

# codex alimentarius commission E



FOOD AND AGRICULTURE  
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Agenda Item 5(e)

CX/FA 10/42/9  
November 2009

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Forty-second Session

Beijing, China, 15-19 March 2010

## DISCUSSION PAPER ON INNOVATIVE PROPOSALS TO EXPEDITE THE WORK ON THE GSFA

(Prepared by the Codex Secretariat)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the document are invited to do so **no later than 31 January 2010** as follows: Secretariat, Codex Committee on Food Additives, National Institute of Nutrition and Food Safety, China CDC, 7 Panjiayuan Nanli, Chaoyang District, Beijing 100021, China (Telefax: + 86 10 67711813, E-mail: [secretariat@ccfa.cc](mailto:secretariat@ccfa.cc) *preferably*), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39 06 5705 4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org) - *preferably*).

### BACKGROUND

1. The 41<sup>st</sup> CCFA, while noting the significant progress made on the GSFA during the session, agreed that it would be worthwhile considering an alternative working mechanism to complete the work on the GSFA in a reasonable period of time. The Committee therefore agreed to issue a Circular Letter, requesting comments and innovative proposals to expedite its work on the GSFA and to request the Codex Secretariat to prepare a consolidated document based on these proposals. The Committee noted that the proposals should be submitted by mid July 2009 so that the Codex Secretariat would be able to analyse them and circulate the document for comments well in advance of the next session, and that the document would contain all submissions in original languages as an attachment<sup>1</sup>.

2. Comments and proposals in response to CL 2009/7-FA Part C were submitted by Australia, China, Costa Rica, European Community, Japan, United States of America, IDF and IFAC (*see* Annex 1).

### ANALYSIS OF COMMENTS SUBMITTED

3. Members and observers fully support that the GSFA be the key priority work of the CCFA and, when completed, become the only authoritative reference for food additives in Codex. They note progress made since 1991 and the remaining considerable workload, i.e. more than 4 200 food additive provisions in Tables 1 and 2 of the GSFA.

4. Comments highlight that work on GSFA should: be clear and efficient to help deliver the outcomes in a timelier manner; be appropriate for clearing the backlog; accommodate the outcomes of JECFA evaluations; take account of the future integration of the food additive provisions from commodity standards; and allow for more active participation of members and observers.

5. Members and observers generally support the current approach to the work on the GSFA and, rather than proposing new alternative approaches, identify a number of areas for improvements to the current

<sup>1</sup> ALINORM 09/32/12, para. 108

working procedures at the level of the work of the Committee and the electronic and physical working groups.

6. There is a general support for approaches that allow the consideration of group of food additive provisions that can be considered together and for which agreed-upon principles can be consistently applied, such as the approach that the CCFA has used for the consideration of colours and sweeteners. This approach has shown to contribute to make the CCFA work on the GSFA more efficient and has minimised the number of food additive provisions that would be considered individually.

7. Countries also consider that CCFA should dedicate more time to the discussion on the GSFA and discussion on other items, such as endorsements of food additive provisions in commodity standards, should be reduced. For this purpose, it is recommended to request commodity committees to provide adequate information to CCFA by following the Procedural Manual.

#### **PROBLEMS AND SOLUTIONS**

8. The following section summarises problems and solutions submitted by members and observers that are directly related to approaches aimed at expediting the work on the GSFA. Issues that are already under discussion in the CCFA, such as use of Note #161, endorsement of food additives provisions in commodity standards are not presented.

9. Problems identified and solutions proposed can be grouped as follows:

#### ***Consideration of food additives provisions***

<u>Problems</u>	<u>Proposed solutions</u>
<p><u><i>Objections not substantiated by science/technology</i></u></p> <p>Objections to the recommendations of the electronic working group often cite national legislation or precautionary concerns, without scientific or technical justification. In other cases, they challenge JECFA recommendations and reports, and express a view that ADI levels are “too high” or could be exceeded without scientific or technical evidence.</p>	<p>Comments to the electronic working group should be substantiated by scientific and technological evidence, particularly if objections are based on possibly exceeding the ADI established by JECFA.</p>
<p><u><i>Difficulty in applying criteria in Section 3.2</i></u></p> <p>Application of the criteria set in section 3.2 of the Preamble of the GSFA for some specific food additive provisions might sometimes be difficult and may lead to divergence of views regarding food additive proposals.</p> <p>Lack of shared understanding of what is necessary in terms of technological needs.</p>	<p>Varying technological needs for food additives should be recognised in the Preamble to the GSFA and appropriate tools should be introduced to allow them to be taken into account.</p> <p>Establish a working group to develop principles for consideration of technological justification to be included in the GSFA.</p>
<p><u><i>Long discussion on individual provision</i></u></p> <p>Long discussion on individual food additive provisions.</p>	<p>Consider together food additive provisions with same functional class and develop principles that can be consistently applied to these groups.</p> <p>Develop criteria to ensure consistent and transparent consideration of exceptions to the application of the above principles.</p> <p>Ensure consistent application of principles and criteria over successive sessions.</p>

<p><u>Limited time for consideration of GSFA</u></p> <p>Although, the GSFA has been recognised as a priority work, the time allocated by the CCFA for its consideration is quite limited.</p>	<p>Allocate more time to the discussion of the GSFA, e.g. one additional working / plenary day meeting and reconsider the allocation of time between the various topics in plenary sessions; and encourage members to contribute more actively to the work on the GSFA.</p> <p>Develop criteria for prioritising the current back-log. Prioritization criteria should be based on needs assessment rather than on the time at which work commenced or the level of consensus on the provision.</p> <p>Establish procedures for implementing approach that ensures consistent implementation in future Committee sessions.</p>
<p>Inconsistencies between the food additive provisions in the GSFA and in commodity standards should be settled promptly.</p>	<p>Given the decision of the CAC regarding the revision of the format of the commodity standards in 2008, the CCFA should request, through the Codex Alimentarius Commission, that all active commodity committees should identify the inconsistent food additive provisions and refer proposed amendments in written forms to the CCFA.</p>
<p><b><i>Electronic working group on GSFA</i></b></p>	
<p><u>Problems</u></p>	<p><u>Proposed solutions</u></p>
<p><u>Limited participation</u></p> <p>The number of participants in the electronic working group is smaller than in the physical working group. This makes the significant investment of the electronic working group at risk as the possibility to reopen discussion on any of the issues considered.</p>	<p>Clearly define and record the terms of reference, including expected outputs, of the electronic working group in the report of the CCFA.</p> <p>Members and observers should be encouraged to provide their early inputs in the form of written comments.</p>
<p><u>Limited discussion / sharing of comments</u></p> <p>The electronic forum used by the electronic working group does not allow for open dialogue between members on a specific provision or group of provisions. Although this approach is useful to handle such workload, the differing views are often not resolved through the electronic working group, the same differing views are then made in the comments on the electronic working group report and in the physical working group.</p>	<p>Participants should be encouraged to voice and document appropriately concerns as early as possible and abide by consensus reached.</p> <p>Allow for members and observers to share and discuss their comments in order to resolve different views.</p> <p>Frequency of comments requested may also need to be considered, e.g. allow for more than one round of comments.</p>
<p><u>Risk to reopen discussion on any issues considered</u></p> <p>Although various opportunities for the provision of comments would ensure transparent and inclusive process, it will also have the risk of allowing countries to reopen discussion on issues already solved or where consensus could be reached by the</p>	<p>Comments to the electronic working group should be substantiated by scientific and technological evidence, particularly if objections are based on possibly exceeding the ADI established by JECFA.</p>

electronic working group.	<p>The recommendations of the electronic working group should be consistent with Section 3 “General Principles for the Use of Food Additives” of the Preamble of the GSFA. Comments in support or against the recommendations of the electronic working group should be supported by scientific and technical evidence.</p> <p>More complete and comprehensive report that fully reflects the comments of the working group’ members.</p> <p>Forward: (i) the recommendations on the matters agreed by the electronic working group to the plenary of the CCFA; and (ii) the outstanding issues to the physical working group for further consideration.</p>
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### ***Physical working group on GSFA***

<u>Problems</u>	<u>Proposed solutions</u>
<p><u>Duplication of work/discussion</u></p> <p>There is a general perception that the work of the physical working group duplicates discussion of the electronic working group and that its work should be more focus on solving issues for which agreement could not be reached in the electronic working group.</p>	<p>Clearly define and record the terms of reference of the physical working group in the report of the CCFA.</p> <p>The physical working group should focus its discussion on the issues for which agreement could not be reached by the electronic working group.</p>
<p><u>Limited time for discussion</u></p> <p>The time of the physical working group is limited and often is not sufficient to complete its agenda.</p>	<p>Consider a longer physical working group (i.e. 3-4 days) to take place between CCFA sessions.</p> <p>Focus the discussion of the working group on the established/agreed priorities.</p> <p>Limit the discussion on issues that could not be solved by the electronic working group.</p>

### ***Others***

<u>Problems</u>	<u>Proposed solutions</u>
<p><u>Inconsistencies of food additives provisions in commodity standards and GSFA</u></p> <p>CCFA is spending too much time for endorsing food additives provisions of commodity standards.</p> <p>Inconsistency of food additives provisions between commodity standards and the GSFA is to be settled promptly.</p>	<p>Communication between commodity committees and CCFA should be improved by informing and encouraging commodity committees to develop standards using GSFA as sole Codex reference for food additives and conforming to the Procedural Manual.</p> <p>All active commodity committees should identify inconsistencies between food additive provisions in commodity standards and the GSFA and propose amendments in written forms to the CCFA.</p>

	<p>Develop a clear detailed explanatory document to be shared with Codex Commodity Committees to ensure food additive activities in these committees are compliant with provisions of the GSFA Preamble and Codex Procedures</p> <p>CCFA should allocate adequate times to discuss the identification of problems and recommendations related to the inconsistent presentation of food additive provisions in codex commodity standards.</p>
<u>Consideration of JECFA recommendations</u>	<p>CCFA should allocate adequate time for consideration of JECFA's recommendations, including new food additive provisions and changes to the safety and/or dietary exposure assessment.</p>
<p><u>Endorsement of food additives provisions</u></p> <p>Proposed uses and use levels of a food additive should be more systematically accompanied by JECFA intake estimates, based on all accepted and proposed uses of the additives.</p>	<p>Codex committees should encourage the collation of relevant data in relation to the possible consumption pattern of the food and its distribution through the various continents.</p> <p>CCFA should take into consideration information on intake estimates of food additives when endorsing food additive provisions.</p>

## RECOMMENDATIONS

10. The Committee is invited to consider the following recommendations as a first step to accelerate the work on the GSFA.

### *Consideration of food additives provisions*

- i. Develop a system for prioritizing work on the GSFA, which would consider all remaining provisions in Tables 1 and 2 (including the provisions of food additives listed in Table 3), by grouping food additive by functional class.
- ii. Develop horizontal principles for the technological justification of a functional class.
- iii. Discuss food additive provisions by groups (including provisions of food additives listed in Table 3) based on functional classes, e.g. colours, sweeteners, etc.
- iv. Only consider comments which are substantiated by scientific and technological evidence.
- v. Establish an electronic working group to clarify how to consider technological justification and develop principles for inclusion in the Preamble of the GSFA.

### *Electronic working group on GSFA*

#### Option 1

- i. Clearly define and record the terms of reference of the electronic working group in the report of the CCFA and specify the expected outputs (e.g. recommendations for adoption, revocation, discontinuation; outstanding issues for consideration by the physical working group, etc.).
- ii. Request the lead country of the electronic working group to revise the working procedures to allow for members of the electronic working group to share and discuss their comments in order to resolve different views.
- iii. The report of the electronic working group should reflect the comments submitted by members.

Option 2

- i. Replace the electronic working group on the GSFA with a physical working group (with clearly defined and recorded terms of reference) to meet between session. The physical working groups (3-4 days) would be held 6-8 months ahead of the CCFA session (e.g. July-September when CCFA session takes place in March) with preliminary work carried out by the lead country.

***Physical working group on GSFA (pre-session)***Option 1

- i. Clearly define and record the terms of reference of the physical working group in the report of the CCFA.
- ii. The physical working group should focus on food additive provisions of the GSFA and only consider those issues that were not solved by the electronic working group.

Option 2

- i. Replace the physical working group by an additional day of plenary discussion (i.e. CCFA session will last 6 days).

**REPLIES TO CL 2009/7-PART C: COMMENTS AND INNOVATIVE PROPOSALS TO EXPEDITE THE WORK ON THE GSFA****AUSTRALIA**

Australia welcomes the opportunity to comment on alternative approaches to managing the work of the GSFA. The development of the GSFA is key priority work for the CCFA and it is noted that there is considerable work to be undertaken before proposed provisions currently being considered are finalised. It is important for CCFA to have a process for establishing food additive provisions in the GSFA that is streamlined, well understood by members and observers and delivers outcomes in a timely manner. Australia supports a system that:

- Is appropriate for clearing the back-log of proposed food additive provisions currently being considered; and
- Can efficiently accommodate consideration of outcomes from JECFA, including new food additive provisions and changes to the safety and/or dietary exposure assessment conclusions for an additive.
- Takes into account the need to facilitate eventual integration of food additive provisions from commodity standards into Tables 1-3 of the GSFA.

At the 41<sup>st</sup> session of the CCFA, the JECFA secretariat raised the matter of an ongoing review program for food additives for consideration. This suggestion will be further considered at the next session of the CCFA via a discussion paper. It would be preferable to have reduced the outstanding work on the GSFA prior to implementation of any ongoing review program for additives so as not to delay any amendments to food additive provisions as a result of predicted ongoing review work by JECFA.

There are currently many opportunities for comments and debate on new food additive provisions including: through electronic working groups (prior to the 41<sup>st</sup> session of CCFA); comments on the report of the electronic working group; at the physical working group ahead of the plenary session; and at the plenary session. In Australia's view the process provides too many different opportunities for provisions that have been thoroughly considered in the electronic working group to be re-opened for debate.

The current process for providing comment on food additive provisions is somewhat complicated and it may be difficult for some Codex members to understand at which stage to provide input to the development of food additive provisions. Additionally, it is resource intensive for Codex members to provide input at each stage of the process and also to read the comments submitted by other Codex members, especially taking into account that Codex members would usually consult with the stakeholders in their respective countries prior to making comment.

The work of the electronic working group has been organised such that comments on provisions are managed in a database, which Australia acknowledges is a practical way of managing such a large workload. The disadvantage of this approach is that it doesn't allow for open dialogue between members with different views on a particular food additive provision. As these differing views are often not resolved through the electronic working group, the same differing views are then made in the comments on the electronic working group report and in the physical working group. It would be ideal if a mechanism could be developed to allow a meaningful dialogue on differences of opinion on food additive provisions prior to finalising the report of the electronic working group.

Australia suggests the following points for further consideration:

- A physical working group held out of session, held over a longer period of 3-4 days could enable substantial progress on the large number of remaining provisions that need consideration. A physical working group held over several days would enable debate over provisions and opportunities to resolve differing views. This working group could be held approximately 6-8 months ahead of the CCFA meeting, e.g. September. This would allow sufficient time for circulation of outcomes and recommendations well in advance of the CCFA meeting and for countries to examine the provisions. Differing views that are not resolved at the physical working group could be considered in the lead up to the plenary by interested parties in consultation with the Chair of the physical working group and/or the CCFA Chair. Secretariat support would need to be considered along with whether interpretation is provided. The secretariat support for the physical working group is usually provided by the country of the Chair of the physical working group and/or other CCFA members. Consideration should also be given to resource implications for additional travel and not all countries would be in a position to attend. Technical experts should be encouraged to attend to provide outstanding information and address questions of a technical nature.
- In the future it may be relevant to also form an electronic working group to provide material for consideration at a physical working group, once the back-log of provisions currently being considered has been cleared.
- The principles for the development of food additive provisions of the GSFA should guide all work on the GSFA, including contributions as part of an electronic working group, and importantly interventions at both the physical working group and the plenary session.

- Some time could be allocated by the Committee to prioritising the remaining work currently in progress on food additive provisions. This should be based on a needs assessment rather than on the time at which work commenced or the level of consensus on the provision. Prioritising work may assist some Codex members to target their input and identify the stage at which it is critical to provide such input.
- Discussion at the physical working group could be focused on the previously established priorities.

## CHINA

The development of the GSFA is an important work for the CCFA. As a host country of CCFA, China would like to submit the following suggestions in order to facilitate the progress of GSFA.

1. The electronic working group on the GSFA should be maintained and expanded so that more member countries and observers could participate in this work actively. We support that the widely communication and discussion on some specific food additive provisions should be encouraged in order to reach consensus as soon as possible.
2. Establish the physical working group before the plenary session right along. Discussion at the physical working group could be focused on the issue which no agreement was found at the electronic working group.
3. The committee should avoid reopening the floor for the issue reached consensus at the electronic and physical working group. For the disputed issues, we suggest that the parts held the different opinions should provide the written materials with sufficient scientific evidence, so that the consensus could be reached in the limited time at the level of committee.
4. All remaining additives should be grouped base on the functional use and discussed on a group basis done with sweeteners and colors, in order to expedite the progress of the GSFA.
5. Safety and technological need are two important factors in the consideration of food additives. Since there were disagreements on the technological need of some specific food additives discussed at the previous committees and working groups, we suggest that the electronic working groups should be established to form the justification standard for the technological functions of food additives as the appendix of the GSFA. At the same time, CCFA should strengthen the communication with Codex commodity committees, if necessary, and invite these committees to respond to the results of discussion on the technological function.

## COSTA RICA

Costa Rica desea realizar los siguientes comentarios con respecto a la carta circular CL 2009/7-FA referente a "Comentarios y propuestas innovadoras para hacer más expedito el trabajo en la NGAA"

Estamos de acuerdo en la necesidad de encontrar soluciones para hacer más expedito el trabajo en la NGAA y queremos proponer lo siguiente:

1. Se facilitaría mucho el trabajo del Comité si se agrupan los aditivos de acuerdo a su función tecnológica, como se realizó con edulcorantes y colorantes. Sugerimos que las propuestas de límites máximos de uso pendientes para ser aprobadas, se agrupen de manera similar y se discutan en grupos de acuerdo a su función tecnológica.
2. Que las consideraciones y propuestas del grupo de trabajo por medios electrónicos sean tomadas en cuenta de manera más efectiva para su adopción, y sólo aquellas que el Comité considere que necesiten más discusión sean llevadas a la siguiente reunión del CCFA
3. Que durante las deliberaciones, las objeciones que se presenten para la propuesta de un nivel máximo de uso de un aditivo o de la propuesta del grupo de trabajo por medios electrónicos, estén basadas en evidencia científica y no sólo en lo que es permitido en un país a nivel nacional.
4. Considerar que si un nivel máximo de uso de un aditivo en una categoría en particular ya ha sido aprobado por JECFA, eso se podría considerar como una justificación tecnológica adecuada. Cualquier objeción al nivel de uso propuesto, debe ser acompañada por un documento que contenga la base científica, por ejemplo nueva información tecnológica que pudiera cambiar la evaluación de JECFA o datos de ingesta (preferiblemente con números estadísticos) que indiquen una preocupación si se excede la IDA.
5. En las sesiones del CCFA se ha tomado tiempo considerable debatiendo las propuestas para normas específicas de productos. Se requiere que los Comités Específicos le provean la información necesaria al CCFA cuando establecen niveles máximos, de tal forma que sea más eficiente la discusión. Además, se les debe informar a los comités específicos que deben seguir el Manual de Procedimientos para considerar la adición o revisión de propuestas de niveles de uso de aditivos alimentarios en la Norma General de Aditivos.



## EUROPEAN COMMUNITY

The European Community (EC) would like to provide the following suggestions aiming at improving the process of completion of the General Standard for Food Additives (GSFA).

The GSFA is based on criteria of safety, technological need and consumer benefit (in order to ensure for instance that consumers are not misled). All these criteria have the same weight and should always be systematically investigated before setting proposed uses and use levels for food additives (GSFA preamble 3.2).

First of all, one of the main issues is a lack of shared understanding of what is necessary in terms of technological need. The EC is of the view that technological functions which are a crucial element driving the proposed use of food additives in foodstuffs should be more substantiated and accompanied with a strong argument of technological need. A robust method should be set for that purpose. Burden of justification should always lay on the stakeholders, the Commodity Committee or the country proposing the use of an additive or highest level of use. This principle should be written down in the GSFA. Whenever necessary, such argumentation could also be completed, taking into consideration other closely related parameters as climatic conditions, hygienic standards, etc so that Codex countries may evaluate whether the request is justified worldwide, or whether some flexibility should be given to Codex countries where these parameters may not be relevant. This should bring more transparency and clarity during the process of adopting forward provisions.

Secondly, proposed uses and use levels of a food additive should be more systematically accompanied by an intake estimate that should be performed by JECFA, taking account of all accepted and proposed uses of the additive. In addition, Codex Committees should encourage the collation of relevant data in relation to the possible consumption pattern of the food and its distribution through the various continents. Such information on intake estimates of food additives should be taken into consideration by the CCFA before endorsing the proposed use and use level for a candidate food additive ensuring that its conditions of use do not lead to safety concern.

These principles are already enshrined in the Procedural Manual of the Codex Alimentarius dedicated to the relations between Commodity Committees and General Subject Committees (section III, p 46) which states that *“All provisions in respect of food additives contained in commodity standards will require endorsement by the Codex Committee on Food Additives, on the basis of technological justification submitted by the Commodity Committees .../...and an estimate of the potential and, where possible, the actual intake of the food additives, ensuring conformity with the Preamble of the General Standard for Food Additives.”*

Even when no active Commodity Committee exists, the section 3.1 of the Preamble of the GSFA relating to the general principles for the use of food additive already mentions that the endorsement of proposed uses for a food additive should take into account information on intake estimates as one can read: *“The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers”*. The EC considers that following the agreed General Principles of the Procedural Manual of the Codex Alimentarius more closely will lead to smoother collective agreement of individual additive provisions.

As the GSFA is seen as the CCFA's number one priority, the EC suggests that more time should be dedicated to the completion of the GSFA during the CCFA. One additional working / plenary day meeting should be allocated to this work and members should be encouraged to contribute more actively to the work of progressing the GSFA.

In terms of procedure, the plenary should avoid reopening conclusions reached in the physical working group and instead concentrate on those issues for which no agreement was found at the working group level.

Then, if the CCFA is of the opinion that the completion of the GSFA is the number one priority, the EC suggests that the allocation of time between the various topics in plenary sessions should be reconsidered. In particular some different route to agreement should perhaps be sought with regard to the adoption of regional standards with potentially less international trade impact. The allocation of time to non standardized food which may not be relevant for international trade could also be reduced, etc...

Finally, the EC acknowledges that the application of the criteria set in section 3.2 of the Preamble of the GSFA for some specific food additive provisions might sometimes be difficult to apply, bearing in mind that various factors (e.g. different climate conditions between different parts of the world, different consumers' perception to food additives (in particular with regard to food colours), different food cultures, food technology or food hygienic standards...) are taken on board by Codex countries, affected to their own ranking of priority, which may end up with divergence of views regarding food additive proposals. The EC's view is that these varying technological needs for food additives should be recognised in the Preamble to the GSFA and appropriate tools should be introduced to allow them to be taken into account.

## JAPAN

The Government of Japan is pleased to submit the following comments on GSFA, in response to Circular Letter CL 2009/7-FA, Part C.

Following the decision of the 28<sup>th</sup> Session of the Codex Alimentarius Commission (CAC in 2005) that the GSFA should be the single authoritative reference point for food additives and this should be made clear in all commodity standards, a lot of effort has been made by all the delegations in the CCFA with a view to aligning all food additive provisions in the GSFA. Under the leadership of the United States of America, as Chairperson of the physical working group, the significant progress of the work has been made.

In the physical working group held in conjunction with the last session of the CCFA, a number of food additive provisions remained not fully addressed due to time constraints. In addition comments submitted in a written form or raised during the physical working group was duly taken into account, however, in the plenary more new comments were raised and it spent a lot of time to reach consensus.

Japan is of the opinion that there is not a complete new mechanism to facilitate the work, but is convinced that the following arrangements may help speed up for the completion of work on GSFA:

### 1. Maximum use of opportunity to participate in or submit written comments to the electronic working group

In the recent two sessions of CCFA, number of participants in the electronic working group is much less than that those in the physical working group, which is held in conjunction with the plenary. In 2009, 22 countries and observers participated in the electronic working group, while 48 countries and observers attended the physical one. Frequency of request for comment to the report of the electronic working group is only one, made a couple of months before the physical working group. Given the fact above, it may be useful for CCFA to consider possible ways to ensure early involvement and more effective participation in the e-WG. Members and observers should be encouraged to provide their early inputs in the form of written comments. Frequency of comments requested may also need to be considered. Japan expects that preparation of the report of the e-WG with fully reflection of the comments may lead to the smooth organization of discussion at both the physical working group and the plenary.

### 2. More physical discussion in the plenary

It is worth to consider spending more energies and time in the plenary aimed to facilitate completion of the work on GSFA. This may require a more complete and comprehensive report of the electronic working group (as mentioned in point 1 above) to be directly submitted to the plenary, but not to the physical working group. If no physical working group meeting takes place prior to the plenary, the CCFA may wish to have a full one day (or one half day or more where necessary) plenary session to discuss the GSFA matter. CCFA may wish to have a six day session (four working days, one for drafting report and another one for report adoption).

### 3. Others

Ongoing work regarding descriptions of groups 5 (confectionary), 6 (flour) and 16(composite foods) should be progressed with no delay as they are closely linked to the work on GSFA.

The issue on inconsistency of food additive provisions between commodity standards and GSFA in certain category of foods is also in high priority to be settled promptly. Given the decision of the CAC regarding the revision of the format of the commodity standards in 2008, the CCFA should make a request through the CAC that all commodity committees in active should identify the inconsistent food additive provisions and refer proposed amendments in written forms to the CCFA in a fixed period of time (e.g. by the year 2011 except for some committees which meet every two years). Further, for the issue on the IDENTIFICATION OF PROBLEMS AND RECOMMENDATIONS RELATED TO THE INCONSISTENT PRESENTATION OF FOOD ADDITIVE PROVISIONS IN CODEX COMMODITY STANDARDS, which was not discussed at the last CCFA (see para. 156 of ALINORM 09/32/12), Japan suggest that the next CCFA should allot adequate times to this matter as is also one of the highest priority matters, for full discussion to make a significant progress of work on GSFA.

## UNITED STATES OF AMERICA

This responds to CL 2009/7-FA Part C (March 2009), which requests comments and innovative proposals to expedite the work of the Codex Committee on Food Additives (CCFA) on the Codex General Standard for Food Additives (GSFA). The United States of America (USA) welcomes this opportunity to provide comments and looks forward to reviewing the Codex Secretariat's paper on this important issue.

Since 1991, the USA has actively supported the work on the GSFA by assisting the Codex Secretariat in maintaining and updating the GSFA and by assisting the CCFA through chairing its GSFA physical Working Group (WG) and various electronic Working Groups (eWGs) that have prepared recommendations for the Committee's consideration.

The remaining work on the GSFA primarily concerns the food additive provisions residing in Tables 1 and 2. Even though the 32<sup>nd</sup> Codex Alimentarius Commission adopted at Step 8 all but one of the recommendations put forward by the 41<sup>st</sup> CCFA, more than 4,200 food additive provisions in Tables 1 and 2 in the Codex Step Process will remain. Almost half of these are for food additives listed in Table 3 of the GSFA for use in food categories listed in the Annex to Table 3.

In considering approaches to expedite progress on the remaining food additive provisions in Tables 1 and 2, the Committee must identify approaches that minimize the need to individually discuss each of the more than 4200 food additive provisions. To this end, the Committee must develop approaches for grouping food additive provisions that can be considered together and for which agreed-upon principles can be consistently applied.

It is likely that exceptions will be proposed to any approach that minimizes the Committee's discussion of individual food additive provisions. It is important that the Committee consider all proposed exceptions in a consistent and transparent process, but it should do so in a manner that does not circumvent the efficiency and effectiveness of the approach. Therefore, the Committee should agree not only on an approach, but also on the criteria for considering exceptions that deviate from the agreed-upon approach. For example, the Committee could only consider exceptions that are based on safety or technological need concerns that are consistent with Section 3 of the Preamble and are supported by data and information.

Implementing a new approach is a significant challenge given that both its formulation and application will likely occur over sequential sessions of the Committee. Therefore to facilitate progress, the Committee should establish procedures for implementing the approach that ensures consistent implementation in future Committee sessions. For example, once the Committee agrees to an approach and criteria for any deviations from that approach, the approach and deviation criteria should be recorded in the Committee's report and referred to in successive sessions to ensure consistency.

Regardless of the "innovative approach" agreed upon to expedite progress on the GSFA, the Committee must ensure consistency in the application of the approach over successive Committee sessions to avoid expending significant resources discussing new approaches and delaying actual progress on the remaining food additive provisions.

### **Potential Approaches for Consideration**

The following alternative approaches for expediting the Committee's work on the GSFA are offered for consideration by the Codex Secretariat in preparing the discussion paper for the 42<sup>nd</sup> CCFA. These approaches are intended to be complementary and are not presented in any preferred order.

#### Approach 1 – Consider Table 3 Additives by Technical Function Groups

All of the food additives listed in Table 3 have been assigned an acceptable daily intake (ADI) of "Not Specified" or "Not Limited" by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The provisions for the "Table 3 food additives" that are listed in Tables 1 and 2 are limited to a subset of the food categories listed in the Annex to Table 3. One approach to collectively address these provisions is to identify food categories in the Annex to Table 3 for which a particular food additive functional class is justified in accordance with Section 3.2 of the Preamble. The relevant food additive provisions in the identified food categories currently in the Codex Step Process would then be compiled and forwarded directly to the Commission for final adoption. Provisions for the "Table 3 food additives" in food categories for which the food additive functional class was not considered technologically justified would be maintained in the GSFA and discussed on a case-by-case basis. Considering "Table 3 food additives" by technical function groups could significantly reduce the inventory of unresolved food additive provisions in the GSFA. Examples of how this approach could be applied to different food additive functional classes are provided below.

#### *Sweeteners and Colors*

The CCFA has identified food categories in which either sweeteners or colors are justified. Some of these food categories are listed in the Annex to Table 3. There are 7 sweeteners listed in Table 3 (erythritol, isomalt, lactitol, mannitol, polyglycitol syrup, thaumatin, and xylitol), which account for 91 food additive provisions in Tables 1 and 2. There are also 4 colors listed in Table 3 (beet red, caramel I - plain (caustic caramel), chlorophylls, and titanium dioxide), which account for 89 food additive provisions in Tables 1 and 2. By identifying those food categories in the Annex to Table 3 for which the CCFA has already agreed that sweeteners or colors are justified, the Committee could compile a list of these food additive provisions and forward them to the Commission for final adoption.

An approach similar to that taken by the CCFA to identify the food categories in which sweeteners and colors are technologically justified could be applied to the food categories listed in the Annex to Table 3 in which the use of other food additive functional classes are technologically justified. This approach would be based on Section 3.2 of the Preamble, with a view toward endorsing the food additive provisions in these food categories for final adoption *en mass* without further discussion. Provisions in food categories listed in the Annex to Table 3 that were not identified as technologically justified to generally contain a particular food additive technical class could be discussed on a case-by-case basis.

The following summarizes the number of food additive provisions for various food additive classes for the “Table 3 additives.” This summary is neither exhaustive nor does it account for all food additive functional classes assigned to all of the “Table 3 additives.” It is important to recognize that in many cases the INS system associates multiple food additive functional classes with an individual food additive. Thus there is some overlap in the additives associated with individual food additive functional classes.

#### *Stabilizers, Thickeners or Emulsifiers*

Approximately 1200 of the more than 2000 provisions in Tables 1 and 2 are for “Table 3 food additives” that are used as stabilizers, thickeners or emulsifiers. The INS system associates all three of these functional classes with virtually all of these food additives. Thus, these three functional classes should be considered together by the Committee.

#### *Acidity Regulators*

Approximately 500 of the 2000 provisions in Tables 1 and 2 are for “Table 3 food additives” that are used as acidity regulators.

#### *Antioxidants*

Approximately 180 of the 2000 provisions in Tables 1 and 2 are for “Table 3 food additives” that are used as antioxidants.

#### *Flavor Enhancers*

Approximately 90 of the 2000 provisions in Tables 1 and 2 are for “Table 3 food additives” that are used as flavor enhancers.

#### *Flour Treatment Agents*

Approximately 90 of the 2000 provisions in Tables 1 and 2 are for “Table 3 food additives” that are used as flour treatment agents.

By focusing on the provisions in Tables 1 and 2 for the “Table 3 food additives” by functional class and advancing them for adoption *en masse* the Committee could significantly reduce the number of GSFA food additive provisions in the Codex Step Process.

#### Approach 2 – Color Additives Listed in Tables 1 and 2

There are approximately 1,150 provisions for color additives in the Codex Step Process. Of these, almost 300 will be discussed by the 42<sup>nd</sup> CCFA. As noted above, the Committee has identified food categories in which the use of color additives is justified. The Committee could agree to advance for final adoption the provisions for color additives in the food categories in which the use of color additives has already been agreed to be technologically justified at the maximum levels proposed, unless a safety issue consistent with Section 3.1 of the Preamble is identified and supported by data and information. If necessary, the Committee could consult with JECFA on any unresolved safety questions.

#### Approach 3 – Implementation of eWG Recommendations

The CCFA has made use of annual inter-session eWGs and physical WGs to provide recommendations to the CCFA plenary. In our view, the eWG and the physical WG have proven useful for progressing work on the GSFA. The Committee’s current practice is for the eWG to consider and provide recommendations (i.e., adopt, revoke, discontinue, discuss further) on as many as 1,000 food additive provisions annually. These recommendations are then discussed by the physical WG and the CCFA plenary. Assuming that the Committee continues to re-establish its GSFA physical WG, one approach to expedite its current practices would be for the physical WG to only discuss the food additive provisions for which the eWG could not reach consensus and has recommended further discussion. All eWG recommendations to adopt, revoke, or discontinue work on specific food additive provisions would be forwarded directly to the Committee’s plenary for discussion. In this way, the physical WG would not repeat the work conducted by the eWG, but instead could focus solely on developing recommendations for the plenary on the food additive provisions for which the eWG could not reach consensus.

Independent of whether the Committee re-establishes its physical WG, it is very important that the eWG have full participation by Codex Members so that the eWG’s recommendations reflect a consensus view. In addition, when establishing an eWG, the terms of reference for the eWG must be clearly stated and recorded in the Committee’s report. Such terms of reference should include a reference to the Preamble, in particular to Section 3, as the basis for the eWG’s deliberation and recommendations. It is critical that the eWG’s recommendations be respected by the CCFA plenary as a consensus view. Deviations by the CCFA plenary from the eWG recommendations should be restricted only to those circumstances where a safety concern, consistent with Section 3.1 of the Preamble, or a food additive technological need concern, consistent with Section 3.2 of the Preamble exists. If such concerns are raised they must be supported by adequate data and information.

#### Approach 4 – Improve Communication with Commodity Committees

Indirectly related to the Committee's work on the GSFA is the large amount of valuable time that can be expended in the CCFA plenary discussing the endorsement of the food additive section of Codex commodity standards. To expedite the CCFA's endorsement of the food additive section of commodity standards, we recommend that the Codex Secretariat routinely inform each commodity committee and their chairman of the Commission's decision that the GSFA is intended to be the sole Codex reference for food additives. The Secretariat should also inform each commodity committee and its chair of the format and procedures for developing the food additive section in Codex commodity standards that are contained in the Procedural Manual (Section III – *Elaboration of Codex Standards and Related Texts; Relations between Commodity Committees and General Subject Committees and Format for Codex Commodity Standards – Food Additives*). With a better understanding of their role and responsibilities with regard to food additives, the commodity committees will be able to forward for endorsement by the CCFA food additive sections that are consistent with the Procedural Manual. In turn, this should reduce the amount of time the CCFA plenary spends reviewing, revising, and endorsing the food additive section of commodity standards and would allow the CCFA plenary more time to discuss other agenda items, in particular the GSFA.

#### **INTERNATIONAL DAIRY FEDERATION (IDF)**

The International Dairy Federation (IDF) would like to compliment the Chinese Secretariat, the Codex Secretariat, and the U.S. Delegation that has led both the electronic Working Group and the physical Working Group on food additives for the Codex General Standard for Food Additives (GSFA) and fellow delegates to the Codex Committee on Food Additives (CCFA). Under the very able leadership of Dr. Chen Junshi, we believe that important and significant work has been accomplished since China became host of the CCFA to incorporate, discontinue or revoke food additive provisions in the GSFA.

We also believe that more recently, difficulties between CCFA delegations have arisen which have delayed the adoption of food additive provisions for the GSFA. In order to improve on the already successful efforts of the CCFA, IDF wishes to provide the following comments and suggestions in response to CL 2009/7-Part C for the Codex Committee on Food Additives (CCFA):

We recognize the importance of achieving consensus on food additive provisions proposed for inclusion in the General Standard for Food Additives (GSFA). However, it is clear that some CCFA delegations have demonstrated difficulty accepting any proposed food additive use or maximum level (ML) that differs from that permitted by their country's laws and regulations. We also have noted that the preparatory value and significant investment of time by CCFA delegates participating in the e-Working Group and the physical Working Group on the GSFA is sometimes lost when delegations participating in the e-Working Group raise new objections in the physical Working Group. Similarly, delegations participating only in the physical Working Group sometimes raise new interventions to the Working Group report during the plenary sessions of the CCFA. These new interventions to Working Group recommendations, in some cases, cite national legislation or precautionary concerns, without scientific or technical justification. Other interventions challenge JECFA recommendations and reports, expressing a view that ADI levels are "too high" or will be exceeded, again without scientific or technical evidence.

It would appear that the multiple opportunities to provide comment via the e-Working Group, physical Working Group and CCFA plenary session increases transparency, but also contributes to an increase in the number of interventions, slowing the process of finalizing the GSFA. In order to resolve these multiple challenges, the plenary has defaulted by significantly increasing the use of Note 161 "*Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble*" which is helpful if used sparingly to resolve only those few food additive issues where CCFA delegates cannot reach consensus. Unfortunately, it has been invoked for a substantial number of food additives uses and/or maximum levels during the 2008 and 2009 CCFA plenary sessions, weakening Codex' purpose of international harmonization and rendering ineffective, the effort to develop an internationally accepted GSFA that reduces trade barriers based on differing national regulations. Note 161 invoked with the frequency demonstrated during the 2009 CCFA plenary threatens the value of the GSFA and the years of effort invested in its development. Under Article 3 of the SPS Agreement, any WTO member can deviate from the Codex standards if there is a scientific justification: "*Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate Page 71 in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5...*"

IDF has considered a number of measures that might resolve some of the existing problems of evaluating food additive provisions for inclusion into the GSFA and have the following recommendations in no particular priority, some of which could be combined together, others which stand alone and some which are mutually exclusive (choosing one will invalidate another).

1. All remaining additives/MLs should be grouped based on the category of technological purposes (functional use) and discussed on a group basis as was done with sweeteners and colors. This would facilitate discussions since it would be more likely for both the CCFA delegates and NGOs to have the correct experts on particular food additive functional classes (colors, sweeteners, etc.) present for CCFA Working Groups and at the plenary session.
2. Whenever possible, all proposed provisions (functional uses and MLs) for a food additive should be presented at the same time for discussion, including those that are proposed for adoption, discontinuance or revocation, so that the delegations can view them together in view of the ADI.
3. Criteria should be established defining the acceptable basis for raising objections to e-Working Group or physical Working Group recommendations during the CCFA plenary. This would encourage more participation in any future e-Working Group or physical Working Group since delegation interventions during the plenary would be constrained to the criteria adopted by the CCFA plenary. Some possible elements making up technological justification criteria document could be:
  - a. According to the GSFA Preamble (Par. 3.2 “Justification for the use of additives”), objections should be substantiated by scientific/toxicological data or evidence of health risk to consumers misleading consumer’s or failure to justify a technological function for a food additive (according to the GSFA Preamble). The use of objections based solely on national legislation, general statements such as “It will mislead consumers” without additional supporting information and other unsupported precautionary-based concerns should not be accepted as substantive.
  - b. Food additive provisions recommended by either Working Group for discontinuance or revocation would be final and adopted by the CCFA plenary together as part of one discussion. The CCFA plenary would either support or oppose the Working Group recommendations for discontinuance or revocation, without the opportunity for discussion on individual food additive uses or levels. This would encourage CCFA delegates to participate in any available CCFA Working Group(s).
4. The use of Note 161 should be limited to cases where justification can be provided in accordance with the GSFA Preamble, in recognition of the protections afforded under Article 3 of the SPS Agreement. It would be helpful to obtain a legal opinion from knowledgeable WTO experts regarding whether Note 161 is compliant with the SPS and TBT treaty provisions or is redundant.
5. Criteria for submission of recommendations to the e-Working Group or physical Working Group should include a requirement that a short written technological justification be included for reference, identifying the science/toxicological basis for a restrictions on the proposed use (food category or food additive function) or maximum level for a food additive, particularly if objections are based on possibly exceeding the ADI established by JECFA. Undocumented objections without supporting scientific/technological justification should not be viewed as substantive by either Working Group.
6. In order to increase the time efficiency of CCFA delegations in addressing, deliberating, and endorsing food additive provisions, the e-Working Group should be re-established, with its recommendations going directly to the CCFA plenary. In theory, the e-Working Group provides a very economical opportunity for CCFA delegations with access to a computer to fully participate in evaluating large numbers of food additive provisions and making recommendations to the e-Working Group and then to the CCFA plenary.
7. Expansion of the e-Working Group authority so it operates on a continuous basis, with recommendations (adopt, revoke, discontinue or hold over) sent to the CCFA Secretariat whenever the e-Working Group has completed their work on a set of food additive provisions. The e-Working Group recommendations should be sent to all CCFA delegations for endorsement, between CCFA plenary sessions. If there are technologically or scientifically-based objections from CCFA delegations, then those e-Working Group recommendations would either be returned to the e-Working Group for additional deliberation or held over to the next CCFA plenary. It is uncertain whether this would require changes in the Codex Procedures Manual, but this approach would allow for almost continuous evaluation of GSFA food additive provisions and should reduce the time needed for CCFA to endorse such provisions.
8. Conversely, if the use of a physical Working Group is preferred, scheduling the meeting just prior to each CCFA plenary as has been done over the past few years could have some value in developing a report on pending food additive provisions for consideration by the CCFA plenary. A physical Working Group would not be able to operate on a continuous basis as described in recommendations for an e-Working Group, but could still be effective in assisting the CCFA plenary evaluate the large number of pending food additives.
9. CCFA should develop a clear detailed explanatory document to be shared with Codex Commodity Committees to ensure food additive activities in these committees are compliant with provisions of the GSFA Preamble and Codex Procedures. This should reduce the amount of time CCFA is required to spend correcting and debating food additive provisions forwarded from Codex Commodity Committees via the endorsement procedure.

IDF appreciates the opportunity to provide input into this important issue and is willing to provide further comments if required.

### **INTERNATIONAL FOOD ADDITIVES COUNCIL (IFAC)**

The International Food Additives Council (IFAC) is an international association representing companies that produce high quality substances used worldwide as food additives. IFAC is recognized by Codex Alimentarius as a Non Government Organization (NGO). IFAC's comments in response to the Codex Committee on Food Additives' Circular Letter CL 2009/7-FA, Part C, are provided below.

The General Standard for Food Additives (GSFA) and progress toward its completion are extremely important to IFAC and other participants of the Codex Committee on Food Additives (CCFA). Progress is unfortunately impeded by participants who appear unwilling to assist in achieving consensus if such is not consistent with their country's regulations. Justification based on scientifically based safety concerns is rarely provided.

IFAC, therefore, provides the following suggestions in the hope of expediting, at least somewhat, the progress on the GSFA.

- 1) Additives to be addressed should be grouped based on either technological purpose or composition. This system has worked well for sweeteners and colors and could likewise work well for other categories. Also if compounds share an Acceptable Daily Intake (ADI) this would appear to be a natural categorization for breaking out compounds for review.
- 2) Also related to the ADI, when possible, all proposed uses and use levels for a given food additive should be addressed at the same time.
- 3) Specific criteria for technological justification should be established to prevent extraneous objections to uses and levels of use. For example, objections must be based on substantiated scientific/toxicological data and documentation required when objections are presented.
- 4) The use of Note 161, "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble," should be either eliminated or severely limited. A legal opinion from WTO experts regarding Note 161 and whether it violates SPS and TBT treaty provisions or is redundant might prove useful.
- 5) The Electronic Working Group (eWG) on the GSFA should be expanded and delegations further encouraged to participate. IFAC supports both the eWG and the Physical Working Group on the GSFA, which provides two opportunities prior to the Plenary Session to resolve issues. Those participating in these groups should be encouraged to voice and document appropriately concerns as early as possible and abide by consensus reached. This would expedite progress in the Plenary Session.
- 6) CCFA should develop a clear explanatory document for Codex Commodity Committees to ensure that the food additive related actions taken by these committees are in line with the provisions of the GSFA Preamble and Codex Procedures. This should reduce time spent by CCFA in correcting and debating Codex Committee food additive provisions.