CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9 **NFSDU/39 CRD/12**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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FOOD ADDITIVES – MECHANISM / FRAMEWORK FOR CONSIDERING TECHNOLOGICAL JUSTIFICATION AND OTHER MATTERS

Comments of Canada, the European Union and the United States of America

CANADA

General Comments

Canada thanks the European Union and the Russian Federation for preparing the background paper and Annex A on the 'Framework for considering the technological justification for substances intended for inclusion on the priority list of substances for JECFA evaluation'.

Canada is proposing for the committee's consideration a simple framework to request that a food additive be placed on the Priority List of Substances Proposed for Evaluation by JECFA when the additive is to be used in any food under CCNFSDU's oversight. Canada considers that because of the case-by-case nature of the uses of additives in products that are considered by the CCNFSDU, JECFA is best suited to determine the appropriate criteria by which to evaluate safety.

If CCNFSDU determines that the use is technologically justified, the request can then be sent to CCFA for consideration at their next meeting, through CCFA's usual process for adding substances to the JECFA Priority List.

The proposed framework from Canada outlines a process where suggested information is to be submitted to CCNFSDU by the petitioner in a new Annex 1 and with the assessment criteria in Annex 2. This will allow CCNFSDU to consider the technological justification for the requested use of the food additive.

Specific Comments on recommendations 1 to 3:

Recommendation 1:

Canada considers that it could be advantageous to use the framework to consider technological justifications for additives that would apply to all foods under the purview of the CCNFSDU. However, this may require either simplification of the questions asked so that they apply to all foods, or clarifications added so as to make it clear as to which questions apply only to infant foods.

Recommendation 2:

Canada remains concerned that the framework as set out in CX/NFSDU 17/39/8 is too complex and goes beyond the need for technological justification. In the hope that a simplified process can be agreed on, Canada is submitting its proposed new framework in Annex 1 (Proposed framework from Canada) and Annex 2 (Proposed assessment criteria for CCNFSDU to use to determine whether the requested use of the additive is technologically justified) as a starting point for consideration by the Committee.

Question 2: Canada considers that Question 2 as written is overly long. In addition, sub-question 2.1 is essentially a re-statement of Question 2 and would not provide any further clarification. Canada recommends that the question be shortened as follows:

"Is the same food currently available without the additive? If yes, explain why the proposed use of the additive is considered necessary."

Question 3: Canada believes that the framework should not contain elements of safety evaluation, which is beyond the scope of the framework, and which is better addressed by the CCFA and JECFA. In particular, the rationale used for Question 3 relies on the assessment of chemical group typing and considerations of

acceptable daily intakes – neither of these is pertinent to technological justification (for an example, please refer to Annex 2). Canada does not object to the question, but recommends that industry's response to this question be revised to reflect technological justification. This is not to suggest that the new proposed additive use should not be considered for justification on a case-by-case basis; but the affirmative or negative answer to this question could help inform how much the technological justification should be scrutinized.

Question 5: The responses to questions on compliance with section 3.2 of the Preamble of the General Standard for Food Additives (GSFA) are among the most important in considering technological justifications. Canada recommends that these questions be placed as Question 2, after Question 1 relating to the aspects of the intended use of the additive.

Question 5.5: Although Canada acknowledges that consideration of practical technological and economical alternatives is included in the Preamble of the GSFA, it is unclear what real value this question provides. It is, in reality, a question that is considered by industry when developing products to be sold in certain markets. In particular, what constitutes an economically practical alternative is very subjective and situational, and scientific committees (such as CCNFSDU and CCFA) do not generally have the competence to adequately consider such matters. Canada recommends that this sub-question not be included in the framework.

Decision tree in Annex B: Canada is concerned by the binary (strict "yes"/ "no") nature of the decision tree presented in Annex B. In particular, the responses to questions 2 and 3 may each relate to multiple variables (such as geography, ingredient supply management, population differences, etc), and a simple "yes" response to both of these questions is not enough to discard the proposed additive use, without further consideration. If, for simplicity, a simple binary decision tree was desired, then Canada recommends that in order for a proposal to proceed through the question process, the responses to each question need to be "satisfactory."

Recommendation 3:

Canada agrees to continue the work on developing the framework and testing the additives referred to in parts b) and c) of the EWG mandate; however, Canada recommends that the process and timelines for this testing be clarified in order to provide a common understanding and to minimize delays.

Annex 1: Proposed framework from Canada:

1. The Codex Secretariat includes in a Circular Letter, issued on behalf of CCNFSDU, a call for requests for food additives to be placed on the JECFA Priority List, when the additives are to be used in foods under CCNFSDU's oversight.

The Secretariat attaches to the circular letter, as an Annex, a **form**[1] that requests the information CCNFSDU will need in order to make a decision about technological justification. Canada's suggested information to request is listed further down in our Annex 1. This process is similar to the one CCFA uses to consider requests to add food additive provisions to the GSFA.

2. The request for the additive is submitted to CCNFSDU by replying to the Circular Letter with the necessary information.

3. At CCNFSDU's next meeting, the Committee evaluates the information on technological justification against assessment criteria that are established as part of this framework. Canada's proposed criteria for the eWG's consideration are in **Annex 2**.

If CCNFSDU agrees that the proposed use of the additive satisfies the established criteria, the Committee records in its report to the Commission that it considers the requested use of the additive to be technologically justified.

4. A request that the additive be placed on the JECFA Priority List is then submitted to CCFA using CCFA's usual process. This involves replying to the Codex Secretariat's Circular Letter "Request for information and comments on the priority list of substances proposed for evaluation by JECFA".

The request is then considered at the CCFA's meeting the March following the CCNFSDU meeting.

5. As part of the request to CCFA, the petitioner cites the report from CCNFSDU to demonstrate that CCNFSDU considers the requested use of the additive to be technologically justified.

Suggested information to be submitted to CCNFSDU by petitioner

Basic information about the proposed use of the additive:

(1) Identify the additive and list the functional classes and technological purposes, if any, that Codex recognizes for this additive in the most recent version of Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989).

(2) Describe how the additive is to be used (e.g. identify the food the additive is to be used in, the proposed level of use for the additive in the food, and the point in food manufacture where the additive is used).

Required information about the proposed use of the additive with which to determine if the proposed use is technologically justified:

Item 1. Explain the specific purpose for using the additive and how such use satisfies one or more of the needs set out in section 3.2 (a) through (d) of the Preamble of the GSFA.

Item 2. Is the same food currently available without the additive? If yes, explain why the proposed use of the additive is considered necessary.

[1]The CCFA form is called the "Form for the Submission of Proposals for New and/or Revision of Adopted Food Additive Provisions in the GSFA".

Item 3. Does Codex already recognize the use of another additive with the same functional class or technological purpose in the food?

Item 4. Explain why the proposed use of the additive is unlikely to mislead consumers.

Annex 2: Proposed assessment criteria for CCNFSDU to use to determine whether the requested use of the additive is technologically justified

In considering the information provided by the petitioner for the proposed food additive use, a satisfactory answer to each question should be apparent, based on the assessment criteria agreed upon by the Committee. Canada proposes the following assessment criteria for consideration.

Item 1. Explain the specific purpose for using the additive and how such use satisfies one or more of the needs set out in section 3.2 (a) through (d) of the Preamble of the GSFA.

Assessment criteria:

(i) The purpose for using the additive is clear

(ii) The information explains how the use of the additive meets one or more of the following:

(a) Preserves the nutritional quality of the food;

(b) Provides necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

(c) Enhances the keeping quality or stability of a food, or improves its organoleptic properties;

(d) Provides an aid in the manufacture, processing, preparation, treatment, packing, transport, or storage of a food.

Item 2. Is the same food currently available without the additive? If yes, explain why the proposed use of the additive is considered necessary.

Assessment criteria if the answer is “no”:

(i) No further assessment of this criterion is required. Proceed to Item 3.

Assessment criteria if the answer is “yes”:

(ii) The information explains why the food without the additive is inadequate for its intended use under the conditions the food is manufactured, distributed, sold, and used by the consumer.

Item 3. Does Codex already recognize the use of another additive with the same functional class or technological purpose in the food?

Assessment criteria:

(i) If the answer is “yes”, Codex already considers the function or technological purpose in the food to be justified, which supports the proposed use of a new additive serving the same function or technological purpose;

(ii) If the answer is “no”, then data should be available to support that the additive will have the intended effect when used as proposed.

As necessary, the data demonstrate the proposed level of use is the minimum amount that is needed for the intended technical effect.

Item 4. Explain why the proposed use of the additive is unlikely to mislead consumers.

Assessment criteria:

(i) CCNFSDU does not identify any specific reason to conclude the proposed use of the additive is likely to mislead consumers.

EUROPEAN UNION

European Union Competence

European Union Vote

The European Union (EU) supports the development of a consistent approach for appraisal of the technological need for the use of food additives in the CCNFSDU standards.

As regards the three recommendations outlined in CX/NFSDU 17/39/8 the EU has the following comments:

Recommendation 1

The EU is of the view that the framework should be used as a general tool for appraising the technological need for food additives intended for use in any food or food ingredient within the mandate of the CCNFSDU.

The EU takes note that the framework would need to reflect the specific considerations applicable to foods intended for infants and young children. A careful approach is especially important for infants under twelve weeks of age since the JECFA ADI is generally not applicable for this age group and the use of food additives would require a specific risk assessment.

Recommendation 2

The EU supports the recommendation.

The EU supports that the criteria are based on checking the eligibility and intended use and the verification of the compliance with section 3.2 of the Preamble to the GSFA.

As for foods intended for infants and young children the EU strongly supports that the criteria also include the principle that "*baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use*".

Recommendation 3

The EU supports continuation of the work on the framework including its testing with the food additives referred to in parts b) and c) of the EWG mandate and if possible also those listed in CRD 15 of the CCFA49.

The EU is concerned that there is no appropriate safety assessment for several adopted food additive provisions for infant formula and formula for special medical purposes intended for infants as outlined by JECFA in CRD 15 of the CCFA49.

The EU is looking forward for a further exchange of views on this matter at the upcoming CCNFSDU Plenary session.

UNITED STATES

General Comments

The United States supports a simpler process that focuses on establishing a technical need (e.g. stabilizer, emulsifier, etc.) then determines if food additives meet that need. The United States views any safety evaluation to be out of scope of the Terms of Reference for this eWG and referable to the Joint Expert Committee on Food Additives (JECFA), the risk assessment body with the relevant expertise to evaluate safety of food additives and their safe level of use. The United States views the issue of additives carried over from raw materials or ingredients, also referred to and in this response as "secondary additives" and the topics of consumer perception, and economic feasibility as out of scope. The TOR is limited to the technological justification of a food additive.

Specific Comments

The United States suggests edits to the framework proposed by the EWG chairs:
Q1: Does the proposed substance meet the Codex definition of a food additive?

Q2: What is/are the functional class(es) and technological purpose(s), if any, of the proposed food additive listed in the Codex Class Names and International Numbering System for Food Additives (CAC/GL 36-1989)?

Q3: What are the specific product(s) and food category (ies) for which the proposed food additive is intended?

Q4: What is the proposed use level of the proposed food additive needed to achieve the intended effect?

Q5: Does the proposed food additive meet the criteria in Section 3.2 of the Preamble to the GSFA?

Q5.1: Which of the needs in Section 3.2 (a) to (d) of the Preamble of the GSFA does the proposed additive meet?

The United States agrees with the need to focus on **Part a)** of the TOR, but recommends also addressing **parts b) and c)** at CCNFSDU39 to progress work and avoid unnecessary delay. The United States suggests that substances addressed in part b) gellan gum and c) xanthan and pectin be used as examples for evaluating or testing the proposed framework. Using these proposed additives as test cases can help illustrate the appropriateness/utility of the questions in the framework and can assist the eWG and Committee members in refining the conceptual framework. Including parts b) and c) will support an informed discussion aimed at reaching a decision on the technical justification for the use of gellan gum, xanthan gum and pectin in all or select products for infants and young children.