discuss further, etc.);

(v) The Plenary discusses the recommendations of the PWG. Based upon the decision of the Plenary, the provision is either recommended for adoption at Step 5/8, is re-circulated for comment, or discontinued.

7. This approach is similar to the current approach taken by the Committee for progressing provisions through the Step Process, with the exception of Step (iii), in which provisions entered into the Step Process at Step 2 will automatically be circulated for comment at Step 3 by the subsequent GSFA EWG, rather than being held for circulation at some later date.

Recommendation 1: That the Committee utilize a new process by which provisions entered into the Step Process at Step 2 will automatically be circulated for comment at Step 3 by the subsequent GSFA EWG.

Colour and Sweetener Provisions / Provisions with Note 161

Analysis of key issues

8. There are numerous draft and proposed draft food additive provisions currently in the Step Process for which consensus has not been reached. Although these provisions are often grouped by technological function (i.e., colour or sweetener), CCFA has explored the criteria of technological function and safety as a basis for consensus numerous times without success. From previous discussions in CCFA it is understood that the barrier to consensus on the use of these additives is not a disagreement on technological function or safety. Rather, the barrier is a fundamental difference in regional philosophies as to how these types of additives should be used.

9. A large number of adopted provisions for colours or sweeteners and several draft provisions for food additives with these technological functions have Note 161 attached to them.[6] The text of Note 161 is as follows: "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble." National legislation is inherently regional, not global, in scope. Therefore, the text of Note 161 demonstrates that the difference in regional philosophies on how food additives should be used results in differing understandings between Codex Members of what is necessary to meet certain criteria in Section 3.2 of the Preamble to the GSFA. As such, any successful approach to reach consensus must address the application of different regional philosophies to the criteria in Section 3.2 of the Preamble to the GSFA.

10. Addressing differences in regional philosophies must also be in compliance with the Codex Procedural Manual (hereinafter "Manual"), which describes the criteria for work done by all Codex Committees. The Manual stipulates that Codex standards should only consider factors which can be accepted on a worldwide basis, while also stipulating that provisions in the GSFA must meet the criteria of Section 3.2 of the Preamble to the GSFA (discussion on this is provided in the "General guidance to all Committees" section of this discussion paper). Any approach to address colours and sweeteners should address this dichotomy and should be sufficiently broad to allow the approach to be applied to provisions for additives with similar issues regardless of functional class.

Codex Procedural Manual

11. The Manual provides specific guidance to individual committees such as CCFA, as well as general guidance that is applicable to all Committees.

(i) Specific guidance to the CCFA and GSFA: Section II of the Manual includes the subsection *Procedures for consideration of the entry and review of food additive provisions in the General Standard for Food Additives*. This subsection references Section 3.2 of the Preamble and states that the use of a food additive must meet these criteria as one of the requirements for inclusion in the GSFA.

(ii) General guidance to all Committees: The Appendix to the Manual includes general decisions of the Codex Alimentarius Commission that are generally applicable to all Codex Committees. This includes the *Statements of Principle concerning the role of science in the Codex decision making process and the extent to which other factors are taken into account*. This Statement of Principle notes that only factors which can be accepted on a worldwide basis should be taken into account in the framework of Codex.[7]

Section 3.2 of the Preamble to the GSFA

12. Section 3.2 of the Preamble states that the use of a food additive is justified only when such use has an "advantage", is safe, "does not mislead the consumer", serves one or more technological functions set by Codex, and serves a need as described in subsections a) through d) of Section 3.2 of the Preamble. Of these criteria, only "advantage" and "does not mislead the consumer" are not defined.[8]

Considerations

13. The fact that "advantage" and "does not mislead the consumer" are not defined results in different understandings between Codex Members of what is necessary to meet these criteria. As a result each Codex Member applies their own regional philosophy to those criteria. Since the Manual stipulates that Codex standards should only consider factors which can be accepted on a worldwide basis, while also stipulating that provisions in the GSFA must meet the criteria of Section 3.2 of the Preamble, it would appear that any approach to resolve the provisions for colours and sweeteners should revise Section 3.2 of the Preamble to either: a) define these criteria in a manner that is globally applicable; b) remove these criteria; or c) acknowledge the regional basis of these criteria in a manner that removes the barrier to consensus (i.e., negates the need for Note 161). These approaches are presented below along with a brief discussion as to the feasibility of each option.

[6] The attachment of Note 161 to adopted provisions for colours and sweeteners has been a barrier to consensus on the remaining provisions for colours and sweeteners in the Step Process for many reasons. In the context of this discussion paper, attaching Note 161 to a provision is a barrier to consensus as it formalizes factors that are not applicable on a worldwide basis (i.e. regional definitions of "advantage" and "misleads the consumer") into the provision.

[7] The Statement of Principle also notes, among other factors, that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide, and that when members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

[8] "Safety" is met if an additive has a relevant JECFA evaluation and exposure assessment. Technological functions for food additives are defined in CAC/GL 36-1989. "Need" is defined in subsections a) through d) of Section 3.2 of the Preamble.

Options

Option 1 - Define "advantage" and "does not mislead the consumer"

14. This option would require CCFA to agree on globally applicable definitions for both "advantage" and "does not mislead the consumer", and those definitions would be added to Section 3.2 of the Preamble. Since they would be placed in the Preamble, which applies to all additives, these definitions should be of a general nature which applies to food additives regardless of functional class, rather than specific to colours and sweeteners only. The definitions could then be utilised for determining if the use described in individual provisions meets those definitions. However, based upon past discussion in CCFA it appears that certain factors considered under these criteria are inherently regionally dependent. For example, Codex Members have previously not agreed to the use of a food additive based on their assertion that consumers in their region would not "expect" a certain additive in a certain food. However, consumers' expectations are inherently regional and vary across the globe. Therefore it is unlikely that CCFA would reach agreement on globally applicable definitions for these criteria. In addition, this option would require a re-evaluation of adopted provisions with Note 161 to determine if those provisions meet the new definitions of "advantage" and "does not mislead the consumer".

Option 2 - Remove "advantage" and "does not mislead the consumer"

15. This option would require CCFA to remove "advantage" and "does not mislead the consumer" from Section 3.2 of the Preamble if globally applicable definitions for these criteria cannot be agreed upon. However, there may be instances where the Committee would agree on a global basis for these factors, such as economic adulteration. It is unlikely that CCFA would reach agreement on removing these criteria from Section 3.2 of the Preamble. This option may or may not require the re-evaluation of adopted provisions with Note 161 prior to removing the note from those provisions.

Option 3 – Acknowledge, in a manner that removes the barrier to consensus, that these criteria are often regionally dependent

16. This option would require CCFA to agree on text to be inserted in Section 3.2 of the Preamble that: 1) acknowledges that factors considered when determining "advantage" and "misleading the consumer" are often regional in nature; and 2) highlights an appropriate mechanism for the recording of Codex Member concerns on these specific factors in a manner that does not create a barrier to consensus.5 This option may or may not require the re-evaluation of adopted provisions with Note 161 prior to removing the note from those provisions.

17. This paper provides suggested text for this option as a starting point for discussion by CCFA. The suggested text utilises text from the Manual, as well as highlights the use of reservations in the Committee Report as a mechanism of recording regional concerns under these criteria while allowing a provision to proceed through the Step Process:[9, 10]

18. "The CCFA recognises that certain factors considered by individual Codex Members when determining if the use of a food additive provides an advantage or misleads the consumer, are regional in nature and, while legitimate when establishing national legislation, may not be generally applicable or relevant worldwide. In situations where CCFA agrees on the other criteria listed in Section 3.2, but agreement could not be reached that the use provides an advantage or does not mislead the consumer, reservations are recorded in the committee report and can be referenced by the year the provision was adopted."

Recommendation 2: That the Committee consider the following options to revise Section 3.2 of the GSFA Preamble to facilitate consensus on provisions for colours and sweeteners:

Option 1 - Define "advantage" and "does not mislead the consumer";

Option 2 - Remove "advantage" and "does not mislead the consumer";

Option 3 - Acknowledge, in a manner that removes the barrier to consensus, that "advantage" and "does not mislead the consumer" are often regionally dependent.

[9] The proposal for the use of reservations in the report to record regional concerns is based on current practice in CCPR to reach consensus on pesticide maximum residue levels (MRLs) when agreement is reached on matters that would require expert panel (JMPR) review but there is disagreement on other factors (these factors are often regionally based). In such instances the Codex Member's reservation, with a brief description of the basis for the reservation, is recorded in the CCPR Committee report. However, the reservation is not associated with the MRL in the MRL database and therefore is not a barrier to reaching consensus on the MRL.

[10] Under this option, Note 161 could be removed from adopted provisions by noting the year of revision in the standard and the recording of reservations in the Committee report for the year of revision.

II. Alignment of Food Additive Provisions in Commodity Standards and GSFA

Analysis of key issues

19. Currently the Chair of the EWG on Alignment recommends groups of commodity standards subject to adjourned Commodity Committees for alignment at each CCFA session. The Alignment EWG utilises the decision tree on alignment to process its work.[11] During recent sessions, CCFA has considered the alignment of food additive provisions in commodity standards under the purview of Committees that have been adjourned sine die. However, there is still a considerable backlog of commodity standards that are awaiting consideration for alignment. Recent discussions on reducing the backlog have focused on approaches to make the alignment of commodity standards for adjourned Committees more efficient, and to clarify the role of active Commodity Committees in the alignment process.

20. The role of Commodity Committees[12] in the alignment process can be classified by its status:

(i) Adjourned Committees: The EWG on Alignment provides recommendations to CCFA for the alignment of food additive provisions in the commodity standards of adjourned Commodity Committees.

(ii) Active Commodity Committees (with physical meetings): It was confirmed during CCFA 48 that it is the primary responsibility of active Commodity Committees (with physical meetings) to progress the work on food additive alignment for commodities within their mandate. Accordingly, the CCFA49 asked the EWG to finalise guidance for Commodity Committees on the alignment of food additive provisions of commodity standards with the GSFA.

(iii) Active Commodity Committees (working by correspondence only): Commodity Committees working by correspondence currently only work on a specific task (e.g. development of a standard). The CCFA may therefore have to unilaterally take on the alignment work for the commodity standards associated with these Committees.

Considerations

21. It is important to note that any suggested options to improve the management of the alignment workload should not influence the quality of the work or increase the workload of the WG Chairs. Such options should aim to reduce the backlog, and to improve efficiency, transparency and awareness of the alignment work.

Options

22. In order to accelerate the alignment work of CCFA, there appears to be three viable options. The options are not exclusive and some or all could be utilized if considered appropriate by the Committee:

Option 1 - Utilize preparatory work undertaken by industry associations

23. This option envisages the greater involvement of the industry associations in preparing the initial alignment proposals using a prescribed format.

24. This approach is being informally trialled following discussions in the margins of CCFA49. The International Dairy Federation (IDF) is currently preparing some sample proposals in relation to some of the commodity standards from the Codex Committee on Milk and Milk Products (CCMMP), in particular cheese standards. The Chair and co-Chair of the Alignment WG would conduct a preliminary evaluation of the proposal and, if found acceptable the proposal could be provided to the EWG on Alignment for formal review.

25. It is recognised that any industry association preparatory work would need to be comprehensively checked and validated by the EWG on Alignment before being presented to the Committee. It is expected that, as industry associations have a good understanding of their sector, they may be able to advise if any provisions in the commodity standards are out of date. Nevertheless, this preparatory work would appear to have the potential to save considerable time and would allow an acceleration of the work for those commodity standards for which there is an interested Codex Observer organization.

Option 2- Involve another country as an additional co-Chair of the WG

26. A number of countries actively participate and provide helpful and relevant comments on alignment proposals as part of the work of the alignment EWG. It is clear from this input that a number of member countries have developed expertise in alignment that could be utilised in accelerating the work of the Committee.

[11] CX/FA 16/48/6, Appendix 1.

[12] In this section, reference to “Commodity Committees” also includes “General Subject Committees”, such as the Codex Committee on Nutrition and Foods for Special Dietary Uses, which develop Commodity Standards.

27. Currently the alignment proposals are prepared by the Chair and co-Chair of the EWG, Australia and the United States of America, respectively. Under this option a third or even fourth country would be assigned specific commodity standards to develop alignment proposals based on the agreed decision tree approach. This approach would result in more resources being applied and could result in a considerable acceleration of the work.

Option 3 - Partnership approach between CCFA and Commodity Committees

28. As outline in the section on "the Role of Commodity Committees", the CCFA48 confirmed that it is the primary responsibility of the active Commodity Committees to progress the work on food additive alignment for commodities within their mandate. However, recent experience with the alignment work that was referred back to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is that the Commodity Committees have only limited competence to undertake this work. Whilst the provision of guidance to the Commodity Committees would assist, it may be unrealistic to expect the Commodity Committees to undertake all of the alignment work for the commodity standards for which they have responsibility. On the other hand, it is the Commodity Committees that understand the technological function of additives needed for standardized products, and whether it is appropriate to list specific food additives or allow all additives of a relevant functional class in these products.

29. Recognising their different mandate and expertise, a partnership approach between the CCFA and the Commodity Committees, based on the guidance for Commodity Committees that is currently being finalised, may be the most realistic option.

Recommendation 3: That the Committee consider the following options to accelerate the alignment of the GSFA and corresponding commodity standards. The options are not exclusive and some or all could be utilized if considered appropriate by the Committee.

Option 1 - Utilize preparatory work undertaken by industry associations;

Option 2 - Involve another country as an additional co-Chair of the WG on alignment;

Option 3 - Partnership approach between CCFA and Commodity Committees.

III. International Numbering System (INS)

30. At CCFA49, several proposals submitted for the consideration of the WG on the INS involved the deletion of entries for substances from the INS (*Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989)). However, although these substances also had provisions in the GSFA, the proposals for deletion from the INS did not discuss the related GSFA provisions.

31. The relationship between the INS and the GSFA is complex. It is not required that a substance be added to the INS with the intent that the substance be added to the GSFA at some point in the future. Section 1 of CAC/GL 36-1989 states that the INS is intended as a harmonized naming system for food additives as an alternative to the use of lengthy substance names. Section 1 of CAC/GL 36-1989 also states that the INS does not imply approval of the use of the substance by Codex, and listed additives may not have been evaluated by JECFA. As such it is implicit that the INS is a stand-alone Codex document that is intended for several purposes and not solely as a reference to be applied to the GSFA.

32. In contrast, it is required that an additive have an entry in the INS (including an applicable functional class and technological purpose) prior to entry into the GSFA. Therefore, if a substance is removed from the INS, any provisions for that substance must also be removed from the GSFA. However, the removal of provisions from the GSFA is not the purpose of the WG on the INS. The removal of provisions from the GSFA requires full consideration by CCFA, which would normally mandate such discussions to the WG on the GSFA.

33. It may be helpful for future work if edits are made to 1) Section 1 of the INS to clarify the relationship between the INS and the GSFA; and 2) the related circular letter to note that CCFA must remove any corresponding provisions from the GSFA prior to the consideration of proposals for deletion of entries in the INS.

Considerations/Options

34. There are two documents pertinent to the current discussion: the INS itself, and the circular letter that is circulated each year requesting proposals for change or addition to the INS. Revisions to these documents may be helpful for the future work of the INS WG. The options presented below are not mutually exclusive, one or both options may be acted on if deemed appropriate by CCFA.

Option 1 – Revise the "Background" subsection of Section 1 of the INS

35. The "Background" subsection of Section 1 of CAC/GL 36-1989 provides information on the scope and intent of the INS. This subsection could be revised to provide further clarity on the relationship between the INS and the GSFA.

Recommendation 4: That the Committee consider the addition of the following bolded text to the Background section of the INS in order to clarify the relationship between the INS and the GSFA:

The International Numbering System for Food Additives (INS) is intended as a harmonised naming system for food additives as an alternative to the use of the specific names, which may be lengthy. Inclusion in the INS does not imply approval by Codex for use as food additives. The list may include those additives that have not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) ***or are not included in the General Standard for Food Additives (CODEX STAN 192-1995****)*

Option 2 – Revise the INS circular letter to request proposals for deletion to address related provisions in the GSFA

36. Requests for revisions to the INS are provided in response to the circular letter

37. "Request for proposals for change and/or addition to Section 3 of the *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989)" (the INS Circular Letter).[13] Annex 1 of the INS Circular Letter provides principles for proposals for revisions to the INS, and Annex 2 provides a form for submission of proposals. Both Annex 1 and Annex 2 include sections on the deletion of an additive from the INS. These sections could be revised to note that any proposal for deletion of an additive from the INS is not appropriate until related provisions have been removed from the GSFA.

Recommendation 5: That the Committee consider the addition of the following bolded text to the Annex 1 and Annex 2 of the circular letter "Request for proposals for change and/or addition to Section 3 of the *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989)":

Annex 1, Point 5 "Deletion of an additive from the INS List":

Proposals for deletion of INS entries cannot be submitted to this circular letter if there are existing provisions (adopted or in the Step Process) for the additive in the General Standard for Food Additives (CODEX STAN 192-1995). The Codex Committee on Food Additives must first remove those provisions from the GSFA prior to the submission of proposals to delete a corresponding INS entry.

Proposals for deletion of INS entries should be accompanied by a suitable justification.

Annex 2, "Justification for the requested INS Change in Section 3: deletion of additive"

(*Please select only the appropriate option and provide details in the space* ***below. Proposals for deletion of INS entries cannot be submitted to this circular letter if there are existing provisions (adopted or in the Step Process) for the additive in the General Standard for Food Additives (CODEX STAN 192-1995).****)*

IV. JECFA Evaluation and Re-evaluation of Food Additives

Prioritization of requests to JECFA

Analysis of key issues

38. An examination of the Priority List of Substances Proposed for Evaluation by JECFA ("Priority List") established during the 49th session of the CCFA shows that there are fifty-one (51) requests on the Priority List. [14,15] Due to the growing number of requests on the Priority List, a priority-setting system should be developed by the CCFA to help advise JECFA as to which requests the Committee considers important. It is recognised that any priority-setting exercise offers no authority on the order in which JECFA chooses to address those requests.

[13] The current INS Circular Letter is CL 2017/46-FA.
[14] REP17/FA, Appendix XI
[15] The request for the evaluation of 70 flavouring substances was counted as 1 request (new substances), as was the request for the evaluation of 13 modified starches (also new substances).

39. Broadly put, requests that an additive be placed on the "Priority List" can be categorised as follows: (1) requests for the re-evaluation of substances already in the GSFA made because of identified safety concerns; and (2) all other types of requests, which generally entail some type of benefit either to the consumer, to industry, or to both. More specifically, these other types of requests can generally be sub-categorised as follows: (i) requests for new additives (those not already in the GSFA); (ii) requests to include additional substances as part of the specifications for an existing additive (e.g., using a new source material, or using different forms of a substance); and (iii) requests for changes to specifications (e.g., revision of an analytical method or of a tolerance on a test method).

Considerations

40. Several considerations were taken into account in developing proposed ranking criteria for entries on the Priority List:

(i) Safety: It was considered whether or not allocating a "high" priority only to those requests for re-evaluation based on an identified safety concern would be the most objective means of setting priorities. The requests for re-evaluation based on an identified safety concern are, from the perspective of the consumer protection, the highest priority for JECFA evaluation. Given that only seven (7) out of a total of fifty-one (51) requests are in response to an identified safety concern, designating "high" priority only to requests for re-evaluation would likely diminish the value of the priority-setting exercise.

(ii) New additives and/or specifications: From the perspective of aiming to populate the GSFA with additive provisions, it can be argued that the evaluation of new additives and the development of new JECFA specifications—those not currently in the GSFA or adopted by the CCFA—are more pressing than other industry-sponsored requests. Therefore, it is reasonable to propose that requests for new additives be given higher priority than requests for changes to the specifications of an additive already in the GSFA.

(iii) Fair trade/economic impact: Considerations of fair trade and economic impact should not be ignored, but these do not change the fundamental natures of the requests to JECFA (*e.g.*, a Member may submit a request to add a new source material to the specifications of an additive because it presents an economic benefit, but the request is still fundamentally a request to add a new source material). Therefore, considerations of fair trade and economic impact should not necessitate the development of a separate priority ranking system. However, this is not to say that the relevant information that informs the nature of the request and provides a complete "story" to justify the request should not be clearly captured and considered (see the discussion of the issue "Information supporting requests for inclusion on the Priority List").

(iv) Substances not included in the GSFA: Because certain additives such as flavourings and processing aids (including enzymes) are not included in the GSFA, special considerations need to be given for these substances (see the discussion of the issue "Requests for substances that are not to be included in the GSFA" below).

Recommendation 6: That the Committee consider the following ranking system to be used for requests for placement on the Priority List for those additives intended for inclusion in the GSFA, in order from highest (1) to lowest (3) priority:

(1) Re-evaluation of an additive, based on an identified safety concern;

(2) Evaluation of a new additive that is intended to be included in the GSFA;

(3) Evaluation of a change to the specifications, including but not limited to the addition of a substance, a new source material, a new chemical form of a substance, a change to an analytical method, a change to a tolerance limit, and a revision of a physicochemical property such as melting point.

Requests for substances that are not to be included in the GSFA

Analysis of key issues

41. For the sole purpose of populating the GSFA, the evaluation of food additives that are not intended for inclusion in the GSFA, by JECFA, seems counter-productive.

42. The majority of requests for JECFA's evaluation concern processing aids, mostly enzymes, and flavourings, which indicates these types of substances present a major interest to the CCFA membership. It may not be practical, therefore, to delay their review. This is particularly true if it is considered that the GSFA will never be "complete," as there is likely to always be requests for JECFA review of new additives that are intended to be included in the GSFA.

Considerations

43. The Committee is encouraged to consider the following options for the management of food additives.

Options

Option 1 - Food additives that are not intended for inclusion in the GSFA are not assigned a priority ranking

44. To implement this option, it is recommended that food additives that are not intended for inclusion in the GSFA would be separated from the additives intended to be included in the GSFA (those which are assigned a priority ranking, as described above), but that they would be kept in a separate part of the Priority List and would continue to be maintained in the working group documents and reports of the PWG. Although food additives that are not intended for inclusion in the GSFA would not be subjected to the priority-setting exercise of the Committee, complete information on the nature of the requests would continue to be available to JECFA, and the JECFA Secretariat could choose to schedule these food additives for evaluation as they see fit.

Option 2 - Food Additives that are not intended for inclusion in the GSFA should be assigned a priority ranking in tandem with other food additives

45. To implement this option, the CCFA would need to assign a priority ranking for food additives that are not intended for inclusion in the GSFA in the context of whatever ranking system is developed by the Committee, be it as described in Recommendation 6 or otherwise.

Recommendation 7: That the Committee consider the following options for the management of requests for placement on the Priority List for food additives that are not intended for inclusion in the GSFA. Respondents are encouraged to provide practical suggestions to implement these options, or propose new options that are both practical and within the scope of the mandate of the Committee.

Option 1 – Food additives that are not intended for inclusion in the GSFA are not assigned a priority ranking;

Option 2 – Food additives that are not intended for inclusion in the GSFA should be assigned a priority ranking in tandem with other additives.

Information supporting requests for inclusion on the Priority List

Analysis of key issues

46. Currently, requests for inclusion of a substance on the Priority List are provided in response to the circular letter Requests for information and comments on the priority list of substances proposed for evaluation by JECFA (the Circular Letter). The Circular Letter includes Annex 1 “Criteria for the Inclusion of Substances in the Priority List”, and Annex 2 “Form for the submission of substances to be evaluated by JECFA”. Annex 1 is a list of criteria and does not request information from the petitioner. Annex 2 is a form filled out by the petitioner to provide information clarifying the request for evaluation by JECFA. These proposals are compiled in an Agenda Item which is discussed by the WG on the Priority List for JECFA Evaluation at each session of CCFA. The WG then puts together a report which provides recommendations to CCFA for the inclusion of substances on the Priority List.

47. In consultation with the JECFA Secretariat, it is considered that the information provided in response to the circular letter and the WG reports is often insufficient to explain the scope of the requests. For example, in response to the question “Justification for use,” a petitioner may state “emulsifier for use in beverages,” instead of providing useful information for ranking purposes such as why the emulsifier is considered necessary for use in beverages and/or what advantages it offers over existing options.

Considerations

48. If petitioners were to provide more detailed information in response to the Circular Letter this would allow both the CCFA and JECFA to understand the natures of the requests and to manage them accordingly.

Options

49. Several options are presented to provide CCFA and JECFA more detailed information on the requests for inclusion of a substance on the Priority List. These options are not exclusive and some or all could be utilized if considered appropriate by the Committee:

Option 1 – Provide guidance in Annex 2

50. Improved guidance could be provided directly in Annex 2 ”Form for the submission of substances to be evaluated by JECFA” to make it clear what type of information is being sought. Improved guidance could come in the form of sub-headers to the questions asked, or by providing examples.

Option 2 – Revise the questions in Annex 2 to address all criteria listed in Annex 1

51. The questions on the ”Form for the submission of substances to be evaluated by JECFA” could be reviewed to ensure that the scope of the information requested is adequate to capture the criteria for the inclusion of substances in the Priority List as listed in Annex 1 of the Circular Letter. For example, several criteria for the inclusion of substances on the Priority List listed in Annex 1 relate to trade and concerns of developing countries, but there are no questions on the form in Annex 2 that specifically relate to these criteria.

Recommendation 8: That the Committee form an electronic working group to explore revisions to Annex 2 of the Circular Letter *Requests for information and comments on the priority list of substances proposed for evaluation by JECFA* to address the following issues:

Option 1 - Provide guidance in Annex 2 of the Circular Letter on the level of detail necessary to adequately respond to the listed questions;

Option 2 - Revise the questions in Annex 2 of the Circular Letter to address all criteria listed in Annex 1 “*Criteria for the Inclusion of Substances in the Priority List”*.

Maintenance re-evaluations of additives in the GSFA

Analysis of key issues

52. In response to the pre-WG consultation request, several comments discussed that the maintenance of additives in the GSFA, such as by JECFA re-evaluating additives with older previous evaluations, or removing additives from the GSFA for which there is no interest in their use, is an important house-keeping component of the GSFA.

Considerations

53. The process of re-evaluations needs to be Member-driven, as Members must indicate which additives continue to be of interest to them (i.e., re-endorsements), and they must provide a review of the literature (notably, any new information).

54. There are additive re-evaluation programs available at national or regional levels that could be utilised to inform the Committee of additives that may be candidates for re-evaluation.

55. As it would be considerable new work to instate a maintenance re-evaluation program, this objective is best left as a future priority of the Committee.

Recommendation 9: That the Committee, as a future priority not to be completed at this time, consider establishing an overall process for the re-evaluations and re-endorsements of additives currently in the GSFA.

V. Processing Aids

Analysis of the key issues

56. In response to the pre-WG consultation request, several comments mentioned concerns regarding processing aids. This issue was also raised at CCFA49. It was suggested that either a general standard for processing aids could be developed or an amendment to the *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), hereinafter “Guidelines”, be made to include a listing of technological functions for processing aids.

57. There are two areas where the Committee’s work on processing aids could be further considered as follows:

Guidelines on Substances used as Processing Aids (CAC/GL 75-2010)

58. The Guidelines was developed as a general guide for the use of processing aids in food manufacturing and handling. In its current version, the definition of processing aids, principles for the safe use of processing aids, and labelling requirements are included. The Guidelines is considered to be sufficient in providing principles for the safe use of processing aids in food manufacturing and handling.

Database of Processing Aids

59. The 33rd session of CCFAC decided that substances used as processing aids should be safe for use but realised that undertaking detailed evaluations of all compounds listed in the Inventory of Processing Aids would be an enormous task.[16] At the 35th session, it was recognised that CCFA resources were insufficient to actively develop a positive list of processing aids until the work on food additives was substantially completed.[17]

60. Based on these considerations, a list of processing aids is maintained in the Inventory of Substances Used as Processing Aids (IPA). IPA is not a Codex tool, and the maintenance and updating of IPA are made by member countries on a voluntary basis. The IPA was transformed into a reference database, collecting data from not only national authorities but also the food industry. The information needed to be provided is marked by asterisk in the online application form, and whether this information is available in the application will be checked before its inclusion in the database. Many CCFA Members and Observers actively participate in the work of the database.

Considerations

61. It is generally agreed that the work on processing aids is not a top priority of the Committee and it is proposed that it be undertaken after the completion of GSFA. In view of the heavy workload and lack of resources at hand, it is not likely for the Committee to develop a Codex standard or positive list for processing aids at the present time. However, it is also recognised that in order to fulfil its Codex mandate, the Committee will need to undertake more work on processing aids after the completion of the GSFA.

Recommendation 10: That the Committee consider the following related options:

Option 1 - Maintain the Processing Aids Database as an up-to-date reference on the use of processing aids;

Option 2 - As a future priority not to be completed at this time, review/amend the *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010*)*

VI. Prioritisation of CCFA future work

62. The draft criteria for CCFA to prioritise its work on certain issues was introduced and discussed at CCFA49[18]. It is generally suggested that a systematic approach or mechanism to prioritise its work would be of value to the Committee. An initial proposal for further reflection is given below:

Question/Criterion	**Rating**
1. Does the topic fall within the mandate of CCFA?	Yes/No If “yes” proceed to the following questions. If “no” discard the proposal.
2. Can the topic be addressed through one of the existing EWGs (EWG on GSFA, Alignment, INS, JECFA priority list)?	Yes/No If “yes” refer to Chair of relevant EWG for prioritisation. If “no” proceed to next question.
3. Is there a risk to public health?	Global Risk: 5 Regional Risk: 3 Little Risk: 0
4. Is there impact on international food trade?	Global Trade Impact: 5 Regional Trade Impact: 3 Little international trade impact: 0
5. Is the topic relevant to completing the GSFA to be the single authoritative Codex Standard for the use of food additives?	Yes: 10 No: 0

[16] ALINORM 01/12A, para. 70
[17] ALINORM 04/27/12, para. 87
[18] CX/FA 17/49/14, para. 27.

63. Questions 1-2 are gatekeeping questions, since the negative answer to question 1 will result in discarding the proposal, whilst the answer to the 2nd question will determine whether a new EWG or discussion paper is necessary. Questions 3-5 will decide the level of priority of the proposal/issue. It will be suggested to the Committee that proposals/issues will be dealt with in order of priority. Taking into account the resources at hand, populating the GSFA will remain the top priority for CCFA.

Recommendation 11: That the Committee consider the questions/criteria that could be used to facilitate a systematic approach to the prioritisation of its work.