CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda Item 8

CX/FA 18/50/13 Add. 2 March 2018 Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

DISCUSSION PAPER ON "FUTURE STRATEGIES FOR CCFA"

Additional replies to CL 2017/92-FA of Brazil, European Union(EU), New Zealand, Nicaragua, Sudan, Enzyme Technical Association (ETA) and Food Industry Asia (FIA)

Brazil

Recommendation 1: Brazil agrees.

Recommendation 2: Brazil believes that no opinion is adequate.

Recommendation 3:

- Option 1 Brazil does not agree, because understands that the attribution of the alignment work is
 primordially from CCFA. Industry can assist in this work through their representative associations or
 through Working Groups.
- Option 2 Brazil agrees.
- Option 3 Brazil agrees. However, as previously reported, Brazil understands that the responsibility for the alignment work should be centralized in CCFA, considering the complexity of this work.

Recommendation 4: Brazil agrees.

Recommendation 5: Brazil agrees.

Recommendation 6: Brazil agrees.

Recommendation 7: Brazil has no comments.

Recommendation 8: Brazil agrees.

Recommendation 9: Brazil agrees.

Recommendation 10: Brazil agrees.

Recommendation 11: Brazil agrees.

European Union (EU)

General comments

The EUMS support the launch of this Discussion Paper encompassing the strategic reflections on the work of the Codex Committee on Food Additives (CCFA) with a view to developing a "one CCFA approach". With this aim in mind, this Discussion Paper, as a first document has a high level of ambition and captures all of the activities of the CCFA. The paper also presents the various challenges and barriers hindering the advancement of CCFA's work which are associated with significantly different level of complexities. It is therefore noted that the role of the Discussion Paper is to outline a strategy for the work of CCFA and not to provide solutions, as further steps will be needed to define subsequent works¹. The EUMS are thus looking forward to the upcoming 50th meeting of CCFA which will facilitate the opportunity for further discussions on the next steps to be taken for each of the areas outlined in the document. This will enable a comprehensive, inclusive and transparent analysis of each of the areas concerned and will enable CCFA to investigate possible ways to address the various challenges faced by the Committee.

¹ REP 17/FA, para. 140

In order to make substantial progress on these challenges, most of which have been long-standing issues, the processes associated with each issue should be framed in a well-defined way thus enabling the complexity of the issues to be addressed in an appropriate manner. It may also be necessary to define priorities within the areas under consideration. The comments provided hereunder have been prepared to contribute to this objective.

I. General Standard for Food Additives (GFSA)

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

The EUMS wish to recall their comments provided previously within the framework of the pre-consultation on this topic:

1. The EU notes the request for more guidance on how to state technological justification when completing the template for new proposals (see REP17/FA para. 135 (iii)). In order to better use the Committee resources (not to waste time on provisions for which no adequate information was provided) would it not be appropriate to develop guidance also for other entries of the template for new provisions (e.g. what appropriate information should be provided on exposure assessment, misleading the consumer etc.)?

2. How can it be ensured that the GSFA provisions remain updated once the work on the standard has been completed - taking into account e.g. developments in food additive uses, evolution of risk assessment approaches and changes in consumptions patters that might have implications on exposure? Is there a need to put in place specific mechanisms for this purpose?

The EUMS are of the opinion that these questions, which are related to key aspects of safety assessment and risk management should be taken into account while considering a possible revision of the current process for the adoption of provisions in the GSFA. It is noted that the need to obtain sufficient information on the justification of use is also identified in this Discussion Paper in the context of the information that is needed to support requests for inclusion on the Priority List².

The EUMS note that the analysis of the key issues provided in the Discussion Paper does not identify a problem of procedure *per se*. The EUMS are of the view that the agenda of the EWG and the PWG on the GSFA should be determined by the CCFA. This is a key element to ensure proper management of CCFA's work and will enable priorities to be set if required. During the discussions on the agenda of the EWG, sufficient time should be foreseen to enable exchange of views and reach consensus on the work that should made on historical provisions and on the work that should be devoted to new provisions.

The EUMS also note that the procedure described in para. 6 does not include a consultation of the appropriate Codex commodity committee for opinion on technological need which should be done, where relevant, according to the applicable procedure described in the Procedural Manual (see 25th Edition of the Procedural Manual, p. 70).

Colour and Sweeteners Provisions/Provisions with Note 161

The EUMS wish to recall its comments provided in the framework of the pre-consultation on this topic:

<u>Sweeteners</u>

3. Is the outcome of the EWG on sweeteners prepared for CCFA47 a good basis to resume the work on these substances or should the work resume on another basis? If the work would resume on another basis, what would be the key elements to consider?

<u>Colours</u>

4. What are the key elements to consider for resuming CCFA work on colours? Are there grounds to divide colours into different categories that would lead to different discussions? For example, are there different risk management approaches for natural and synthetic colours considering that no such concept as "natural" is recognised for the substances to be included in the GSFA?

Analysis of key issues

The EUMS recognise the complexity of this topic and are of the view that a transparent and inclusive process should be put in place to proceed with a thorough analysis of the key issues associated with this topic. This will enable the consideration of possible options to facilitate the process of adoption of provisions for colours and sweeteners in the GSFA in a timely manner. In order to achieve this objective, there may be merits in identifying sub-topics that could be addressed either independently or in a phased manner.

² CX/FA 18/50/13 para. 47.

With respect to the analysis of the key issues, the EUMS would like to highlight that the adoption of note 161 had enabled the Committee to reach consensus on the adoption of a significant number of provisions for colours and sweeteners which would otherwise not have been included in the GSFA. As such, the note has thus contributed to the inclusion of GSFA provisions while acknowledging that, due to lack of consensus on risk management aspects, these provisions are subject to restrictions in line with national legislation conforming to the Preamble of the GSFA. It is noteworthy that references on the role of national legislation or national authorities are not unique to the GSFA and are also included, for example, in several standards developed by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) or the Codex Committee on Processed Fruits and Vegetables (CCPFV). It is acknowledged that the use of note 161 did cease to contribute to the consensus building for the inclusion of new provisions on colours and sweeteners in the GSFA. An alternative approach which would enable the adoption of provisions by consensus should be developed.

With a view to pursuing discussions on this topic, the EUMS note that the Preamble is an integral and critical part of the GSFA and that it is under the auspices of this Preamble that all the provisions have been adopted. Any possible modification to the Preamble would thus need a thorough analysis in terms of its impact on the value of the GSFA as such and on any potential impact this may have on existing provisions.

Exploring alternatives to the use of note 161

Detailed exchanges on the rationale underlying the use of note 161 would provide the grounds by which alternatives to this note could be explored.

The rationales for using note 161 might be different for sweeteners versus colours. The Discussion paper links Note 161 with "advantage" and "misleading" only. It is however acknowledged that the use of note 161 is associated with a range of risk management considerations related to Section 3.2 of the Preamble including "technological function" and "health risk to consumers". In addition, the risk management considerations also encompass policies on nutrition or potential risks of fraud.

It is also noted that the criteria of "advantage" and "not misleading the consumer" are used for other technological functions without drastically preventing the adoption of provisions by consensus. Discussions on alternatives to this note would thus be facilitated if the specificities of the risk management criteria associated with sweeteners and colours are specifically considered.

Regarding sweeteners the EUMS consider that their use is in line with Section 3.2 of the GSFA Preamble, if it is for one of the following purposes:

- (a) replacing sugars for the production of energy-reduced food, non-cariogenic food or food with no added sugars; or
- (b) replacing sugars where this permits an increase in the shelf-life of the food; or
- (c) producing food intended for particular nutritional uses.

More generally in the EUMS' view the decisions on the appropriate use of sweeteners are an integral part of the measures that may be taken to promote healthy diets. The GSFA as an international standard and the development of national policies should thus be mutually supportive and contribute to the WHO Global Strategy on Diet, Physical activity and Health³.

Regarding food colours the EUMS consider that their use is in line with Section 3.2 of the GSFA Preamble if it is for one of the following purposes:

- (a) to restore the original appearance of food of which the colour has been affected by processing, storage, packaging and distribution; or
- (b) to make food more visually appealing; or
- (c) to give colour to food otherwise colourless.

Furthermore, the use of food colours must always comply with the general condition that they do not mislead the consumer. For example, the use of colours should not give the impression that it contains ingredients that have never been added.

³ This strategy was endorsed by the Resolution WHA57.17

The EUMS are of the view that further discussions should consider how these aspects related to sweeteners and food colours could be reflected in the process of adoption of GSFA provisions and/or in the GSFA, including through appropriate footnote(s). It is noted that extensive exchange of views on this matter did already take place in preparation for the 46th and 47th sessions of the CCFA and that this work provides valuable information to consider for any future discussions on sweeteners⁴.

Resuming the examination of the GSFA provisions on sweeteners and colours: consideration of pending provisions

The EUMS are of the view that, in addition to the work that could be pursued in the future on alternatives to note 161, it would be worthwhile considering whether progress on provisions in the step process could be subject to consensus. In this respect, the report of the eWG led by UK on the application of alternative notes to provisions for sweeteners to replace note 161⁵ includes proposals to replace note 161 with other specific notes that are used in the GSFA that could be relevant.

Conclusion

The EUMS are of the opinion that an inclusive and transparent process should be put in place to carry out an analysis of the key issues including the different rationales underlying the use of note 161, explore alternatives to note 161, and consider the examination of provisions for sweeteners and colours.

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

The EUMS support reflections aimed at resource-efficient procedures for the alignment of the GSFA and corresponding commodity standards provided that the quality of the work is maintained.

The EUMS agree with the analysis provided in the Discussion Paper and identify option 3 as the most realistic option provided in recommendation 3 since the expertise of the Commodity Committees on the technological use is essential in the alignment process. The other options might be further considered on a case-by-case basis provided that adequate conditions are met. The more active involvement of other countries as either "normal" members of the WG or additional vice-chairs should be explored provided that countries do volunteer. The possible contribution of industry associations should only be considered if their contribution is provided in agreement with their status of observer and thus with the appropriate involvement of Codex members.

III. International Numbering System (INS)

The EUMS look forward to further discussing these recommendations during the meeting of the Committee.

IV. JECFA evaluation and re-evaluation of food additives

Prioritization of requests to JECFA - Requests for substances that are not included in the GSFA

The EUMS wish to recall its comments provided in the framework of the pre-consultation on this topic:

5. The use of enzymes as processing aids is on increase and more Codex members take measures on their use. This may increasingly result in food trade issues. How can CCFA address these developments to ensure both the protection of public health and fair trade practices?

The EUMS are of the view that recommendation 6 and the underlying analysis of key issues and considerations are a good starting basis for the prioritisation of requests to JECFA. Re-evaluations of additives based on an identified safety concern should in particular always be treated with the highest priority.

Further discussions should aim at a further clarification of the proposal and a refinement of the proposal with the view to put in place mechanisms allowing a transparent, predictable and global management of all the requests submitted to JECFA. It should in particular be clarified how the work on requests that would fall under lower priority categories would be considered in order to ensure that these requests are also addressed within an appropriate time period. For example, the trade impact due to a possible modification of the specifications should not be underestimated and should be duly taken into consideration. The increasing needs and concerns of developing countries should also be taken into account. These mechanisms should enable the Committee to establish priorities while providing the necessary flexibility to JECFA to organise its work.

⁴See CX/FA 14/46/14 and CX15/47/13

⁵ CX15/47/13

Information supporting requests for inclusion on the Priority List

In line with the comments submitted during the pre-consultation (see above the comment recalled under the point "Principles and Procedures for Reviewing the Provisions Currently in the Step Process"), the EUMS agree that further steps should be taken in order to ensure that more detailed information is included in the requests for inclusion of a substance on the Priority List. The EUMS are thus in favour of developing further guidance regarding the submission of information on the technological use but also for other aspects such as exposure assessment and misleading the consumer. This information is relevant for both the CCFA and JECFA. Ensuring that only eligible requests accompanied by all the necessary information is entered into the priority list is an action that has the potential to significantly increase the efficiency of the work of CCFA and JECFA.

Maintenance re-evaluations of additives in GSFA

Appropriate mechanisms should be put in place to ensure that the GSFA remains updated. As outlined in Section IV and recommendation 6 of the Discussion Paper, re-evaluations of food additives should be treated with the highest priority if a safety concern is identified.

V. Processing Aids

As indicated under Section IV, the handling of pending requests relating to enzymes, including processing aids, should receive due attention of CCFA and JECFA.

The EUMS agree that further work in this area such as a revision of the existing guidelines should only be considered on the basis of a proposal to revise a standard and in accordance with the normal Codex procedures.

The Inventory of Substances Used in Processing Aids (IPA) is not a Codex tool. Its update and maintenance are thus independent from the activities of the Committee and do not need to be considered in the framework of the management of CCFA work.

VI. Prioritisation of CCFA future work

The EUMS are in favour of having further reflections on the prioritisation of CCFA work. Such reflections should take place in accordance with the existing Codex rules of procedures and in particular the procedures for the elaboration of Codex Standards and related texts. With respect to the development or the revision of guidelines, it should in particular be considered whether the criteria already included in the critical review to undertake new work or to revise a standard are sufficient. For example, the availability of the resources to undertake a given topic depends on the commitments of the Codex members and should thus be evaluated on a case by-case basis.

The opportunity for the CCFA to proceed with a revision of the procedures for the maintenance of the GFSA or the INS as foreseen in the Codex rules of procedures will depend on the evolution of the discussion on these two topics that are covered in previous sections of the Discussion Paper.

New Zealand

I. General Standard for Food Additives (GSFA)

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

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

New Zealand supports

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

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

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

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

As the discussion paper notes, there are fundamental differences in regional philosophies as to how some additives should be used. Paragraph 18 of the agenda paper CX/FA 18/50/13 Rev.1 presents a suggested text.

New Zealand supports Option 3 as a starting point.

While the ultimate aim of the GSFA and alignment is not to have differences, we agree that it may be necessary on a case by case basis to concede that there may be two or more positions that cannot be resolved. One solution then is to respect the different positions and acknowledge them in the GSFA.

New Zealand does not support options 1 and 2 for the following reasons:

Option 1 - In our view the ordinary meaning of the words "advantage" and "does not mislead the consumer" are sufficiently clear and therefore do not require further definition in the Preamble.

Option 2 – These terms are cornerstones of the GSFA and should be retained. The terms impact on the permissions for all additives.

The 'advantage' of an additive use is often very subjective (for example, the importance of colour in soft drinks). Added colours in other foods (such as spices, fruit juice or wine), which are good examples where added colour has the likelihood to mislead consumers. We note that the use of colour is usually required to be declared in ingredient lists, so consumers will be informed of use. In addition, other requirements must be met, including that the quantity of an additive added to food is the lowest level needed to achieve the intended technical effect, and when added for an organoleptic property, the use of the additive does not change the nature, substance or quality of the food so as to deceive the consumer.

Colour and Sweetener Provisions/Provisions with Note 161

The need for a note such as Note 161 may be strongest for colours as the technological justification for colour is very subjective. Some may argue that added colour has little value other than for appearances. The sweetener issue centres on the deep running views of whether or not the use of intense sweeteners must be linked to a significant reduction in energy.

Thinking of the Note 161 issue more broadly than colours and sweeteners, it may be helpful to consider the simple case where a high level and a low level are proposed for an additive entry to the GSFA. It will be of value to consider the four possible scenarios that can occur when two countries trade foods containing the additive. These are: both countries permit the high level, both permit the low level, one permits the high level and the other the low level and vice versa. Only one of the four scenarios raises a trading issue, where the importing country permits the lower level and the exporting country the higher level. It is likely that the lower level is technologically justified for local production in the importing country, just as the higher level is technologically justified in the exporting country. The big question is whether the importing country is willing to accept imported products with the higher level of the additive. It will be helpful to consider the rationale and justification where imported foods with the higher level are not acceptable.

Examples of where regional differences in additives use might arise where:

- Differences due to different agricultural practices in the growing of the crop or food, meaning different levels of additives are used in the production of the food (e.g. food acids in wine)
- Differences due to the dietary exposure of additives with an ADI, such that a country needs to limit exposure to a particular additive (e.g. a country might have a particularly high exposure to an additive with a low ADI, due to dietary use patterns)
- Differences in philosophies regarding the use of food additives, for other reasons.

Where the CCFA accepts a region difference is justified, it may be possible for the GSFA to recognise regional levels and clarify whether such levels apply to regional production only, and whether higher levels are acceptable as imports into the region, and recognising the technological justification in the exporting country region.

A comparable situation exists in New Zealand for maximum residue levels (MRLs) of agricultural compounds and veterinary medicines. Under current law, New Zealand allows the importation of foods that comply with Codex MRLs even if these are higher than levels applied in New Zealand. Local foods must comply with the New Zealand MRL standard. This recognises different agriculture practices and the need to control pests and health in different regions.

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

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

Option 1 - Utilize preparatory work undertaken by industry associations;

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

Option 3 - Partnership approach between CCFA and Commodity Committees.

New Zealand supports the use of all options on a case by case basis, in order to expedite the alignment work using the most efficient processes and resources.

III. INS

Recommendation 4: regarding the additional wording or are not included in the General Standard for Food Additives

New Zealand supports this recommendation.

Recommendation 5 regarding the additional wording i.e. INS entries cannot be removed unless entries in GSFA are removed.

New Zealand supports this recommendation. We comment however that the INS working group could still collate and maintain a list of proposals for deletion of entries, so that the CCFA has a list of additives that need consideration for deletion from the GSFA (on the basis of INS numbering).

IV. JECFA Evaluation and Re-evaluation of Food Additives

Prioritization of requests to JECFA

Recommendation 6 regarding the priority ranking system for JECFA evaluation.

New Zealand supports consideration by the CCFA of a ranking system, and considers that the order proposed is a good starting point for the discussion. Another factor for consideration is the type of food the additive will be used in. For example, additives intended for use by vulnerable populations (such as infants), could be considered to take higher priority. This is particularly important for additives already permitted, that do not have a current safety assessment (refer to the list compiled by JECFA, in CRD15 Rev 1, provided at CCFA49). Some consideration should also be given to assessing whether a new substance is more appropriately classified as something other than a food additive or processing and hence outside the scope of CCFA. This would include situations where a substance is a food, novel food, or therapeutic product.

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

Recommendation 7: regarding the requests for substances that are not to be included in the GSFA.

Option 1 could mean that substances on this list are never assigned priority, and remain on a list outside of the JECFA priority setting process.

Option 2 proposes that "Food additives that are not intended for inclusion in the GSFA should be assigned a priority ranking in tandem with other additives". New Zealand supports this option which is more pragmatic and allows for case by case consideration. It also allows for these substances to be accorded a priority if they meet the criteria. This is important, as while these additives (such as processing aids and flavourings) are not in the GSFA, they are still within the scope of the work of the CCFA.

Information supporting requests for inclusion on the Priority List

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

New Zealand supports the formation of an electronic WG to consider the increased demand for JECFA resource, considering both options 1 and 2.

Maintenance re-evaluations of additives in the GSFA

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

New Zealand agrees with this approach, and that it should be a future priority after the work of the GSFA and alignment is completed.

V. Processing Aids

New Zealand comments that the proposed recommendations do not adequately capture the discussion points raised in paragraphs 58 - 61, and suggests the following amendments (shown in **bold** text):

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

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

Option 2 - As a future priority not to be completed at this time, review/amend the *Guidelines on Substances* used as Processing Aids (CAC/GL 75-2010) and consider the need for a horizontal standard on processing aids. This more clearly reflects the view of CCFA and the progression from the Database to a future Codex standard.

VI. Prioritisation of CCFA Future work

Recommendation 11 - New Zealand agrees that these questions/criterion should be discussed by CCFA.

Nicaragua

(i) Comentarios generales

Nicaragua agradece la elaboración del documento y por brindarnos la oportunidad de presentar observaciones.

(ii) Comentarios específicos

Recomendación 1: que el Comité utilice un nuevo procedimiento por el cual las disposiciones insertadas en el Trámite 2 del procedimiento de trámites sean distribuidas automáticamente para formular observaciones en el Trámite 3 por el posterior GTE sobre la NGAA.

Nicaragua está de acuerdo con simplificar los procedimientos de revisión para facilitar la aprobación de disposiciones, siempre y cuando no se comprometa el criterio científico de éstas.

Recomendación 2: que el Comité someta a consideración las siguientes opciones de revisar la Sección 3.2 del Preámbulo de la NGAA para facilitar el consenso sobre disposiciones de colorantes y edulcorantes:

Opción 1: Definir "ventaja" y "no engaña al consumidor";

Opción 2: Eliminar "ventaja" y "no engaña al consumidor";

Opción 3: Reconocer, de forma que se elimine la barrera para el consenso, que "ventaja" y "no engaña al consumidor" dependen a menudo de la región.

Nicaragua considera que es necesario con información más detallada sobre esta recomendación, para realizar el análisis correspondiente.

Recomendación 3: que el Comité someta a consideración las siguientes opciones para acelerar la armonización de la NGAA y las normas sobre productos correspondientes. Las opciones no se excluyen entre sí y podrían utilizarse algunas o todas si el Comité lo estima conveniente: CX/FA 18/50/13 Rev.1 7

Opción 1: Utilizar los trabajos preparatorios realizados por las asociaciones sectoriales;

Opción 2: Implicar a otro país como Copresidente adicional del GT sobre la armonización;

Opción 3: Establecer un modelo de colaboración entre el CCFA y los comités de productos

Nicaragua apoya las opciones 2 y 3 que se proponen, para efectos de facilitar y agilizar el trabajo es conveniente involucrar un mayor número de países en la presidencia, a su vez se considera pertinente coordinar dichos trabajos con los comités de productos específicos, para evitar contradicciones de criterios entre una norma y otra.

Recomendación 4: que el Comité someta a consideración la adición del siguiente texto en negrita a la Sección Información general del SIN a fin de aclarar la relación entre el SIN y la NGAA:

La intención del sistema internacional de numeración de aditivos alimentarios (SIN) es que sea un sistema de denominación armonizado para aditivos alimentarios como alternativa al uso del nombre específico. La incorporación en el SIN no implica la aprobación por el Codex del uso como aditivo alimentario. La lista puede incluir los aditivos que no han sido evaluados por el Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA) o no están incluidos en la Norma general para los aditivos alimentarios (CXS 192-1995).

Nicaragua apoya la redacción de la recomendación.

Recomendación 5: que el Comité someta a consideración la adición del siguiente texto en negrita al anexo 1 y anexo 2 de la circular "Solicitud de informaciones y observaciones para cambios/adiciones en la sección 3 de Nombres genéricos y Sistema internacional de numeración para aditivos alimentarios (CXG 36-1989)":

Anexo 1, punto 5 "Eliminación de un aditivo de la Lista del SIN":

Las propuestas de eliminación de entradas del SIN no pueden presentarse a esta carta circular si hay disposiciones vigentes (adoptadas o en el procedimiento de trámites) sobre el aditivo en la Norma general para los aditivos alimentarios (CXS 192-1995). El Comité del Codex sobre Aditivos Alimentarios debe eliminar primero esas disposiciones de la NGAA antes de presentar propuestas de eliminación de una entrada correspondiente en el SIN.

Las propuestas de eliminación de entradas del SIN deben acompañarse de una justificación adecuada.

Anexo 2, "Justificación del cambio al SIN solicitado en la Sección 3: eliminación de un aditivo"

(Por favor, elegir solamente la opción adecuada y proporcionar detalles en el espacio a continuación) Las propuestas de eliminación de entradas del SIN no pueden presentarse a esta carta circular si hay disposiciones vigentes (adoptadas o en el procedimiento de trámites) sobre el aditivo en la Norma general para los aditivos alimentarios (CXS 192-1995).

Nicaragua está de acuerdo con las opciones 1 y 2 de la recomendación.

Recomendación 6: que el Comité someta a consideración el siguiente sistema de clasificación que se utilizará para las solicitudes de inclusión en la Lista de prioridades para los aditivos destinados a incorporación en la NGAA, por orden de mayor (1) a menor prioridad (3):

- (1) la reevaluación de un aditivo, basada en una preocupación de inocuidad identificada;
- (2) la evaluación de un nuevo aditivo destinado a ser incluido en la NGAA;
- (3) la evaluación de un cambio en las especificaciones, incluyendo, pero sin limitarse a la adición de una sustancia, una nueva sustancia de base, una nueva forma química de una sustancia, un cambio en un método analítico, un cambio a un límite de tolerancia y una revisión de una propiedad fisicoquímica, como el punto de fusión.

Nicaragua está de acuerdo con la recomendación para priorización de evaluaciones y reevaluaciones, de esta forma se establecerá un trabajo más organizado y eficiente.

Recomendación 7: que el Comité someta a consideración las siguientes opciones para la gestión de las solicitudes de inclusión en la Lista de prioridades de aditivos alimentarios que no están destinados a ser insertados en la NGAA. Se anima a quienes contestan a que ofrezcan sugerencias prácticas para poner en práctica estas opciones, o que propongan nuevas opciones que sean prácticas y formen parte del mandato del Comité.

Opción 1: No asignar una clasificación de prioridad a los aditivos alimentarios no destinados a ser incluidos en la NGAA;

Opción 2: Asignar a los aditivos alimentarios que no se van a incluir en la NGAA una clasificación de prioridad junto con otros aditivos.

Nicaragua considera que la opción 1 de la recomendación es la más viable, ya que si el aditivo no será incluido no necesita ser priorizado.

Recomendación 8: que el Comité forme un grupo de trabajo electrónico para estudiar revisiones al anexo 2 de la carta circular Solicitud de información y observaciones sobre la lista de prioridades de sustancias propuestas para su evaluación por el JECFA para abordar las siguientes cuestiones:

Opción 1: Proporcionar orientación en el anexo 2 de la carta circular sobre el nivel de detalles necesarios para responder adecuadamente a las preguntas mencionadas;

Opción 2: Revisar las preguntas en el anexo 2 de la carta circular para abordar todos los criterios enumerados en el anexo 1 "Criterios para la inclusión de sustancias en la Lista de prioridades".

Nicaragua está de acuerdo con la opción 1 de la recomendación. Es más práctico indicar cómo se deben llenar y con qué información se deben completar los formularios, que realizar una revisión en un Gte.

Recomendación 9: que el Comité someta a consideración, como prioridad futura no a realizar en estos momentos, establecer un proceso global para reevaluar y apoyar de nuevo aditivos que actualmente están en la NGAA.

Nicaragua apoya la recomendación, sin embargo, se solicita que una vez que se revise este tema nuevamente, se proporcionen todos los detalles sobre la metodología para el análisis de dicha información.

Recomendación 10: que el Comité someta a consideración las siguientes opciones relacionadas:

Opción 1: Mantener la base de datos de coadyuvantes de elaboración como una referencia actualizada sobre el uso de coadyuvantes de elaboración;

Opción 2: Como una prioridad futura que no se llevará a cabo en estos momentos, revisar/modificar las Directrices para sustancias utilizadas como coadyuvantes de elaboración (CXG 75-2010)

Nicaragua apoya que se tomen en cuenta ambas opciones de esta recomendación.

Recomendación 11: que el Comité someta a consideración las preguntas/criterios que podrían utilizarse para facilitar un enfoque sistemático para dar prioridad a su trabajo.

Nicaragua está de acuerdo con esta propuesta y considera que es importante contar con una herramienta que facilite la priorización y selección de temas para el establecimiento de Grupos de trabajo electrónicos, concentrando esfuerzos y recursos en las temáticas priorizada.

Sudan

The GSFA should be the sole undertaker for reviewing the provisions currently in the step process.

The committee (CCFA) may accept a new process to work with comment of GSFA and EWG step 2 to proceed to step 3.

For colour and sweetener provision with note 161 in addition to difference in regional philosophies we recommended to discuss the risk health hazard of some allowed food colours which are banned by some countries and referred to by FSA and to be considered by CFSA.

For alignment of food additives provisions in commodities standards and GSFA it is recommended to adopt any of the options at the appropriate case.

Processing aids are intended to facilitate food processing and thus are not food additives. We agree to develop standards for processing aids.

We recommended to point out clear whether some food additives were omitted in the revised new product specification, so as to avoid confusion.

Enzyme Technical Association (ETA)

The Enzyme Technical Association ("ETA" or "Association") is a trade association that represents manufacturers and marketers of enzyme products in North, Central, and South America. It has been in existence since 1970 and maintains an active role in assisting in the development of regulations and policies that affect the enzyme industry. The ETA represents the majority of the enzyme product industry in the Americas.

The ETA appreciates the opportunity to comment on the Discussion Paper on "Future Strategies for CCFA" (Codex document CX/FA 18/50/13). In short, the ETA supports the positions of the Association of Manufacturers and Formulators of Enzyme Products⁶ ("AMFEP") as well as the EU Specialty Food Ingredients⁷ ("EU SPI") and share their strong support for option 2 under Recommendation 7.

The ETA believes it is important that the Joint FAO/WHO Expert Committee on Food Additives ("JECFA") timely reviews enzymes so as to not create unnecessary regulatory and trade barriers for the use of enzymes in food production. To this end, JECFA evaluations are important for enzymes because they represent international evaluations, facilitating their acceptance by national authorities that do not make their own evaluations.

Additionally, the ETA also supports the positions of the AMFEP and EU SPI on Recommendation 10, that both options 1 and 2 are preferred. There is enormous value in maintaining the Processing Aids Database given its use as an important point of reference by national authorities around the world.

FOOD INDUSTRY ASIA (FIA)

GENERAL COMMENTS

⁶ Comment Letter dated February 15, 2018.

⁷ Comment Letter dated February 14, 2018.

FIA welcomes the move of putting up a discussion paper on "Future Strategies for CCFA" as it provides essential analysis and recommendations to tackle current issues and provides a more inclusive and harmonised framework towards achieving a "one CCFA approach".

FIA supports the move to prioritise GSFA (**Recommendations 1 & 2**) as the highest priority. We believe that this move will help to better manage work of the CCFA in a bid to complete its work on the remaining historical provisions for which no 'outstanding issues' have been identified, and to make GSFA the sole authoritative reference point for food additives globally by its 52nd session in 2020 (**Recommendation 1**). More importantly, FIA strongly encourages the Committee to advance the historical issue of Provisions with Note 161 (**Recommendation 2**).

Aside from the Recommendations 1 and 2 under GSFA, FIA believes that in order for CCFA to attain alignment work with much progress, it is important to prioritise the consideration of all pending draft maximum permitted levels (MLs) being held in the Step Process, regardless of the nature of the substance considered. In this light, discussions on fundamental pending provisions included in Table 1 and 2 of the GSFA (see CCFA50 INF01 document)⁸ could be potentially removed and progress could be made for colour provisions stalled at step 4 or 7.

FIA encourages CCFA to resume its work on pending colour provisions as of the year 2018. 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 bodies. FIA 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 paper⁹. We noted that all pending provisions for colours in these food categories have been evaluated, and in some cases recently re-evaluated, by JECFA with no safety concern. Therefore, we recommend that CCFA50 could also consider such provisions on the 2018 terms of reference of the electronic working group (EWG) for GSFA under Agenda Item 5 of CCFA50.

Currently, there is a trend of an increasing number of countries proposing to implement only adopted additives in the GSFA. While it is applaudable that the GSFA is being acknowledged and implemented by more and more countries worldwide, the CCFA should look at ways to accelerate the important provisions of colours and sweeteners with or without Note 161 so that the trade barriers and inconveniences are reduced to a minimum. Therefore, FIA would highly support the CCFA to prioritise GSFA for harmonisation.

FIA comments to each of the recommendations are provided below.

General Standard for Food Additives

Recommendation 1:

FIA agrees with the use of a new process by which provisions entered into the Step Process at Step 2 will automatically be circulated for comments at Step 3 by the subsequent GSFA EWG in order to accelerate the Step process.

Recommendation 2:

FIA acknowledges that fundamental difference in regional philosophies that are associated with Note 161 played a major role in blocking consensus on the provision for use of food additives with technological functions including various colours and sweeteners which are held in the Step Process (i.e. Step 4 and Step 7).

As Note 161 entails adopted provisions of colours or sweeteners and draft provisions for food additives with these technological functions to meet Section 3.2 of the Preamble, FIA agrees that the ambiguity in the undefined terms "advantage" and "does not mislead the consumer" in the Preamble, as well as the fundamental difference in regional philosophies on how these types of additives should be used, are the root problems for not reaching consensus.

Looking at the three recommended options to improve the situation, FIA is of the view that Option 1 presents high possibility of a deadlock in consensus and greater resource constraints due to the different regional philosophies on consumers' expectations which could not be resolved based on past experience. As such, FIA does not support Option 1.

FIA does not support Option 2, either, as the principles of "advantage" and "does not mislead the consumer" are still important criteria to ensure the integrity of food businesses when using food additives. Removing these criteria from the Preamble could potentially pose significant risks to consumers and fair trade, in cases such as economic adulteration.

⁸ See <u>http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFA&session=50</u>

⁹ See in particular Para. 135, indents (ix), (x) and (xi) in REP17_FA, at <u>http://www.fao.org/fao-who-codexalimentarius/meetings/archives/en/?y=2017&mf=07</u>

FIA could support <u>Option 3</u>, which is amongst the most feasible method of resolving the long-term backlog of additives held in the Step Process due to differences in regional philosophies. Not only does having this process add greater clarity to the Preamble, it also provides a mechanism for registering of voices of opposing parties towards any factor as reservations without blocking consensus when provision meets all other factors in the Preamble. On the other hand, should there be predominant consensus by the Committee that a provision does not provide advantage or would mislead the consumer, the provision would not be adopted. All these factors embrace Codex principles of openness and transparency. Therefore, option 3 is preferred.

FIA would like to recommend that should the re-evaluation of adopted provisions with Note 161 be necessary upon the adoption of Option 3, it shall be carried out after pending provisions are first adopted. FIA would also recommend the CCFA to conclude discussion on pending provisions in Table 1 and 2 of the GSFA, especially for those not associated with Note 161.

FIA believes that CCFA shall also take into account pending provisions on colours and sweeteners not covered by Note 161. These include important colour provisions which are not associated with Note 161 nor covered by any commodity standard, but have been commonly used by the food industry and have been approved in many national legislations. Among the pending provisions, some of them do not have readily available replacement, causing technical challenges and affecting market access.

FIA therefore recommends that CCFA to place GSFA as the topmost priority because any delay in execution of the GSFA provisions would mean an ever more challenging situation where more countries that directly adopt GSFA at national level would face difficulties.

Alignment of Food Additive Provisions in Commodity Standards and GSFA

Recommendation 3:

FIA believes that Options 1, 2 and 3 are all viable in accelerating the alignment of work of CCFA.

Option 1 on utilising the preparatory work undertaken by the industry associations provide means of saving considerable time through contributing knowledge and up-to-date information in respective sectors.

Option 2 on involving another country as an additional co-Chair of the WG and assigning it specific commodity standards to develop alignment proposals would mean there is an additional resource to speed up the alignment of food additive provisions in the commodity standards. FIA would suggest that during assignment of specific commodity standards to the country, consideration could be taken into the type of commodity that a country has expertise and experience in, as this would mean the country could provide both its expertise and also knowledge about the commodity sector effectively. Nonetheless, countries of the WG can always work with Industry Associations from Option 1 to develop the alignment proposal more efficiently.

Option 3 on partnership approach between CCFA and Commodity Committees does hold valid possibility of accelerating the alignment process. FIA believes that if the relevant Commodity Committees could come forward to partner on alignment for provisions in the commodity that they are related to, the alignment process could be greatly accelerated.

Therefore, FIA supports the utilisation of all three options.

On top of the above recommendations, FIA recommends the CCFA to consider communicating further the mechanism or process for the adoption of any new food additive for use in a commoditized food when a commodity committee has adjourned. FIA noted that at present, the EWG on Alignment provides recommendations to CCFA for the alignment of food additive provisions in the commodity standards of adjourned Commodity committees. However, FIA believes that CCFA could provide more insights into the process of adoption of new food additive provisions of adjourned Commodity committees. In addition, we support that adjourned commodity committees should not be re-activated for the purpose of alignment. Industry groups from some adjourned commodity committees that have technical expertise in relevant products (e.g. IDF for CCMMP products) could provide technical support as per option 1.

International Numbering System (INS)

Recommendation 4:

FIA agrees with the refinement of the Background section of the INS for clarity through the addition of addition sentence "or are not included in the General Standard for Food Additives (CODEX STAN 192-1995)". We believe that stating out clearly would help provide more clarity and avoid confusion or ambiguity.

Recommendation 5:

FIA supports the inclusion of additional texts in Annex 1 and Annex 2 with regard to the deletion of INS entries. These texts would provide applicants who wish to request for deletion of an additive from the INS with a clear criterion and help avoid incidences where INS for certain additives (especially those in the step process) are accidentally deleted and the manufacturers have to initiate a new round of application for the additive to be included in the GSFA again.

Prioritization of Requests to JECFA

Recommendation 6:

FIA agrees with the ranking order recommended for the three evaluation issues. It shall be noted that an identified safety concern is perceived as a result of new credible findings or data showing that the intake of certain approved additives would present some form of safety concern to consumers. Therefore, this identified safety concern warrants the need to conduct a re-evaluation. The evaluation of a new additive intended to be included in the GSFA remains important. In addition, evaluation changes to specifications should be of the lowest priority among the three, but it should not be left out.

Recommendation 7:

FIA supports Option 1 that the food additives not intended for inclusion in the GSFA shall not be assigned a priority ranking if these additives are still continuously maintained in the working group documents and reports of the Physical Working Group (PWG) through a separate Priority List. This would then ensure that while much focus is placed on the acceleration of GSFA work, evaluation of food additives outside of GSFA such as processing aids and flavours is still progressing.

The current approach where industry (IOFI) has worked with JECFA to schedule evaluations of flavours is a successful practice that could be considered for processing aids. The FIA recommends that this similar approach shall continue to be kept in a separate part of the Priority List so that the importance of evaluating processing aids and other flavours are not ignored totally while CCFA prioritise the GSFA works.

Recommendation 8:

FIA supports that an EWG be formed to explore revisions based on both Options 1 and 2 in Recommendation 8 to Annex 2 of the Circular Letter.

Recommendation 9:

FIA supports that the Committee establish an overall process for re-evaluation of additives currently in the GSFA from time to time, but as a future priority.

Processing Aids

Recommendation 10:

FIA agrees that processing aids may not be a top priority for CCFA at the moment due to the pressing workload to populate the GSFA and the lack of resources. FIA supports consideration of both Options 1 and 2.

Prioritisation of CCFA Future Work

Recommendation 11:

For a start, FIA agrees that Prioritisation of CCFA future work is important. FIA supports that the Committee consider the questions/criteria that could be used to facilitate a systematic approach to the prioritisation of its work.