CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 8 **CX/FA 18/50/13 Add. 1**

February 2018

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

DISCUSSION PAPER ON "FUTURE STRATEGIES FOR CCFA"

Replies to CL 2017/92-FA of Costa Rica, Ecuador, Russian Federation, AMFEP, BEUC, CCC, CEFS, EU Specialty Food Ingredients, FoodDrinkEurope, IACFO, IACM, ICA, ICBA, ICGA, ICGMA, IDF, IFAC, IFU, IOFI, ISA, ISDI and NATCOL

Costa Rica

Recommendation 1: Costa Rica supports this recommendation.

Recommendation 2: Costa Rica supports option 3.

Rationale: the CCFA has failed to reach consensus on note 161. In that sense, Costa Rica considers that option 3 that follows a similar approach to the CCPR, could offer a way out; therefore, it supports the following proposed text:

"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."

Rationale: Costa Rica considers that the lack of progress in completing the draft provisions for colours has already caused that some countries ban the use of these food additives because there are no Codex provisions. In that sense, trying to define "advantage" or "does not mislead the consumer" would face similar value judgements that have led to the lack of consensus, therefore it would be better to recognize the existing philosophical differences to move forward on this. The approach to reach consensus applied by the CCPR has been used for many years and can serve as an example to consider. According to note 9 of CX / FA 18/50/13 Rev1., "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."

Recommendation 3: Costa Rica considers that the three options should be combined in a single format, in a way that allows considering multiple options depending on the situation.

Regarding option 1: While international NGOs in the industry have a better understanding of the actual uses of food additives in products that they represent, we note that some NGOs are regional by nature/philosophy and not always fully represent the overall usage patterns.

Recommendation 4: Costa Rica supports the addition of the sentence in bold "***or are not included in the General Standard for Food Additives (CXS 192-1995)***".

Rationale: There are additives that have not been listed yet in the GSFA but have an assigned INS.

Recommendation 5: Costa Rica supports the texts in bold.

Rationale: Provide more clarification.

Recommendation 6: Costa Rica supports this recommendation and the proposal of the priority ranking.

Recommendation 7: Costa Rica supports continuing with the current approach to prioritize flavouring assessments using a procedure that is based on consultations with the flavourings industry (IOFI) and the JECFA Secretariat that has resulted in agreeing on the schedules for JECFA evaluations every two years.

In addition, Costa Rica wishes to point out that assessments of the flavourings by JECFA are important and should be maintained as a priority since there is no other positive list in the Codex. We also note that any doubt of safety based on new data on a flavouring already evaluated must be a priority.

In the same sense, we recommend considering a similar approach for processing aids, which are not listed in the GSFA.

Recommendation 8: Costa Rica supports this recommendation with options 1 and 2.

Rationale: From our point of view the more guidance is provided, the easier it will be to judge the priority and the integrity of the available data that allow a more efficient assessment process.

Recommendation 9: Costa Rica supports this recommendation. We consider it a priority to complete the work relating to the draft provisions, before starting new work related to the maintenance of the GSFA.

Recommendation 10: Costa Rica supports the adoption of options 1 and 2 of this recommendation.

Rationale: The database of processing aids is a valuable reference on the current uses of processing aids and keeping it will have a major impact on the fulfilment of the objective of the Codex Alimentarius. Once the current work priorities have been finalized, it will be important to promote new work to consider the revision of the Guidelines.

Recommendation 11: Costa Rica supports the additional discussions on a more systematic approach to the prioritization of work, but the priority must be to complete the analysis of outstanding provisions in the GSFA before starting work on new topics, such as processing aids.

Rationale: The development of a systematic prioritization approach for the CCFA should consider the risk element to public health in the strength of scientific criteria, in addition to the possible geographical scope of the question.

Ecuador

I. General Standard for Food Additives (GSFA): Principles and Procedures for Reviewing the Provisions Currently in the Step Process.

Ecuador accepts Recommendation 1, set out in the document.

Colour and Sweetener Provisions / Provisions with Note 161 - Ecuador would agree with option 3 since the regional realities are different, but here it is suggested to consider that the legitimate objectives of each country in the same region tend to be different and we could have difficulties for consensus in the different regions.

II. Alignment of Food Additive Provisions in Commodity Standards and GSFA - Ecuador considers that the three options would be valid since there may be cases in which one option is applicable and the others are not, as well as in other cases that the three can be used to generate efficiency in the work of harmonization.

III. International Numbering System (INS) - Ecuador agrees with Recommendations 4 and 5 given for this point.

IV. JECFA Evaluation and Re-evaluation of Food Additives - Ecuador considers the following order of priority:

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

(2) evaluation of a change in specifications, including, but not limited to the addition of a substance, a new base substance, a new chemical form of a substance, a change in an analytical method, a change to a limit of tolerance and a review of a physicochemical property, such as the melting point.

(3) evaluation of a new additive to be included in the GSFA;

V. Processing aids - Ecuador supports option 2 so that the revision and modification of the *Guidelines on Substances used as Processing Aids* (CXG 75-2010) is carried out at the appropriate time.

VI. Prioritisation of CCFA future work - Ecuador agrees with the questions proposed on this point.

Russian Federation

I. General Standard for Food Additives (GSFA)

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

Recommendation 1:

The Russian Federation does not agree with the proposal that in the 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.We believe that the eWG should be making recommendations and the CCFA meeting should approve the transition from step 2 to step 3.This transition is quite a significant step, which requires more extensive discussion by all member countries of the Codex Alimentarius Commission.

We also believe that the process needs further discussion of steps 4, 6 and 7.

1.2 Colour and Sweetener Provisions / Provisions with Note 161

The Russian Federation agrees that Note 161 reflects the difference in regional philosophies on how food additives should be used and difference of opinion between Codex member countries.

At the same time, we believe that such a difference of opinion is allowed within the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). Article 1, 1994" (In. Committee on sanitary and phytosanitary measures Major Decisions and Documents.-2011 September.- p.1-14).The SPS agreement allows WTO member states to introduce additional SPS measures that ensure higher sanitary and phytosanitary protection than that achieved through measures based on there relevant international standards, guidelines and recommendations, provided there is scientifically justified reasoning.

It should also be noted that the standard "Principles for food import and export inspection and certification - CAC / GL 20-1995" contains a requirement that the quality and safety indicators of foodstuff (including food additives) **should comply with the state legislative and regulatory documents, whose territory the produce is in circulation**.

In compliance with Section 3.2 GSFA the principles, listed in the preamble 3.2 "The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable" are the main fundamental for the use of food additives. However, representations about terms "advantage", "mislead the consumer", can could be greatly different in different regions.

In connection with the foregoing, the Russian Federation believes that in order to unify these terms in Codex member countries, it is necessary to approve Option 1 (Recommendation 2) - Define "advantage" and "does not mislead the consumer".

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

The Russian Federation considers that the performance of the CCFA will increase significantly in case of adopting two options of Recommendation 3:

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

Option 3 - Partnership approach between CCFA and Commodity Committees.

The adoption of these options would help reduce the burden on countries traditionally chairing of eWG's and attract qualified experts of Commodity Committees.

III. International Numbering System (INS)

For the purpose of better regulation of food additives, the Russian Federation considers Recommendation 4which should be adopted in the redaction: "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 (CXS 192-1995)~~**

The presence of a food additive in a positive list that have not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are often misleads the producers about the possibility of using it in the food industry. The same situation would be in case of food additives which are not included in the General Standard for Food Additives (CXS 192-1995).

The Russian Federation is fully agrees with Recommendation 5 which consider the addition of the following bolded text to the Annex 1and Annex 2 CXG 36-1989.

IV. JECFA Evaluation and Re-evaluation of Food Additives

1. Prioritization of requests to JECFA

The Russian Federation considers that the prioritization of requests to JECFA for the evaluation and reassessment of food additives is an issue of high importance. We support

Recommendation 6: The Committee considers the following ranking system for requests on inclusion in the Priority List, 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;

More specific analytical methods, a change to a tolerance limit – these indicators that both ensure a high degree of safety of food additives.

(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.

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

The Russian Federation is fully agrees with Option 1 of Recommendation 7 – Food additives that are not intended for inclusion in the GSFA are not assigned a priority ranking.

3. Information supporting requests for inclusion on the Priority List

The Russian Federation support Option 2 of Recommendation 8 and the revision of all criteria listed in Annex 1 “Criteria for the Inclusion of Substances in the Priority List”.

4. Maintenance re-evaluations of additives in the GSFA

The Russian Federation supports Recommendation 9.

V. Processing Aids

Due to the fact that the risk assessment and compilation of the list of processing aids authorized for food industry in the near future could not be completed, we consider it appropriate to adopt Option 2 Recommendation 10- As a future priority not to be completed at this time, review/amend the Guidelines on Substances used as Processing Aids (CXG 75-2010)

The adoption of this option could allow unifying, expanding and strengthening the requirements for procedures for assessing the risks of processing aids held in different countries. Particular attention should be given to the description of the procedure for assessing the risk of enzyme preparations and the strains of microorganisms producing of these enzymes, as more than 90% of such products are produced using genetically modified microorganisms.

VI. Prioritization of CCFA future work

The Russian Federation could not agree with the draft criteria for CCFA to prioritize its work on certain issues as they do not account for all the principles of the food additive use as stated in the 3.2 of the GSFA preamble and discussed elsewhere in this paper.

In particular, we cannot agree with the suggestion that the chairs of the eWGs should be those giving the right to prioritize the topics. This is an exclusive prerogative of the CCFA meeting.

Association of Manufacturers and Formulators of Enzyme Products (AMFEP)

AMFEP agrees with the comments submitted by EU Specialty Food Ingredients, with particular strong support for 'Recommendations' 7 & 10, which are of importance to the enzyme industry, as below.

Recommendation 7: Although food enzymes are not foreseen for inclusion into the General Standard for Food Additives (GFSA), their approval for use is nevertheless important for the improvement of food processes *worldwide.* Therefore, we would like to stress that JECFA evaluations are important for enzymes because they represent international evaluations, facilitating their acceptance by national authorities that do not make their own evaluations (which is the majority). If JECFA evaluations of enzymes are not prioritized by CCFA and JECFA, it could represent a barrier to trade and limit the innovation brought to the market of these substances with benefits for the society. We note that the evaluation of enzymes may require other types of expertise within the JECFA than the expertise needed for the assessment of food additives. Thus, a priority ranking in tandem with other food additives (option 2) may not be feasible as it may require considerable adjustments for JECFA how to staff the experts' panel.

In our view, an approach where enzymes are evaluated by batches could be an interesting solution. This should be based upon a risk assessment recognizing the low risk profile of enzymes used in food processing due to low exposure as Processing Aids combined with low toxicity profile of the enzyme (evidenced as all 70 enzymes evaluated by JECFA until now concluded an "ADI not specified"). It is further suggested that an expedited JECFA evaluation approach, taking into consideration existing national country evaluations and mutually recognizing those, could be considered.

AMFEP is working closely with the ETA, the U.S. based Enzyme Technical association, on a proposal how to address the risk assessment of enzymes under JECFA.

Recommendation 10: We agree that processing aids are not an immediate priority. We nevertheless recognize the value of the database being used as an important point of reference by national authorities globally and support option 1 to maintain the processing aids database as well as option 2. The wording "*not to be completed at this time"* may require more precision, e.g. that in terms of future strategy a timeline be set for re-visiting the topic, such as: Processing aids (database, guideline CXG 75-2010) shall be revisited for a potential priority setting at the 54th session of CCFA, for instance.

Bureau Européen des Unions de Consommateurs (BEUC)

BEUC position on the proposed options for dealing with Note 161:

BEUC **cannot support any of the three suggested approaches to dealing with Note 161** for the following reasons:

- *Option 1*: considering the current disagreement over the use of Note 161, we believe it is highly unlikely CCFA members will be able to reach an agreement on a definition of "*advantage*" and of "*does not mislead the consumer*".
- *Option 2*: BEUC strongly opposes the removal of the criteria "*advantage*" and "*does not mislead the consumer*" from Section 3.2 of the GSFA Preamble. As further explained below, European consumers expect that food additives are only authorised if they are safe, technologically needed, and their use has benefits for the consumer. From the perspective of European consumers, the sole criteria of safety and technological function, although necessary, are insufficient grounds for approving new additive uses. This expectation is reflected in EU legislation on food additives.
- *Option 3*: for the sake of clarity, we support recording Codex members' concerns over certain food additive provisions in relation to the criteria '*advantage*' and '*does not mislead the consumer*' in the form of a note inserted in the GSFA itself, next to each relevant provision.

Against this background, BEUC firmly supports **maintaining note 161 as it presently stands**. Alternatively, we would recommend that the 50th CCFA Session agree to resume discussions of the recommendations prepared by an electronic Working Group led by the United Kingdom on *Note 161 – Application of alternative note to provisions for sweeteners* (CX/FA 15/47/13)[1]. BEUC could support Note 161 being replaced with more specific Notes clearly spelling out the restrictions for the use of sweeteners in various food categories.

[1] http://www.fao.org/tempref/codex/Meetings/CCFA/CCFA47/fa47_13e.pdf

Background:

In general, the use of food additives is a growing cause for concern among many consumers in the European Union[2]. In a 2012 consumer survey[3], 77 per cent of respondents said they want foods that are free from additives. The study also found that 72 per cent of consumers would be willing to pay more for foodstuffs without additives.

Several BEUC member organisations have developed databases[4] that inform consumers on which food additives should better be avoided due to concerns over their health effect (e.g. risk to exceed the Acceptable Daily Intake in certain population groups, allergenicity) or their potential to mislead consumers.

Section 3.2. of the GSFA Preamble provides that the use of food additives shall be deemed justified "*only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves [one or more technological functions]*". Similar provisions are in place in the EU, where Article 6 of Regulation (EC) 1333/2008 on food additives provides that a food additive may only be authorised if it is safe at the proposed use level, if there is a "*reasonable technological need that cannot be achieved by other economically and technologically practicable means*", and if "*its use does not mislead the consumer*" and has "*advantages and benefits for the consumer*".

Regarding food colours, BEUC member organisations have criticised their use as often unnecessary[5,6], and even sometime misleading when aiming at masking the absence of a quality ingredient in the food (e.g. fruit in yogurts or eggs in mayonnaise).

When it comes to sweeteners, the above-listed criteria/requirements translate into the need to ensure a significant calorie reduction whenever these additives are used in food products for their sweetening properties, or at least a total replacement of added sugars (Article 7 of Regulation (EC) 1333/2008). So far in the EU, it has been generally accepted that an energy reduction of 30% would be considered as "*significant*". BEUC does support this approach. Indeed sweeteners, even the non-caloric ones, have the potential to reinforce consumers' sweet tooth. Consumer organisations across the EU therefore tend to recommend that people should try to eat less sweet food (e.g. neither add sugar nor sweeteners to their coffee or yoghurt, drink more plain water, etc.)[7,8].

We would be grateful if the 50th Session of the CCFA would consider our comments.

Calorie Control Council (CCC)

CCC is an international association of manufacturers and end users of low-, no-, and reduced calorie ingredients, foods and beverages and holds non-governmental observer status with Codex Alimentarius.

CCC supports efforts to make the work of the Codex Committee on Food Additives (CCFA) more efficient and effective wherever possible. While we are interested in several topics in the discussion paper, our highest priority relates to the General Standard for Food Additives (GSFA) and Recommendation 2 which addresses Note 161.

CCC appreciates efforts to update the GSFA. However, Note 161 has represented a significant barrier to the advancement of provisions for sweeteners and other functional classes in the GSFA process. CCC supports work to resolve issues with Note 161, including through Recommendation 2 in the discussion paper, and facilitate endorsement of sweetener provisions in the GSFA.

CCC supports Option 3 in the discussion paper. As the concepts of "advantage" and "does not mislead the consumer" are important within the context of the GSFA, it is important that they not be removed from the GSFA Preamble. In addition, as CCC agrees the barrier to consensus on the use of sweeteners and other additives in the GSFA has been more related to "a fundamental difference in regional philosophies as to how these types of additives should be used" rather than disagreement on technological function or safety, we do not believe CCFA could come to consensus on the definitions for these concepts.

[2] Special Eurobarometer 354 on food-related risks (2010): "*Concerns have increased regarding the lack of freshness of foods (9%, +3 points vs. 2005) and food additives, colours and preservatives (9%, +2 points vs. 2005)*".
[3] Survey conducted by the market research company e-Research24.de on behalf of Kampffmeyer Food Innovation in eight European countries.
[4] See for instance the database developed by the Belgian consumer organisation Test Achats and the database developed by the Italian consumer organisation Altroconsumo.
[5] Test-Achats. *Colorants : un arc-en-ciel sur votre assiette*. Test Santé November/December 2010. See also here.
[6] Organización consumidores y Usuarios (2016). *Colorantes: aditivos estéticos pero innecesario*. See here.
[7] UFC – Que Choisir. *Edulcorants: juste une illusion*. December 2014. See here.
[8] Test Achats. *Edulcorants: omniprésents dans les sodas*. Test Santé 140. August 2017.

Option 3 would allow for reservations to be noted when CCFA agrees on the other criteria in Section 3.2 but cannot agree on whether the use of an additive would provide an advantage or does not mislead the consumer. This seems like the best available option to resolve Note 161 issues.

CCC appreciates the opportunity to comment on this CL and intends to actively participate in this issue at CCFA. If you have any questions, please contact me.

Comité Européen des Fabricants de Sucre (CEFS)

Recommendation 2 - Colour and Sweetener Provisions / Provisions with Note 161

Generally speaking, we welcome the on-going reviews to make the GSFA the single authoritative reference point for the use of food additives. We also welcome considerations with the aim to improve the manner how the GSFA will be developed, specifically if it is the intention to speed up the work.

However, the Preamble of the GSFA (incl. the GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES) is the most important reference source laying down principles and legitimate factors which shall be used when developing the GSFA Tables I to III. The Preamble has been agreed in consensus.

Deleting or substantially changing the core guiding principles enshrined in the GSFA Preamble, in hindsight after substantial parts of the standard have been developed, could undermine the worth and usefulness of the GSFA as the accepted international single reference point for the use of food additives. This may instead provoke the strengthening of national or regional additive standards.

Against this background Recommendation 2 in paragraph 18 seems to be too restrictive as to the possible outcome of the intended review as laid out in CX/FA 18/50/13 Rev. 1. If a majority of Codex Member States feel that the Preamble must be revised, this should be discussed openly and without restricting the intended outcome to the 3 options laid out in Recommendation 2 in paragraph 18 only.

Federation of European Specialty Food Ingredients Industries (EU Specialty Food Ingredients)

Recommendation 1: EU Specialty Food Ingredients generally supports this recommendation as it aims to progress with draft provisions more efficiently. We however fear that this approach might increase the number of draft provisions the physical working group (p-WG) will have to review at its next session, once this approach is put in place. We also expect the process to also be delayed, due to the limited time available for the p-WG.

Recommendation 2: We support this recommendation and suggest that option 3 be pursued to resolve the issue.

Recommendation 3: We are in support of both options 1 and 2. In our view, utilizing preparatory work undertaken by the experts from industry associations, could be a useful means to make use of limited resources. As mentioned in paragraph 25 of the Discussion Paper [9], this preparatory work can be comprehensively checked and validated by the electronic working group (EWG) on Alignment. The use of preparatory work is also advisable because the information from industry experts is needed both at CCFA and Commodity Committee levels. Although such input would also be needed under option 3, there is a risk that the partnership approach between CCFA and Commodity Committees might delay the adoption process. On the other hand, option 2, in combination with option 1, seems to be an efficient way forward.

Recommendation 4: We fully support option 1 and the additional text proposed in italics in the recommendation 4 box. In our view, this addition is helpful for business operators as well as regulators.

Recommendation 5: In addition to the proposal of recommendation 4, we also support the amendment to Annexes I and II of the Circular Letter (CL) that relates to *Class Names and International Numbering System for Food Additives* (CXG 36-1989). We are of the view that recommendations 4 and 5 help to ensure a consistent approach for the work relating to the Internal Numbering System (INS).

Recommendation 6: We are in principle supportive of a ranking system. Whereas issues related to the safety of a substance shall indeed be treated with the highest priority, we consider that the other criteria would need to be considered carefully when establishing this ranking system.

With regard to the priority setting between the evaluation of a new additive and the revision of a specification of an already authorised additive, we noted that it was stated in paragraph 40 (ii) of the Discussion Paper that "*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".* We would like to express our disagreement with this statement as we believe that they are both equally important.

New additives serve the purpose of assuring global trade and business at a future date; the perspective being mid- to long-term. The revision of a specification, on the other hand, is of immediate global trade relevance as

[9] See CX/FA 18/50/13 Rev.1.

it is a key determining factor whether a market in a country can be entered or not. Requests for revision of a specification are typically needed for the following two reasons: a parameter in the JECFA monograph is not determinable because the proposed method for use is not appropriate, and thus a compliance determination with the JECFA monograph is not possible. Secondly, a parameter is not appropriate at all to describe the material of any manufacturer currently in commerce. Demonstration of compliance with an JECFA monograph is however frequently needed in registration processes to enter a market in a country, thus of highest relevance for industry.

The reference to inappropriate methods or the presence of non-applicable parameters in the JECFA Monographs can be due to a lack of dialogue between a manufacturer that initially proposed a specification and the JECFA experts. To support our argument, we would like to refer to this recent, concrete example: an applicant proposed in the reply to the JECFA call for data an identification assay in which 'glass cuvettes' need be used for a measurement. That proposal for specification however was changed to using disposable plastic cuvettes. Later, in practice it turns out that the analyte gets strongly absorbed on the plastic surface of the cuvette and due to this becomes unavailable for the ID assay determination leading to a completely false result. A wrong result when using the prescribed method in the JECFA Monograph means that a product is non-compliant for registration purposes. This has a direct impact on international food trade in all countries where Codex compliance is a pre-requisite. Other examples could be mentioned to demonstrate how errors unintentionally get into the JECFA Monographs, including the example of the melting range in point 3 of recommendation 6 in the Discussion Paper, which appears marginal at first sight but has a substantial impact on global trade.

To conclude, we would suggest that a priority setting between a JECFA evaluation for a new additive of the revision of a specification is done on a case-by-case basis. We would also like to stress that the revision of a specification is unlikely to absorb JECFA's resource as much as a full safety evaluation.

Recommendation 7: Although food enzymes are not foreseen for inclusion into the General Standard for Food Additives (GSFA), their approval for use is nevertheless important for the improvement of food processes worldwide. Therefore, we would like to stress that JECFA evaluations are important for enzymes because they represent international evaluations, facilitating their acceptance by national authorities that do not make their own evaluations (which is the majority). If JECFA evaluations of enzymes are not prioritized by CCFA and JECFA, it could represent a barrier to trade and limit the innovation brought to the market of these substances with benefits for the society. We note that the evaluation of enzymes may require other types of expertise within JECFA than the expertise needed for the assessment of food additives. Thus, a priority ranking in tandem with other food additives (option 2) may not be feasible as it may require considerable adjustments for JECFA how to staff the experts panel. In our view, an approach where enzymes are evaluated by batches could be an interesting solution. This should be based upon a risk assessment recognizing the low risk profile of enzymes used in food processing due to low exposure as Processing Aids combined with low toxicity profile of the enzyme (evidenced as all 70 enzymes evaluated by JECFA until now concluded an "ADI not specified"). It is further suggested that an expedited JECFA evaluation approach, taking into consideration existing national country evaluations and mutually recognizing those, could be considered.

Recommendation 8: We consider that it is indeed crucial that CCFA has sufficient information from the applications submitted in response to the Circular Letter (CL) relating to JECFA's evaluation in order to assess these requests and establish the priority list. If the CCFA identifies the need to form an electronic working group to review the content of the CL, we are of the view that option 1 would be fully sufficient. The effort put into this should be proportionate and reflective of the need, especially if the Annex 2 to the CL is not systematically filed with insufficient/inappropriate information. We note that it could be made more explicit in the CL that the criteria mentioned in Annex 1 to the CL must be duly considered when filing the Annex 2 while still keeping the notion of providing brief information as mentioned in Annex 2. Overall, we wonder whether an electronic working group is needed to address the problem of insufficient information for CCFA/JECFA.

Recommendation 9: We fully support this recommendation. While we are of course in favour a continued and safe use of food additives, we nevertheless think that the existing priority setting scheme is sufficient to address any new safety concern that may arise (see recommendation 6). We also note that a system based on the Recognized Authoritative Scientific Bodies (RASBs), as developed by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), might be considered by this Committee in a similar fashion. Such an approach would allow the CCFA to endorse recent safety evaluations made by any of the RASB determined to be acceptable by the CCFA.

Recommendation 10: We agree that processing aids are not an immediate priority. We nevertheless recognize the value of the database being used as an important point of reference by national authorities globally and support option 1 to maintain the processing aids database as well as option 2. The wording "not to be completed at this time" may require more precision, e.g. that in terms of future strategy a timeline be set for re-visiting this topic, such as: Processing aids (database, guideline CXG 75-2010) shall be revisited for a potential priority setting at the 54th session of CCFA, for instance.

Recommendation 11: We agree with a ranking system to help the priority setting of the CCFA work. As regards questions 3 to 5, we are of the view that question 5 should be downgraded to 5 points. Making the GSFA the single reference point is a noble and honourable endeavour. However, from a very practical aspect in relation to the role and relevance of Codex for public health and international trade, this goal is likely of sub-ordinate importance only.

Finally, as likely correctly mentioned in paragraph 3 of the Discussion Paper, 15 replies were received during the pre-consultation to this future strategy paper, and footnote 5 lists only 14 of them. The one actually missing in footnote 5 from the pre-consultation is the contribution from this our organisation: EU Specialty Food Ingredients.

EU Specialty Food Ingredients would like to thank the authors of the Discussion Paper and hopes that our points will be taken into account when preparing the discussions under agenda item 8 of the 50th session of the CCFA.

FoodDrinkEurope

In addition to our comments on the recommendations on the future strategies for CCFA, an additional remark is that it would be beneficial to clarify that food ingredients may be used for the primary purpose of imparting colour, and that such use does not turn a food ingredient into a food additive. We propose that this is addressed with the following:

Remark: We propose to add to the Strategy paper a further clarification, e.g. by means of a footnote or an additional sentence that states that “The INS does not include food ingredients, which are used for imparting colour and which have not undergone selective physical and/or chemical extraction.”

Recommendation 1:

In favour of the recommendation and limiting the time gap between the steps. On the same time it would be useful having a set of guidelines considering the information that should be provided in order to fill in the template.

Recommendation 2:

First of all we would like to start with the observation that such an important paper has not been developed by an e-WG.

The way the text is written it leads to Option 3, which reflects the current status.

Recommendation 3:

In favour of option 1 in combination with option 2.

Recommendation 4:

In favour of the recommendation.

Recommendation 5:

Support as a logical consequence of the previous paragraphs.

Recommendation 6:

Support

Recommendation 7:

Recommendation 8:

Both options are seen as independent and can be combined.

Recommendation 9:

Support

Recommendation 10:

In favour of Option 1 i.e. *Maintain the Processing Aids Database as an up-to-date reference on the use of processing aids*. In addition, it has to be made clear that this database serves as a guidance and it is not an endorsed paper by Codex.

Recommendation 11:

In favour of this recommendation. The group shall reflect on who is undertaking this work and the way the work will be conducted.

International Association of Consumer Food Organizations (IACFO)

General Standard for Food Additives: Color and Sweetener Provisions/Provisions with Note 161

IACFO Position

Food Additive Uses Must Not Mislead

As an international consumer organization, IACFO is familiar with practices that mislead consumers and make it more difficult for consumers in both developed and developing countries to follow World Health Organization and other authoritative dietary recommendations to eat more fruits, vegetables, and whole grains, and to reduce consumption of added sugars.

While Section 3.2 of the Preamble clearly identifies the limited circumstances in which the use of additives is acceptable, colors, often in combination with sweeteners (both nutritive and non-nutritive), are frequently used both to mislead consumers, and to intentionally reduce the nutritional quality of the food. This occurs both by substituting for nutritious and more expensive ingredients such as fruits, vegetables, or eggs and by disguising their absence. For example, Tropicana Twister Cherry Berry Blast, despite its name and a label showing images of cherries and berries, has no cherry or berry juice.[10] Much of its dark red color comes from Allura Red (Red 40), and there is more high fructose corn syrup than even apple and grape juice concentrate. Similarly, Betty Crocker Carrot Cake Mix[11] has no carrots. Instead, it has "carrot flavored pieces" made with corn syrup, flour, corn cereal, partially hydrogenated cottonseed and/or soybean oil, a small amount of "carrot powder," unspecified artificial color, and Sunset Yellow (Yellow 6) and Allura Red (Red 40), which together impart the desired color. There are many other examples, such as blueberry muffins,[12] pancakes,[13] and cereals [14] that don't contain blueberries, only sweetened blue-colored concoctions made to resemble blueberries, and egg noodles with yellow dye to simulate the presence of more egg yolk.[15] Food dyes are, by their very nature and intended purpose, misleading to consumers about the character of food; they are the chemical equivalent of misleading label and advertising claims.

Codex Should Not Advance Standards for Misleading Uses of Food Additives

Despite examples that appear to violate the preamble in one or more ways, some Committee participants appear determined to forge a consensus by dropping or expounding upon problematic terminology, or bypassing a consensus altogether.

But to remain consistent with the Codex Procedural Manual, which stipulates: (1) the importance of achieving consensus at all stages of the elaboration of standards and that draft standards should, as a matter of principle, be submitted to the Commission for adoption only where consensus has been achieved at the technical level;[16] and (2) that CXSdards should consider only those factors that can be accepted on a worldwide basis, the Committee should also consider simply discontinuing work on those dyes and sweeteners that lack consensus and not adopt CXSdards for them. **Especially in the case of colors, which are added for cosmetic reasons only, and have no health or nutritional advantages, there does not appear to be any significant downside for consumers from not adopting CXSdards for these additives and for discouraging their use, especially where such use substitutes for, simulates the presence of, or disguises the absence of, healthy ingredients such as fruit, vegetables, and eggs**.

Definitions Could Be Considered; CCFA Not Appropriate Body to Elaborate Widely Applicable Definitions

Of the three options presented, IACFO only supports further consideration of Option 1, to define "advantage" and "does not mislead the consumer," and strongly opposes Options 2 and 3, as explained below.

Furthermore, regarding Option 1, IACFO believes that the Codex Committee on Food Additives (CCFA) is not the appropriate body to elaborate upon what is meant by "does not mislead the consumer." This is an important and far-reaching general concept not specific to food additives, that thus extends beyond the remit of CCFA. In addition, regarding the term "advantage," it should be clarified to whom the advantage is given. IACFO maintains that advantages to consumers should be explicitly considered and prioritized over advantages to manufacturers or other members of the food industry.

---

[10] http://www.tropicana.com/products/trop-twister/cherry-berry-blast
[11] https://www.bettycrocker.com/products/betty-crocker-baking-and-cake-mixes/carrot#!
[12] http://www.jiffymix.com/product.php/27/Blueberry_Muffin_Mix and https://www.pillsburybaking.com/products/muffin-mix/blueberry are two examples
[13] For example https://krusteaz.com/products/pancakes-waffles/blueberry-pancake-mix
[14] For example http://smartlabel.kelloggs.com/Product/Index/00038000576249#ingredients
[15] For example http://tiptopnoodles.com/egg-noodles.html
[16] Codex Alimentarius Commission Procedural Manual 24th edition, page 104, http://www.fao.org/3/a-i5079e.pdf.

The discussion paper states that, based upon past discussion in CCFA, consumers' expectations are inherently regional (e.g., in what additives they would expect a certain food to contain) and vary across the globe, and that therefore it is unlikely that CCFA would reach agreement on globally accepted definitions (Option 1). **However, no real evidence is provided for this statement.**

Furthermore, the notion that standards that would mislead the consumer should not be established is a *universally accepted precept* and is in accordance with the Statutes of the Codex Alimentarius Commission, which identifies the purpose of the work of the Codex Alimentarius Commission as "protecting the health of the consumers and ensuring fair practices in the food trade." Not misleading consumers is integral to ensuring fair practices. IACFO believes that all consumers would agree that the use of food additives should be justified and authorized only when such use is safe and not misleading. It is not a coincidence that note 161 pertains to colors and sweeteners and no other additives. This is because colors and artificial sweeteners have such a large and widespread impact on the appearance and taste of a product, compared to other additives. They are specifically used to make products more appealing than they otherwise would be, which can result in consumers being misled.

Options 2 and 3 Should Not Be Considered

IACFO is adamantly opposed to Option 2. IACFO agrees with Section 3.2 of the Preamble that the use of an additive is justified only when such use is safe, does not mislead the consumer, serves a technological function, and confers an advantage. These are essential, fundamental concepts for consumer protection that have stood the test of time. Their potential removal would seem to serve the sole purpose of removing a roadblock to consensus.

IACFO also disagrees with Option 3, which would require CCFA to insert text in Section 3.2 of the Preamble, stating that factors considered when determining "advantage" and "misleading the consumer" may be regional in nature, and for including a mechanism for recording Codex Member concerns on these factors in a manner that does not create a barrier to consensus. Such a mechanism might entail recording Codex Members' reservations in the report of the meeting, and not in the standard. Option 3 is flawed and inconsistent with the spirit if not the letter of the Codex Procedural Manual as described above and would result in less consumer protection in certain countries. In effect, this removes the requirement for a consensus in order to reach consensus. It should also be noted that not all countries, especially developing countries, may be present at the meeting to register their concerns.

Labelling Considerations

In cases in which certain additives, such as colorings, would not be expected by consumers to be present, if such uses are permitted at all, they should be accompanied by prominent front-of-package disclosure. This is consistent with 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," as recorded in the Codex Procedural Manual.[17]

Alignment of Food Additive Provisions in Commodity Standards and GSFA

IACFO Position

IACFO strongly opposes option 1 (i.e. utilize preparatory work undertaken by industry association) and has no objection to options 2 and 3.

While Codex observer organizations, including industry associations, should continue to be welcomed as members of Codex working groups, IACFO considers it inappropriate for industry associations to take the lead on work normally undertaken by Codex members, even if comprehensively checked and validated by the Electronic Working Group on Alignment before being presented to the Committee. Relying on the discretion of industry associations and industry funded experts, whether Officially Recognized Observers or not, introduces conflicts of interest into the public policy-making process.

Prioritization of requests to JECFA

IACFO Position

[17] These Statements of Principle, one of three general decisions of the Commission contained in the Appendix of the Codex Procedural Manual, read: (1) The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply. (2) When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade. (3) In this regard it is noted that food labelling plays an important role in furthering both of these objectives. (4) When the situation arises that 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.

IACFO agrees that the highest priority should be given to additives where there is an identified safety concern. However, the discussion paper does not define what a safety concern is, nor discuss how safety concerns are or should be identified. (The paper does state in footnote 8 that "safety" is met if an additive has a relevant JECFA evaluation and exposure assessment.)

In IACFO's view, safety concerns may be identified by JECFA itself, or by a member, observer, or working group of CCFA, and then conveyed by the Committee to JECFA. A safety concern generally results from new information or understanding regarding the hazard of or exposure to the additive, including an assessment by a member government or other authoritative body (e.g., the International Agency for Research on Cancer (IARC)), or a published paper in the scientific literature, suggesting that an additive may pose a hazard or a risk.

IACFO also considers that priority should be given to additives to which consumers may receive relatively high exposure (e.g., sweeteners, fat substitutes).

IACFO's position is that these criteria should be applied regardless of whether the additives are intended for inclusion in the GSFA or not.

IACFO also takes this opportunity to recommend that JECFA further consider the adoption of criteria to systematically and transparently evaluate the quality of scientific evidence, and that JECFA convey information about this system generally, and specifically for each additive, to CCFA. We note that the World Health Organization uses the GRADE (Grading of Recommendations Assessment, Development and Evaluation) system.

International Association of Color Manufacturers (IACM)

IACM appreciates and supports that many developing countries, as well as countries that are revising their food law, look to CXSdards for guidance. However not all additives, including many colors that are approved in countries such as the US and the EU have made it through the Codex step process for inclusion in the General Standard for Food Additives (GSFA). It has recently been trending that countries, in developing or revising their food law, are considering the tables of the GSFA (only adopted additives) as a positive list. Due to the stoppage of work related to color additive provisions pending a resolution of Note 161, this trend is resulting in what is essentially a ban on some color additives that are widely approved and commonly used on a global basis and creating a trade barrier as food companies are forced to pull otherwise widely distributed products out of these markets.

We also note that most colors under discussion have been already approved in several Codex member states based on JECFA safety assessments. While the other countries await Codex decision, the lack of harmonization further hampers international trade as businesses must deal with artificial trade barriers resulting in product registration rejections and costly regional product reformulations.

Therefore, IACM strongly encourages the Committee to focus initially on the recommendations in the first section of the discussion paper regarding the GSFA, and primarily to resolve the color and sweetener provisions/provisions with Note 161 as the priority. If this issue is not resolved in short order, the GSFA will continue to lose value as a global standard.

While IACM will support any reasonable option proposed that will allow for resolution, of the options presented, IACM feels that Option 3 has the best chance of achieving consensus. This option will allow for recognition of regional differences without allowing those differences to stand in the way of progress. IACM also recognizes that there is precedence for Option 3, as the Codex Committee on Pesticide Residues (CCPR) uses a similar approach when there is regional disagreement to reach consensus on pesticide maximum residue levels (MRLs). This option would also alleviate the need to reconsider those provisions already adopted with Note 161, which would create further backlog in the work of the Committee.

IACM also supports the proposed 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 as proposed in Recommendation 1. This recommendation will help put in place an additional safeguard to avoid situations in the future where draft provisions are held for an unlimited length of time due to reservations expressed by one or more Codex members.

International Confectionery Association (ICA)

Para	Wording	Comments
Principles and Procedures for Reviewing the Provisions Currently in Step Process		
6	As noted in the "Discussion Paper on the Management of CCFA	Of the three outstanding issues listed in the Discussion Paper on the Management of CCFA Work (CX/FA 17/49/14) that must be resolved before work on the provisions held at different steps of the approval

Para	Wording	Comments
	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).	process can be completed, the issue of colors and sweeteners stands out as it blocks approximately 1200 out of 2000 provisions held at different steps. We dispute the significance of the other two issues listed as stumbling blocks for the GSFA provisions: • Issue 1: the use of table 3 additives in the production of wine is applicable to only two subcategories in the food categorization system; • Issue 2: the current provisions for nitrites and nitrates represent less than 2 percent of all provisions held at steps. At the same time, the issue of colors and sweeteners has not been formalized in the CCFA documents. The discussion paper argues that many colors and sweeteners have not been not approved due to a controversy associated with the use of Note 161. However, it does not explain why selected provisions for colors were approved at Step 8 in the recent years (most recently in 2017) and why the majority of color provisions without Note 161 attached remained on hold since 2009. In this regard, the proposal to complete the work on the remaining historical provisions for which no "outstanding issues" have been identified by the CCFA 52nd session (2020) could not be accepted before the issue of the use of colors and sweeteners is clearly stated, discussed and hopefully resolved by the CCFA50.
6 (i-v)	Presentation of the new approval process for GSFA provisions	We believe that the minor modification proposed for the existing process could add efficiency to the GSFA work. However, the process still lacks clarity on actions associated with provisions at steps 4, 6 and 7. This is critical issue considering that majority of the current GSFA draft provisions have been held at steps 4 and 7 for extensive periods of time.
Colour and Sweetener Provisions / Provisions with Note 161		
8	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.	This is critical point of discussion and it is unclear why differences in regional philosophies should stop approval of GSFA provisions. Codex Guidelines CXG 36-1989 CLASS NAMES AND THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES offers simple definitions for additives classes allowing a considerable number of food additives to be safely used as colors and sweeteners around the world in accordance with the GSFA provisions. We believe that the CCFA should not be discussing how colors and sweeteners should be used outside of the step process.
10	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.	We do not agree with applying this approach to the provisions held at step 7. Before reaching step 7, GSFA provisions are assessed through the six steps of discussion by the CCFA (preceded by the JECFA assessment) allowing for consensus over most aspects of the additive use including technological justification, safety and consumer health. The proposal to address the dichotomy of the regional interpretations of the GSFA preamble and the need for globally recognised Codex documents for provisions held at Step 7 demonstrates inefficiency of the approval process and could not be accepted. We also note that most colors and sweeteners under discussion have been already approved in several Codex member states based on JECFA safety assessments. While the other countries await Codex decision, the lack of harmonization hampers international trade as

Para	Wording	Comments
		businesses have to deal with artificial trade barriers resulting in product registration rejections and costly regional product reformulations.
12	Of these criteria, only “advantage” and “does not mislead the consumer” are not defined	We believe that the terms "advantage" and "does not mislead the consumer" are self-explanatory and should not have any impact on the "outstanding" issue of colors and sweeteners. Nevertheless, if the committee is prepared to embark on the lengthy discussion of the definitions for "advantage" and "does not mislead the consumer," it is proposed to review the outstanding provisions related to colors and sweeteners, especially those held at step 7, and release those not associated with the note 161 for approval.

The International Council of Beverages Associations (ICBA)

ICBA represents the interests of the worldwide non-alcoholic beverage industry. The members of ICBA include national and regional beverage associations as well as international beverage companies that operate in more than 200 countries and territories and produce, distribute, and sell a variety of non-alcoholic sparkling and still beverages, including soft drinks, sports drinks, energy drinks, bottled waters, flavored and/or enhanced waters, ready-to-drink teas and coffees, 100 percent fruit or vegetable juices, nectars and juice drinks, and dairy-based beverages.

Recommendation 1:

ICBA supports the proposed new process as proposed in Recommendation 1.

Recommendation 2:

ICBA believes that Option 3 that follows the approach taken by CCPR would offer a way forward and supports further considering the proposed suggested text:

ICBA notes that the lack of progress on finalizing draft provisions for colors already has caused some countries to propose bans of these food additives in the absence of adopted Codex provisions. We believe that trying to define “advantage” or “does not mislead the consumer” would face similar value judgments that have led to lack of consensus thus far. It would be best to recognize the philosophical differences that exist in order to make progress on this. The approach to reach consensus applied by CCPR has been used for many years and can serve as an example to consider. As per footnote 9 in CX/FA 18/50/13 Rev1., “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.”

Recommendation 3:

ICBA believes that all three options should be combined into a single format that allows for multiple options to be considered depending on the situation. Concerning Option 1, we note that while industry INGOs have best knowledge on the actual uses of food additives in the products they represent, we note that some INGOs are regional by nature/philosophy and do not always fully represent the global use patterns.

Recommendation 4:

ICBA supports adding the proposed bolded text as it points out the fact that there are additives that have not yet been included in the GSFA but which have received an INS number.

Recommendation 5:

In general, **ICBA supports** the proposed bolded texts to provide clarity.

Recommendation 6:

ICBA supports this recommendation and the proposed priority ranking.

Recommendation 7:

ICBA supports continuing the current approach, prioritizing the flavoring evaluations using a procedure that is based on consultations with the flavor industry (IOFI) and the JECFA Secretariat that has resulted in scheduling flavorings for JECFA evaluations every other year using an agreed-to schedule. ICBA notes that

the JECFA evaluations of flavorings are important and should be maintained as a priority as flavorings are not captured within the Codex General Standard for Food Additives. We also note that any safety question based on new data on an already evaluated flavoring should be prioritized.

ICBA notes that a similar approach could be considered for processing aids, e.g., enzymes that are not included in the GSFA.

Relative to food additives (not flavorings nor processing aids) not intended for inclusion in the GSFA, Option 2 should be supported.

Information supporting requests for inclusion on the Priority List

Recommendation 8:

ICBA supports the recommendation and encourages considering both options as, in our view, the more guidance that will be provided, the easier it will be to judge the priority and the completeness of the data available enabling a more efficient evaluation process. Importantly, however, relative to Option 2, ICBA suggests that the questions in Annex 2 would be 'clarified' to the extent that they align with the criteria captured in Annex 1. Additional questions could be added for criteria not currently captured in way of questions in Annex 2. None of the existing questions in Annex 2 however should be eliminated.

Recommendation 9:

ICBA supports the recommendation. We believe that the priority should be the completion of work related to the draft provisions before embarking into new work associated with the maintenance or re-evaluation of the GSFA.

Recommendation 10:

ICBA supports the adoption of both options of the recommendation. The Processing Aids Database is a valuable reference on current uses of processing aids and maintaining it will be impactful to fulfilling the mission of Codex Alimentarius. Following the completion of current work priorities, new work to consider reviewing and possibly amending the *Guidelines* will be important to furthering the mission of Codex Alimentarius.

Recommendation 11:

ICBA supports further discussions on a more systematic approach to the prioritization of its work but notes that the priority must be finishing the draft provisions in the GSFA before embarking on other issues such as processing aids. ICBA also notes that in considering the development of a systematic prioritization approach for CCFA, the element of risk to public health and safety be ranked on the strength of science-based criteria in addition to the potential geographical scope of the question.

International Chewing Gum Association (ICGA)

ICGA believes that the recommendations included in the discussion paper offer some interesting new ways of handling procedural aspects of the work of CCFA. However, ICGA does not believe the working document goes far enough because it appears to have been limited in its ambitions in relation to some important aspects to improve transparency and inclusiveness.

ICGA also believes that the role of any Codex subsidiary body is to focus on its mandate without trying to solve issues that are contentious in nature and delay the core work of that subsidiary body. In other terms, ICGA believes that CCFA's primary (and most important) task is to consider all pending draft maximum permitted levels, regardless of the nature of the substance considered. There is no substantive reason for CCFA to continue to hold discussions of fundamental pending provisions included in Table 1 and 2 of the GSFA (i.e. see CCFA50 INF01 document)[18] and stalled at step 4 or 7 for several years, if not decades, especially color provisions in the food category 05.3 chewing gum, as well as in other confectionery categories i.e. 05.1.4, 05.2, and 05.4, **none of them being associated with Note 161 nor covered by any commodity standard** (thus no extra burden on alignment).

ICGA encourages CCFA to resume its work on pending color provisions **as of 2018**, **possibly by starting with those in food categories 05.1.4, 05.2, 05.3 and 05.4.** This would be without prejudice to other discussions on broader aspects that may be discussed under other new work proposal(s), or as part of the revision of internal CCFA ways of working or deferred in time or considered in light of discussions held within other international competent UN bodies. ICGA would like to draw the attention of the Committee on its CCFA49 report regarding trade issues which are not covered specifically enough in the present discussion paper.[19] ICGA notes that all pending provisions for colors in these food categories have been evaluated – and

[18] See http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFA&session=50

[19] See in particular Para. 135, indents (ix), (x) and (xi) in REP17_FA, at http://www.fao.org/fao-who-codexalimentarius/meetings/archives/en/?y=2017&mf=07

in some cases recently reevaluated - by JECFA with no safety concerns. ICGA hopes that CCFA50 will take wise decisions in considering such provisions on the 2018 terms of reference of the electronic working group on GSFA **under Agenda Item 5** of CCFA50.

ICGA specific comments on each recommendation

ICGA comments on R#1: ICGA believes that this recommendation goes in the right direction. However, ICGA suggests an even more automatic process for those provisions which served as the basis for JECFA evaluations.

ICGA submits that any proposed provision (i.e. intended maximum use level), that has been included initially in the CCFA request for safety evaluation by JECFA - once the JECFA evaluation returns back to CCFA for consideration under Agenda item 3–

(i) Should be automatically included in the GSFA at step 2 and allocated immediately to the terms of reference of the same CCFA session renewed electronic working group on GSFA, where the EWG recommendations would be considered at the immediate next CCFA meeting (and at its pre-session physical working group), and
(ii) Should use the yearly Circular letter issued on *New and Revised Provisions* to consider other provisions – which were not included in the JECFA review of the applicant dossier. Should the latter set of provisions being included at step 2 by the year n+1 CCFA, then those provisions could be subject to CL requesting comments at step 3 , or as an alternative be put on the terms of reference of the year n+1 electronic working group on GSFA for consideration by the CCFA n+2 plenary.

ICGA rationale on R#1*:* Recommendation 1 is essentially a return to past practices, where, following JECFA review of new food additives, a circular letter would be issued requesting use levels on that substance (regardless of what JECFA reviewed in terms of intended uses). This way of seeking comments frequently led to hundreds of provisions included at step 3 into the draft Table 1 and 2 and is one of the reasons the Committee was facing lengthy discussions before Note 161 was created.

ICGA's proposal is to ensure that when JECFA has reviewed the safety of a given substance and its associated intended uses in the application dossier, such intended uses are automatically considered for discussion by the EWG on GSFA so that the comments (at step 3) would be those automatically performed within that electronic working group and on the limited number of provisions that have been endorsed by CCFA when considering that list of intended use in allocating the work to JECFA. Other intended uses would be subject to the normal procedure of New or Revised Uses. Then, the normal review by CCFA of those additional provisions for inclusion at Step 2 would occur, and, if CCFA agrees to their inclusion at step 2, a dedicated CL could seek comments at step 3, as per recommendation 1.

ICGA comments and rationale on R#3: ICGA believes that any alignment should happen at the time of endorsement of food additive provisions included in each commodity standard by the CCFA. Therefore, when an existing commodity committee decides on food additive provisions relevant to a certain standardized food, such provisions should be reviewed by CCFA at the time of the endorsement phase and immediately reflected in the corresponding food categories and associated notes in Table 1, 2 and 3 of the GSFA. At that point, CCFA should inform the relevant commodity committee that those food additives provisions have been duly adopted in the GSFA and the Commodity Committee in return should make the cross-reference to the GSFA, as instructed in the Codex alimentarius Commission Procedural Manual. In other terms, no specific food additive provisions should remain in any Codex Commodity standard once such an alignment in ensured. In order to achieve this objective, an Option 4 combining Option 1 to 3 could be suggested and further worded along the lines of the suggested above new ways of proceeding to such alignments between GSFA and Codex Commodity Standards.

ICGA comments on R#4: ICGA supports this recommendation, provided that the following amendment is made to the last sentence (marked underlined bold): ***"****The* ***INS*** *list may include those additives that have not* ***yet*** *been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)* ***or are included in the latest published version of the General Standard for Food Additives ~~(CXS 192-1995)~~ (CXS 192, as amended), or are listed as permitted food additives in more than one country****.*

ICGA rationale on R#4: The amendments aim at indicating that GSFA and JECFA work is not exhaustive and may evolve in the future. It should also be recalled that the INS list initially came from a consolidation of many countries' food additives regulations, and not necessarily ever reviewed by JECFA or CCFA. Therefore, their presence in the INS list still makes sense, even in the absence of such JECFA review or any provisions adopted or present in the step process in the GSFA.

ICGA comments on R#5: ICGA supports the first suggested change in the recommendation. While supportive in principle of the second suggested change in the recommendation, ICGA suggests an amendment to the last part as follows: ***Proposals for deletion of INS entries cannot be submitted in this circular letter if there are existing provisions (adopted or in the Step Process) for the additive in the General Standard for Food Additives ~~(CXS 192-1995)~~ (CXS 192, as amended) or if there are adopted provisions for such an additive in more than one country.***)

ICGA rationale on R#5: As mentioned for Recommendation 4, the original intent of the constituted list of the INS was to reflect as exhaustively as possible all food additives permitted in many countries around the world, regardless of whether such food additives have been reviewed by JECFA or by CCFA for inclusion in the GSFA. The amendment is intended to reflect these origins and further explain the presence of some substances in the Codex INS, and not necessarily related to their international clearance.

ICGA comments on R#6: ICGA strongly supports the recommendation.

ICGA rationale on R#6: ICGA submits that the highest priority of JECFA work should be given to the safety evaluation and establishments of specifications for new food additives, and equally to a reevaluation of existing food additive, should any safety concern be identified and characterized.

ICGA comments on R#7: ICGA supports Option 2.

ICGA rationale on R#7: ICGA considers that priority ranking always should depend on (i) the amount of priorities suggested and (ii) the relative priorities among the various requests based on criteria and scoring to be defined. ICGA believes that unless a new food safety concern may arise, priority should be given to new food additives/food extracts. ICGA also believes that GSFA being the priority, JECFA work assigned by CCFA should be for food additive only -- not enzymes or other chemicals intended for use as processing aids. Once GSFA is seen as substantially complete, other work may be assigned to JECFA.

ICGA comments on R#8: ICGA supports Option 1. However, ICGA wonders whether an electronic working group is the most suitable way of considering this new work, which would normally be included in a proper Project Document for New Work, and then subject to a formal approval by the Codex alimentarius Commission. Perhaps a Discussion Paper could be prepared by the JECFA and CCFA secretariats for consideration at next year's CCFA before any change is made to the Annex 2.

ICGA rationale on R#8: The main hurdle for applicants suggesting new work priority in response to the yearly circular letter is rather to assess what is the level of detail necessary to respond to the listed question.

ICGA comments on R#9: ICGA supports this proposal. However, it should be noted that CCFA has already developed such a tool in the past, based on work led by Canada for colours, with a precise list of questions/criteria and an associated scoring/weighing system to identify the order by which the food additives may be considered for reevaluation by JECFA. ICGA believes this tool developed for colors may well be relevant to other food additives as well and could be tested for other substances, such as preservatives. Therefore, it is less the process or tool to be defined, than establishing a new electronic working group to run the already existing screening tool, and make recommendations to each plenary based on that screening t and the relative JECFA workload on new food additives, in the absence of safety concerns.

ICGA comments on R#10: While supportive of Option 1, ICGA recommends that CCFA not work on processing aids until the main piece of work on food additives is viewed as close to completion (except for new food additives which are separate from the backlog).

ICGA rationale on R#10: ICGA suggests having China and New Zealand continue "maintain" the processing aids database, but ICGA is looking forward to CCFA50 discussion to get more clarifications on how such maintenance is performed (who is deciding inclusion and on what specific grounds and under whose supervision, etc.) and how industry groups such as ICGA may eventually submit new proposals in food categories not yet covered by the database. The organization of a side-event by China and New Zealand would be very helpful to prepare the discussion on this Recommendation.

International Council of Grocery Manufacturers Associations (ICGMA)

The International Council of Grocery Manufacturers Associations (ICGMA) is a nongovernmental organization that represents foods and consumer packaged goods manufacturers globally. ICGMA promotes the harmonization of food standards and policies based on science and is a staunch supporter of Codex Alimentarius. ICGMA also works to facilitate international trade of food products by eliminating barriers to trade and believes that global harmonization of science-based food standards is important to achieve that goal.

ICGMA is very supportive of efforts to evaluate and improve the efficiency, effectiveness and process of CCFA. We believe the excellently written and thoughtful discussion paper is a crucial step towards realizing improvement at CCFA.

General Comments:

Overall, we are generally supportive of the recommendations presented in the discussion paper. We hope the Committee approaches the recommendations as starting points for further discussion rather than prescriptive proposals.

We also wish to recognize the measured way in which the discussion paper approaches considerations associated with the use of Note 161. We have provided additional commentary on Note 161 below, but welcome this systematic approach with great promise for making progress on a fundamental barrier to long-term progress at CCFA. Although all the issues noted in this paper are significant to CCFA, ICGMA believes that further progress on Note 161 (e.g., Recommendation 2) is the clear priority for the Committee.

Below, we have offered additional feedback on the recommendations where we believe additional consideration is warranted. We look forward to a robust discussion in Xiamen.

Given the CCFA mandate and importance of furthering the General Standard for Food Additives (GSFA) as the single authoritative reference standard for food additives, ICGMA encourages CCFA to prioritize consideration of the issues identified and recommendations provided in this section of the document. Should CCFA determine that it will take multiple meetings to work through all the issues and recommendations identified in the discussion paper, ICGMA encourages the Committee to give the section on the GSFA highest priority and review those issues related to the GSFA first.

Recommendation 1: This recommendation is primarily intended to address an anticipated situation CCFA will face once the backlog of provisions awaiting entry into the GSFA is cleared. ICGMA is extremely supportive of removing this backlog and agrees with the approach presented in paras. 5-7 and this recommendation. Adopting the process outlined will provide predictability and enhance transparency for stakeholders like ICGMA who have supported or proposed provisions for entry into the GSFA.

Recommendation 2: ICGMA believes addressing the issues related to Recommendation 2 is among the most fundamental and important tasks before CCFA. As noted earlier in CX/FA 18/50/13 Rev1, the discussion paper envisions that by CCFA52 in 2020, “CCFA can complete its work on the remaining historical provisions for which no ‘outstanding issues’ have been identified.” The implications of this statement are serious. Should CCFA not make progress towards addressing these “outstanding issues,” the most important workstream of CCFA, the GSFA, will essentially grind to a halt in two years. It is, therefore, absolutely essential that progress be made on this recommendation at the CCFA50.

ICGMA agrees with the assessment that the “outstanding issues” identified with provisions for colors and sweeteners are primarily a result of “a fundamental difference in regional philosophies as to how these types of additives should be used.” We support an approach that allows regional differences to be noted and recorded, but find it unacceptable that provisions in a global standard should be blocked due to differences in regional philosophies. Codex and the standards it renders are global standards. Regions and individual nations may have different approaches, but their regional or national interests must not block Codex from delivering a global standard of such significance. Finally, we also agree that any solution to “outstanding issues” must be broad enough to address any type of additive and should not focus only on colors and/or sweeteners.

Although the Preamble of the GSFA provides no specific or implied definition of “advantage” and “does not mislead the consumer,” the concepts remain important for many Codex members, including ICGMA. It is also important that consumer considerations and consumer acceptance not be excluded from CCFA decisions. When consumer trends or consumer patterns are consistent on a global scale and CCFA participants are in widespread agreement about them, they are a legitimate consideration for a global standard.

However, we agree with the commentary provided in para. 14 that it would be challenging to define these terms given past CCFA experience with how differently certain regions define such terms. As a result, we cannot support Option 1 as presented in Recommendation 2. We simply do not believe this would be a productive use of time and seriously doubt that we could come to a consensus-based definition. Additionally, as these concepts remain important to many Codex members, including ICGMA, we do not believe Option 2 is viable.

As a result, ICGMA can support proposed Option 3 in Recommendation 2 as a starting point for this extremely important discussion. If agreement can be reached that Options 1 and 2 are not viable, we recommend CCFA work towards consensus on wording of the text proposed in para. 18 as an immediate next step. We further encourage the Committee to be very deliberate in considering any changes to the Preamble of the GSFA. Reaching consensus on language like what is proposed in para. 18 must be the primary and initial focus, where the language is eventually recorded is a secondary concern at this stage.

The procedural mechanism envisioned by the recommendation achieves an efficient compromise and would add greater clarity to Preamble concepts. It would also provide a mechanism for indelible reservations to be recorded without blocking consensus when all other conditions are met for inclusion into the GSFA. In fact,

this proposal is similar to the current practice used by the Codex Committee on Pesticide Residues 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. As noted in footnote 9 of CX/FA 18/50/13 Rev1, these "other factors" are often regionally based and can be recorded with a brief description of the basis for the reservation allowing the MRL to proceed without blocking global consensus.

Any consensus text should clearly recognize the reality that CCFA has faced for many years—regional differences may exist for certain additives when used in certain foods. Although such differences are legitimate for regional or national regulation given differences in consumer acceptance patterns that are often local or even hyperlocal, they should not be used to block consensus in a global standard when such additives are determined to be safe, technologically justified, and other members of CCFA have indicated their support for inclusion in the GSFA.

Importantly, this option still allows the Committee to consider the "advantage" and "does not mislead the consumer" criteria when reviewing a proposed GSFA provision without allowing a single country or region to define these criteria based on their specific circumstances. If there is widespread consensus that an additive does not provide an advantage or would mislead consumers on a global basis, the provision would not be adopted.

ICGMA believes this solution offers the best prospect for achieving several very important and pragmatic goals for CCFA and is consistent with practices used by other Codex Committees when faced with similar regional differences. First, by providing a solution to address those color and sweetener provisions that have languished due to disagreements about Note 161, this will immediately address trade barriers in countries that adopt the GSFA, but do not permit the use of key colors and sweeteners stuck in the step process. Second, this will provide a pathway for work to continue after 2020 on CCFA's most important work product—the GSFA. Finally, it will ensure the safety of the global food supply while providing a constructive means for certain countries or regions to indicate when they have a difference of opinion or different approach to the use of a certain additive in their specific geographic locale.

For these reasons, ICGMA supports advancement of Option 3 in Recommendation 2 and encourages the Committee to begin review of the proposed text as soon as possible. If a consensus is reached on language, the Committee can determine how and where to record the text. Once consensus is reached, it is vital that CCFA immediately begin considering those provisions for colors and sweeteners stuck in the GSFA backlog. We understand this backlog is causing hardships and negatively impacting trade, particularly for products containing certain colors stuck in the step process. Thus, advancing these backlog color and sweetener provisions should be considered an immediate Committee priority.

Reconsideration of any adopted provisions for which Note 161 has been applied, should only occur after those provisions for colors and sweeteners stuck in the step process are reviewed and the remaining backlog is cleared. ICGMA is not prepared to comment at this time on whether we would support reevaluation of those provisions that currently include Note 161, but agree that they should be viewed as the lowest priority.

Recommendation 3: ICGMA appreciates the amount of work that the Chair and co-Chair of the eWG on Alignment regularly dedicate to this activity. The three options presented in this recommendation do not appear to be mutually exclusive, and ICGMA encourages the Committee to consider all three of them. In particular, we strongly support Option 1 in Recommendation 3, which is exemplified by the efforts of the International Dairy Federation (IDF). We encourage CCFA to embrace this as a solution, but note that it cannot be the only solution as there will be commodities for which industry groups may not be engaged, differences of opinion exist between groups, or for which it may not be feasible for industry members to engage. As a result, we recommend a solution that combines options 1 and 2 in Recommendation 3, where industry can be tasked as appropriate/feasible, but additional countries can be invited to share the labor of the eWG.

We are less optimistic about the viability of Option 3 in Recommendation 3, although suggest that commodity committees still be encouraged to at least attempt to align their standards with the GSFA. Unfortunately, experience has shown that commodity committees are limited in their ability to complete the complex task of alignment, and we remain concerned that CCFA will have to duplicate their efforts.

Additionally, we note a possible omission from this section of the paper and believe the authors have missed an opportunity to improve the efficiency and process of the alignment work. Although ICGMA agrees that food additive provisions set for commodity standards should be determined by the appropriate commodity committee, the Alignment Decision Tree (see appendix V of REP12/FA) is silent on how CCFA should consider proposals (or existing draft provisions in the step process) for entry into the GSFA for additives intended for use in commoditized foods not listed in the relevant commodity standard.

CCFA precedent dictates that the provision is referred to the relevant active commodity committee for further review if such a committee is active. However, there is no clear mechanism for CCFA to consider a proposal related to a new food additive provision for use in a commoditized food when a commodity committee has

adjourned. While most agree, and precedent dictates, that CCFA has authority to update food additive provisions for adjourned commodity committees, there is significant hesitation for CCFA to adopt any new food additive uses in commoditized foods even if such adoption is justified.

Some commodity standards were developed many years ago by commodity committees that have either adjourned sin die or are meeting by correspondence only on specific issues. Advances in food technology occur every day and the speed of reformulation is only accelerating as consumers awareness of food ingredients increases and companies seek new consumer friendly additives. In a limited number of cases, there may be innovations and new materials developed that warrant use in commoditized foods and a clear process should exist for CCFA to systematically review and reach consensus in these limited cases.

While there is limited precedent that CCFA has the authority to allow the use of new or different additives in commoditized foods for adjourned commodity committees, past cases have demonstrated that the lack of a process hinders efficiency. We encourage CCFA to use this review of the alignment work and CCFA future strategies as an opportunity to address this gap. As additional commodity committees adjourn and innovation in food technology continues, CCFA will be faced with more of these situations.

Recommendations 4 & 5: These recommendations both relate to a unique scenario where proposals were presented to remove substances from the INS because of unique circumstances with these specific materials. ICGMA believes these were isolated incidents and future proposals to remove materials from the INS are unlikely. However, ICGMA can support the proposed addition to the background section of the INS and to Annex 1 and 2 of the circular letter. Both recommendations will make it clear that removal from the INS list is not permitted until GSFA provisions are removed and that removal from the INS is not a backdoor way to negate adopted provisions in the GSFA.

Recommendation 6: ICGMA can support the ranking order presented in Recommendation 6 as a starting point for discuss, although we have some reservations. We agree that a safety concern should be the highest priority criteria and that new additives for inclusion in the GSFA also merit high priority given the CCFA mission. If this ranking system were to move forward, it would be necessary to clearly define some of these terms, namely what is a “identified safety concern.” For example, an identified safety concern is not the same as a potential safety concern based on the age of a JECFA evaluation.

We also caution CCFA that specification changes should not be viewed as low priority. They remain important for global food trade and innovation. We also note that JECFA reviews for specification changes generally require less time and resources than would be required for a new evaluation, which may be warranted when considering JECFA’s limited resources and the implications of specification changes (or lack of a specification) on trade.

Finally, as alluded to above, we see an omission as there is no priority ranking for requests for reevaluations of materials for which no safety concern has been identified, but for which the JECFA evaluation may be old. We note that reevaluations of substances evaluated by JECFA in the 1960s have been undertaken in some cases and proposed in other cases. In the absence of an identified safety concern, we believe these requests should receive lowest priority since such materials generally have several decades of common use in foods to support their safety.

Recommendation 7: Many ICGMA members formulate their products using ingredients that may not meet the criteria for listing in the GSFA. ICGMA is unaware of any issues created by the current approach prioritizing flavoring evaluations using a procedure that is based on consultations with the flavor industry (IOFI) and the JECFA Secretariat. In fact, we note this process has resulted in scheduling flavorings for JECFA evaluations every other year using an agreed schedule. JECFA evaluations of flavorings are important and should be maintained as a priority as there is no other positive list at Codex.

We also note that any safety question based on new data on an already evaluated flavoring should be prioritized. As such, we would favor maintaining the current process. This might be possible under Option 1 presented in Recommendation 7, but this would require further consideration. ICGMA also notes that a similar approach could be considered for processing aids, e.g., enzymes that are not included in the GSFA.

Recommendation 8: We support the general recommendation here that an eWG be formed to explore revisions to Annex 2 of the circular letter. We appreciate the challenges noted in para. 46-47 of CX/FA 18/50/13 Rev.1, and feel they would benefit from further exploration as part of an eWG. ICGMA will also commit to join this eWG and contribute to the discussion. Given the other pressing issues identified in this discussion paper, it may not be feasible to form this working group for CCFA51.

Recommendation 9: Like other members of CCFA, ICGMA agrees that basic maintenance of the GSFA will include reevaluation of certain additives periodically if evidence is presented that they may no longer be used or necessary. However, we fully support the recommendation that this is a future priority. At this time, CCFA has far more pressing matters to address and should revisit this only after the backlog of provisions for entry into the GSFA has been cleared.

Recommendation 10: Overall, ICGMA can support both options as presented. Neither appear to be mutually exclusive. Instead, Option 1 in Recommendation 10 seems to be an immediate action while Option 2 presents a future priority. As noted above, CCFA has many far more pressing priorities then revising CXG 75-2010 now. Once the GSFA backlog is addressed and recommendations presented earlier in this document have been considered, we could support revising this workstream.

Recommendation 11: ICGMA supports further discussion of the proposed decision-making table presented following para. 62 and agrees that a systematic approach is needed to evaluate new work. Although generally satisfied with the table, we encourage risk to public health be ranked on the strength of science-based criteria in addition to the potential geographical scope. Risk to public health is inherently a question of scientific evidence, and strength of evidence as well as global applicability should be considered.

We also believe that it would be beneficial to clearly delineate a process for determining a proposal that is of such low priority that it does not warrant work even if it is within mandate of CCFA. As currently written, only those proposals that do not fall within the CCFA mandate would be discarded. An important component of prioritization is not just assigning a priority score, but also clarifying a mechanism where a proposal can be defined a low priority and discarded. This could potential be accomplished by accompany text establishing a minim score to proceed with work.

Although presented at the end of the document, we would encourage CCFA to prioritize consideration of such a decision-making table as a priority.

Conclusion

ICGMA is extremely optimistic about the potential for this discussion paper to begin a productive dialogue at the CCFA50 on challenges and opportunities for the committee moving forward. ICGMA intends to be an active contributor to that discussion and looks forward to working with all stakeholders to advance our shared goals, enhance CCFA efficiency and ensure the Committee continues to achieve its important mandates.

International Dairy Federation (IDF)

Recommendation 1

IDF supports the recommendation. We also believe additional efficiencies could be attained overall if:

- The JECFA recommendation was “ADI – Not Specified (NS)” then the food additive be automatically considered for Table 3 of the GSFA at a GMP level and enter the step process at Step #5
- The JECFA recommendation was “ADI – Specified” and all other conditions in the (i) step above are met, then this could be circulated at Step 3 for comments.

IDF also suggests that those additives currently in the step be either determined to be held (no delegation requests for advancement), discontinued if the Plenary reaches a consensus to do so or moved into the accelerated Step 5 process. This would address that fact that many provisions have been in suspended animation in the step process for a long time.

Recommendation 2

The Committee has attempted multiple times to reach consensus on how to resolve non-scientific and non-technical issues that are determined to be important in some countries. While none of the options are likely to be supported by all delegations and an alternative option might be the best solutions, based on the three options available, however, Option 3 could be acceptable and is in line with the approach taken by CCPR. Option 3 is more likely to be acceptable to a broader number of CCFA delegations.

Recommendation 3

IDF would support all three options, depending on the topic and would propose that this should be “Option 4”. As has been pointed out in the discussion none of the options are exclusive and therefore picking only 1 of the 3 is highly restrictive and could hinder the alignment process rather than advance it. Therefore, in our view, the recommendation should be modified to add “Option 4” that would be “All of the above”, with the only reservation being that level of knowledge and expertise of industry associations and Codex Commodity Committees related to the CCFA procedures on food additive adoption.

Recommendation 4

IDF supports this recommendation

Recommendation 5

IDF supports this recommendation

Recommendation 6

IDF believes that the priority list needs to be reworked as it does not provide enough detail or qualifications related to all three priorities. For example, the term in (1) . . . "identified safety concern" is not defined or qualified and has the potential to create impasses for the CCFA plenary if adopted as currently worded. Therefore, we support the recommendations in theory, but cannot support the individual priority recommendations as currently worded.

Recommendation 7

IDF supports Option 1 as at the current time, both the CCFA WG on the GSFA, JECFA and the CCFA plenary have a significant backlog of food additives in the step process that are intended to be included in the GFSA. As some point in the future when this backlog has been addressed, then Option 2 may be viable, but not at the present time.

Recommendation 8

IDF supports Option 1 as the simplest and least disruptive. Option 1 will also avoid the potential uncertainty and confusion on the actual questions required to be addressed a Circular Letter that could occur if Option 2 was chosen.

Recommendation 9

IDF believes this recommendation is premature and the plenary should not allot time in the agenda to this subject until more food additives in the step process and under consideration as a colour or sweetener are addressed. Also, taking up this subject could further encumber the established CCFA food additive deliberations process. The resources that CCFA might utilize to address this issue should be invested in moving pending food additives to Step 8 or out of the Codex system.

Recommendation 10

Again these 2 options could be combined and accepted as 1 option, i.e. (continue) to maintain the PAD as an up-to-date reference and as a future priority review/amend the Guidelines.

International Food Additives Council (IFAC)

IFAC is a global association representing manufacturers of food ingredients and holds non-governmental observer status with Codex Alimentarius. IFAC strives to promote science-based regulations, standards and specifications for food ingredients worldwide.

IFAC is supportive of efforts to ensure the work of the Codex Committee on Food Additives (CCFA) and all Committees is as efficient and effective as possible. We thank the co-authors for their work in developing the discussion paper regarding future strategies of CCFA and appreciate the opportunity to offer the following comments. While IFAC is generally interested in most of the topics and recommendations included in the discussion paper, the topic of highest priority is the General Standard for Food Additives (GSFA) and Recommendation 2.

IFAC is very supportive of efforts to update the GSFA and appreciates the work to date by CCFA in general and the GSFA electronic Working Group in particular to advance this important standard. The GSFA remains one of the top CCFA priorities for IFAC, and Note 161 continues to present obstacles for the advancement of provisions for several additive functional classes in the GSFA process. Therefore, addressing Note 161 in a way that facilitates progress within the GSFA and meets the needs of all interested stakeholders is vital.

With regard to Recommendation 2, IFAC agrees the most significant issues with Note 161 relate to provisions for colors and sweeteners, and "that the barrier to consensus on the use of these additives is not a disagreement on technological function or safety," but rather "a fundamental difference in regional philosophies as to how these types of additives should be used." We agree any solution needs to work for all types of additives, continue to allow for national and regional differences to be noted and comply with the Codex Procedural Manual. However, noting regional differences should not prevent acceptance of a global standard and inhibit the overall work of Codex.

IFAC agrees the concepts of "advantage" and "does not mislead the consumer" are important, especially as they relate to the incorporation of CXSdards into national legislation. Therefore, removing these terms from Section 3.2 of the GSFA Preamble as is proposed in Option 2 is not desirable and IFAC does not support this option. At the same time, as interpretation of these terms and how they will be addressed in national legislation will vary significantly depending on the region, IFAC also does not support Option 1 as a viable solution to address this issue.

As a result, IFAC supports Option 3 for this Recommendation and agrees it should be considered as a starting point for addressing this topic. As stated previously, regional philosophies will lead to very different interpretations of how an additive should be used and therefore cannot be applied worldwide. As noted in paragraph 18 of the discussion paper, when CCFA agrees on the other criteria in Section 3.2 but cannot agree on whether the use of an additive would provide an advantage or does not mislead the consumer, reservations can be noted in the Committee report in the year the provision is adopted. It should be noted Option 3 continues to allow for the Committee to continue to consider the terms "advantage" and "does not mislead the consumer" when reviewing GSFA provisions.

In summary, IFAC supports Option 3 as the best available option for addressing Recommendation 2 and facilitating a solution for Note 161. We look forward to positive progress on this and other Recommendations and support activities that result in more efficient and effective Committee.

International Fruit and Vegetable Juice Association (IFU)

Recommendation 1

IFU: Agree with the proposal.

Recommendation 2

IFU: Whilst we do not have a specific issue with the colours and sweeteners provisions we foresee that adopting any of these 3 options would establish a precedent in CCFA that could be applied to other matters under consideration, therefore we will provide an opinion. For fruit juices and nectars IFU believes it is in the consumer's best interest to maintain the purity, quality and authenticity of the product category as defined in the Codex general standard for fruit juices and nectars (CXS 247/2005). It is important that consumers should be able to trust the product names of juices and nectars without worrying about the need to check the ingredient list for the presence of unnecessary additives. We therefore prefer to retain the term "does not mislead the consumer" in the preamble, if it helps to develop a definition then we can support option 1. We do not support option 2 as we wish to ensure the consumer is not misled. We do not support option 3 for juices and nectars as it would not provide a uniform approach with the Codex commodity standard.

Recommendation 3

IFU: We can support all 3 options. IFU is prepared and willing to assist codex committees on all matters relating to fruit and vegetable juices and nectars. We believe it should be the responsibility of the commodity committee to consider additives for their commodity standards.

International Organization of the Flavor Industry (IOFI)

1. Particularly, regarding the sections III. International Numbering System and IV. JECFA Evaluation and Re-evaluation of Food Additives, IOFI wishes to reiterate the fact that flavouring substances are not included in the General Standard on Food Additives (GSFA), as they are covered by the Guidelines for the Use of Flavourings (CXG 66-2008). Moreover, flavourings do not have INS numbers, which is a requirement for inclusion of food additives in the GSFA. Instead, flavouring substances do have a JECFA number, as stated in the Background section of CXG 36-1989 – Class Names and the International Numbering System (INS) for Food Additives: "*The INS does not include flavourings, which have a JECFA number as identifier, [..]".*

2. Recommendation 4 under section III. International Numbering System (INS) of CX/FA/50/13 Rev.1 contains considerations for adding text to the Background section of the CXG 36-1989, likely resulting in additional clarification regarding the relationship between the INS and the GSFA. IOFI suggests borrowing the opportunity to add a reference to the Guidelines for the Use of Flavourings to the Background section, as well (proposed addition in bold): *"The INS does not include flavourings, which have a JECFA number as identifier* ***and are covered by the Guidelines for the Use of Flavourings (CXG 66-2008),*** *[..]"*

3. Regarding section IV. JECFA Evaluation and Re-evaluation of Food Additives -Requests for substances that are not to be included in the GSFA, IOFI wishes to make the following observations:

The current approach for prioritizing flavourings is based on scheduling flavouring evaluations at JECFA every other year. This process was primarily intended to obtain efficiency gains in the evaluations by concentrating groups of flavourings into a single JECFA meeting, instead of two consecutive meetings. However, this means flavourings are already "(de-)prioritized" versus evaluations of food additives, somehow conforming with Option 1 of recommendation 7 in section IV.

In this context, IOFI trusts that the current approach for the evaluation of flavourings can "*at least*" be maintained in view of the need to complete evaluations of flavouring substances that are in the global trade. There is an estimated backlog of 200 + flavouring substances in global use that have not yet been evaluated by JECFA, including a stated need for re-evaluations by JECFA of previously evaluated flavourings to maintain the existing JECFA flavouring safety evaluations up-to-date.

4. Considering the recent developments throughout the world of flavouring regulations that are increasingly referring to the JECFA evaluations, it is critical that JECFA continues to have the highest consideration for the assessment of flavouring substances. Therefore, IOFI hopes that any further prioritization effort shall not lead towards excluding, from a JECFA evaluation, substances that are not included in the GSFA.

International Sweeteners Association (ISA)

The International Sweeteners Association (ISA) particularly appreciates the inclusion of a discussion on Note 161, which is attached to many sweeteners provisions. As ISA has expressed to the CCFA in previous correspondence, the lack of consensus on the adoption of sweetener provisions due to Note 161 is having an impact on global trade in these ingredients.

Having read the section of the discussion paper on 'Provisions with Note 161', the ISA is generally supportive of the analysis of key issues. The ISA appreciates the clear identification of '*a fundamental difference in regional philosophies on how food additives should be used'* as the barrier to consensus. The ISA also appreciates the important reflection of the two key references of the Codex Procedural Manuel, which stipulate that CXSdards should only consider factors which can be accepted on a worldwide basis and that provisions of the GSFA must meet the criteria of Section 3.2 of the Preamble. On this basis the ISA would agree with the assertion that any approach to address the barrier to consensus should be tackled through a revision of the Section 3.2 of the Preamble.

Having considered the three options presented in Recommendation 2 to revise Section 3.2 of the Preamble, the ISA would support Option 3, "*Acknowledge, in a manner that removes the barrier to consensus, that" advantage" and "does not mislead the consumer" are often regionally dependant*.

We believe that Option 3 would allow the Committee to address the root of the issue by recognising that these terms may be interpreted in different ways by different countries/regions, which may result in a Codex Member expressing a reservation in this regard, but this remains a regional interpretation without creating barriers to consensus on the adoption of a standard at an international level.

International Special Dietary Foods Industries (ISDI)

Recommendation 3

ISDI supports either Option 1 or 2. As described by the chairs, commodity committees (such as CCNFSDU) often do not have the expertise with additives to appropriately manage the alignment activity. Therefore, we encourage CCFA to maintain responsibility for this activity through Option 1 or 2.

Recommendation 6

ISDI supports the need to establish a priority-setting system. ISDI strongly agrees that consumer protection is the highest priority for JECFA evaluation and therefore, fully supports (1) Re-evaluation of an additive, based on an identified safety concern, as the highest ranking priority.

In considering the intended meaning of (1), ISDI considers it essential to distinguish between identified safety concern, and potential safety concern. ISDI supports strong focus on any additive with an identified safety concern which is supported by safety data from interventional or observational studies, as well as other relevant safety information. We consider that potential safety concerns such as "gaps" in knowledge, dated evaluations, potential long term effects, or population-specific evaluations are *excluded* from identified safety concerns.

For consideration of the Committee, ISDI suggests that for any identified safety concerns, a summary of newly available data and implications of all available data be provided in order to assist the priority-ranking of requests.

Recommendation 8

ISDI supports the formation of an eWG to address revisions to Annex 2 of the CL Requests for information and comments on the priority list of substances proposed for evaluation by JECFA, and would welcome participation in such eWG.

Recommendation 9

ISDI strongly supports that establishing a process for re-evaluation of additives currently in the GSFA could be a future consideration of the Committee. Given Recommendation 6 which endorses highest priority re-evaluation of an additive based on any identified safety concern, judicious risk assessment is assured.

To facilitate coordination between Codex Committees, ISDI believes it is important for the outcome of this discussion to be shared with relevant Commodity Committees to ensure similar prioritization of work. For example, CCNFSDU is currently discussing the potential for a re-evaluation of infant formula additives (REP18/NFSDU, para 143). Since the JECFA priority list is managed by CCFA, it is important for CCFA to align their recommendations for a process for re-evaluation with other Committees (such as CCNFSDU). Failure to align these processes could result in recommendations being made by Commodity Committees to CCFA that do not align with the CCFA priorities and thus result in inefficient communications between these Committees.

Recommendation 10

ISDI agrees with the chairs that the completion of the GSFA should take priority over a review of processing aids. ISDI supports the guidance approach (Option 2) to addressing this issue in the future.

Recommendation 11

ISDI supports the proposal of the chairs to facilitate discussion on CCFA priorities. As with the previous recommendations, ISDI believes that definition of criteria for determining whether an additive poses and identified risk (as opposed to a potential risk) is critical for these discussions.

Natural Food Colours Association (NATCOL)

Recommendation 2

As follows 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 how these types of additives should be used.

From this perspective, NATCOL supports Option 3 acknowledging the fact that the concepts of "advantage" and "does not mislead the consumer" are often regionally dependent. We indeed believe that this option would stand better chances to be agreed by Codex members and therefore unlock the current situation for many natural colours that have been already assessed by JECFA but have not been approved for inclusion in the GSFA.

Due to the global trend to use natural source colours, we wish to emphasize that the necessary work to resolve the issues surrounding Note 161, should not hinder the Committee to advance the provisions for food colours with high priority, leaving out any food category for which Note 161 may presently still be relevant.

The lack of the CCFA approval hinders the international trade artificially restricting the use of generally-recognised-as-safe additives in certain regions and countries and is eroding the authority of the GSFA. This inconsistency causes a lack of global harmonization, erects trade barriers as well as forces the industry to reformulate products at extract cost and time.

We think that those natural colours that are not subject to the discussions concerning Note 161 should be considered a high priority within the work of the GSFA and included within the normal workload at the earliest opportunity. We are supportive of a procedure whereby members or observers can initiate circulation for comments for critical provisions held in the step process would allow progress on this topic.

NATCOL believes that as the GSFA is considered as the single authoritative reference point for all additives at Codex, its work should give a higher priority on proposals based on identified global markets whilst giving a lower priority to any other items.

Recommendation 6

NATCOL supports the prioritisation of re-evaluation of additives based on an identified safety concern, however does not support a low priority for the evaluations of changes to specifications. Compliance to the JECFA specification is critical for international trade and can affect products currently traded internationally therefore it is important that proposed changes can be reviewed quickly, especially if they result from inappropriate methods or parameters in the original specifications. As this work may not absorb as much JECFA time, we would instead propose that requests for new additives be given equal priority as requests for changes to the specifications of an additive already in the GSFA and that they be considered on a case by case basis.