CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CRD08**

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

Forty-fourth Session

Dresden, Germany

2 - 6 October 2024

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND ITS SUBSIDIARY BODIES

(Comments by Burundi, Panama, Senegal, Thailand)

Burundi

Position: Burundi agrees that the food additives listed in CXG10-1979 part D may be used as carriers in baby foods in the standard for CXS 73-1981.

Rationale: Considering that they are technologically justified and approved for use in FC 13.2, complementary foods for infants and young children, canned baby foods are also considered as complementary foods and thus the additives are justified to be used.

Issue 2: CCNFSDU to appraise the technological need/justification of methacrylate copolymer, basic (BMC) in commodity standards under their purview in GSFA FCs 13.1, 13.2, and 13.3 as requested by CCFA54(2024) and inclusion of General Principles for the Addition of Essential Nutrients to Foods (CXG 9-1979) on the list of Codex texts requiring technological justification.

Position: Burundi agrees that there is a technological justification for use of BMC as a carrier/glazing agent for nutrients in FC 13.1, 13.2 and 13.3 for products covered by CXS 72-1981, CXS 156-1987, CXS 73-1981, CXS 74-1981, and CXG 95-2022.

Rationale: JECFA has conducted risk assessment and concluded that BMC may be used at GMP level. Therefore, there is no known risk of exposure on using BMC.

In addition, during food fortification of oil with vitamin A, there is a high risk of vitamin A loss due to environmental conditions, thus reduced availability in the food carrier/vehicle. Therefore, coating vitamin A with BMC will significantly increase the availability and retention of vitamin A in fortified foods like oil for food consumption hence allowing the objective of strengthening the immune system and reducing the risk of mortality in young children and other vulnerable populations.

Issue3: Adoption of the Nitrogen to protein conversion factors Annex in CXS 234-1999 and revoking Nitrogen conversion factors in the standards

Position: Burundi supports the inclusion of an annex into CXS 234-1999 for the nitrogen conversion factors and subsequent revocation of nitrogen conversion factors in commodity standards. However, there is need to provide a standard text as a guideline for the commodity standards users linking the proposed annex in CXS 234-1999 and commodity standards regardingNx values.

Rationale: A single point of reference will ensure consistency in the Nx values of products and avoid different values for similar products. This is consistent with ongoing efforts on alignment of food additives with CXS 192-1995 and well as alignment between CXS 1-1995 (General Standard for the Labelling of Prepackaged Foods) and commodity standards.

Panama

Panama appreciates the exhaustive work carried out by the Codex Alimentarius Commission and its subsidiary bodies in preparing document CX/NFSDU 24/44/2. We value the commitment of all members in identifying and reviewing the issues referred.

We support the review of the issues raised and suggest that a more detailed assessment of the potential impacts of the recommendations in various regional contexts be undertaken. Understanding how each recommendation may affect different countries is crucial to ensuring their effectiveness and relevance.

We also consider it useful to incorporate a broader impact analysis, which can help tailor recommendations to the specific needs of each region and promote best practices in the implementation of food regulations.

Spanish:

Panamá agradece el trabajo exhaustivo realizado por la Comisión del Codex Alimentarius y sus órganos auxiliares en la preparación del documento CX/NFSDU 24/44/2. Valoramos el compromiso de todos los miembros en la identificación y revisión de los asuntos remitidos.

Apoyamos la revisión de los temas planteados y sugerimos que se realice una evaluación más detallada de los impactos potenciales de las recomendaciones en diversos contextos regionales. Comprender cómo cada recomendación puede afectar a los diferentes países es crucial para garantizar su efectividad y pertinencia.

También consideramos útil incorporar un análisis de impacto más amplio, lo cual puede ayudar a adaptar las recomendaciones a las necesidades específicas de cada región y promover mejores prácticas en la implementación de normativas alimentarias.

Senegal

Questions soumises par les organes subsidiaires

Questions demandant une action

Cinquante-quatrième session du Comité du Codex sur les additifs alimentaires

Question 2: Le CCFA 54 a demandé au CCNFSDU d'évaluer la nécessité/justification technologique du copolymère de méthacrylate basique (BMC) dans les normes de produits relevant de sa compétence dans les FC 13.1, 13.2 et 13.3 de la NGAA, comme demandé par le CCFA54 (2024) et l'inclusion des Principes généraux pour l'adjonction d'éléments nutritifs essentiels aux aliments (CXG 9-1979) sur la liste des textes du Codex nécessitant une justification technologique.

Contexte: Au cours du CCFA51, le JECFA a soumis l'évaluation des risques pour le BMC (INS 1205) avec des résultats de données toxicologiques indiquant une faible adsorption et n'indiquant aucun effet nocif sur la santé, même aux doses les plus élevées testées. Le Secrétariat du JECFA a également souligné que l'évaluation de la sécurité ne couvrait que les utilisations proposées du BMC comme agent d'enrobage ou de glaçage pour les compléments alimentaires solides, pour les aliments destinés à des fins médicales spéciales, encapsulation de micronutriments pour l'enrichissement des aliments et aux niveaux d'utilisation prévus (REP19/FA Para 16). En conséquence, le CCFA51 a convenu d'émettre des lettres circulaires sur le niveau d'utilisation pour renseigner la NGAA. Le CCFA52 (2021) a adopté l'utilisation du BMC dans les farines et le sel. Le CCFA54 a reçu une demande d'inclusion du BMC dans les catégories d'aliments 13.1, 13.2 et 13.3, mais comme l'exige la procédure lorsqu'il existe un comité actif, le CCFA demande à ce comité un besoin/une justification technologique. C'est dans ce contexte que le CCFA54 demande au CCNFSDU44 d'évaluer la justification technologique de l'utilisation du BMC dans ces catégories d'aliments.

Position: Le Sénégal convient qu'il existe une justification technologique à l'utilisation du BMC comme support/agent d'enrobage pour les nutriments des catégories FC 13.1, 13.2 et 13.3 pour les produits couverts par les normes CXS 72-1981, CXS 156-1987, CXS 73-1981, CXS 74-1981 et CXG 95-2022.

Justification: Le JECFA a mené une évaluation des risques et a conclu que le BMC peut être utilisé au niveau des BPF. Par conséquent, il n'y a aucun risque connu d'exposition lié à l'utilisation du BMC.

De plus, lors de l'enrichissement alimentaire de l'huile en vitamine A, il existe un risque élevé de perte de vitamine A en raison des conditions environnementales, ce qui réduit la disponibilité dans le support/véhicule alimentaire. Par conséquent, l'enrobage de la vitamine A avec du BMC augmentera considérablement la disponibilité et la rétention de la vitamine A dans les aliments enrichis comme l'huile destinée à la consommation alimentaire, permettant ainsi d'atteindre l'objectif de renforcement du système immunitaire et de réduction du risque de mortalité chez les jeunes enfants et autres populations vulnérables.

La Justification technologique du BMC est en annexe

MATTERS ARISING FROM OTHER SUBSIDIARY BODIES

Matters for action

54th Session of the Codex Committee on Food Additives (CCFA54)

Issue 2: CCNFSDU to appraise the technological need/justification of methacrylate copolymer, basic (BMC) in commodity standards under their purview in GSFA FCs 13.1, 13.2, and 13.3 as requested by CCFA54 (2024) and inclusion of General Principles for the Addition of Essential Nutrients to Foods (CXG 9-1979) on the list of Codex texts requiring technological justification.

Background: During CCFA51, JECFA submitted the risk assessment for BMC (INS 1205) with toxicological data results indicating low adsorption and did not indicate any adverse health effects even at the highest doses tested. The JECFA Secretariat also stressed that the safety evaluation only covered the proposed uses of BMC as a coating or glazing agent for solid food supplements; for foods for special medical purposes; micronutrient encapsulation for food fortification and at the intended use levels (REP19/FA Para 16). As a result, CCFA51 agreed to issue circular letters on use level to populate the GSFA. CCFA52 (2021) adopted the use of BMC in flours and salt. CCFA54 received a request to include BMC in FC 13.1, 13.2 and 13.3 but as required procedurally where there is an active committee, CCFA request for technological need/justification from that Committee. It is against this background that CCFA54 requests CCNFSDU44 to appraise the technological justification for the use of BMC in these food categories.

Position: Senegal agrees that there is a technological justification for use of BMC as a carrier/glazing agent for nutrients in FC 13.1, 13.2 and 13.3 for products covered by CXS 72-1981, CXS 156-1987, CXS 73-1981, CXS 74-1981, and CXG 95-2022.

Rationale: JECFA has conducted risk assessment and concluded that BMC may be used at GMP level. Therefore, there is no known risk of exposure on using BMC.

In addition, during food fortification of oil with vitamin A, there is a high risk of vitamin A loss due to environmental conditions, thus reduced availability in the food carrier/vehicle. Therefore, coating vitamin A with BMC will significantly increase the availability and retention of vitamin A in fortified foods like oil for food consumption hence allowing the objective of strengthening the immune system and reducing the risk of mortality in young children and other vulnerable populations.

Annex II: Form for appraising the technological need for the use of additives in foods within the mandate of CCNFSDU (i.e. standardized or non-standardized foods following a request by CCFA)

THE PROPOSAL IS SUBMITTED BY:	**SENEGAL**
Q1 IDENTITY AND INTENDED USE	
Q1.1 Name and INS number of the food additive as listed in CXG 36-1989: For substances not yet included in CXG 36-1989, chemical name of the substance.	**METHACRYLATE COPOLYMERE, BASIQUE INS 1205**
Q1.2 Describe the food and its form (e.g. liquid, powder) for which the additive is intended to be used and indicate the relevant CCNFSDU standard and if known the GSFA food subcategory	
13.1 Infant formulae, follow-up formulae, and formulae for special medical purposes for infants: Foods that are intended for infants and for young children as defined in the sub-categories 13.1.1, 13.1.2, and 13.1.3. 13.2 Complementary foods for infants and young children: Foods that are intended for infants 6 months of age and older, and for progressive adaptation of infants and children to ordinary food. Products may be ready-to-eat or in powder form to be reconstituted with water, milk, or	

other suitable liquid. These foods exclude infant formulae (13.1.1), follow-up formulae (13.1.2), and formulae for special medical purposes (13.1.3).78 Examples include: cereal-, fruit-, vegetable-, and meat- based "baby foods" for infants, "toddler foods," and "junior foods"; lactea flour, biscuits and rusks for children.

13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1):

Foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein, or who have other special medically-determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

CCNFSDU standard

Reference	**Name of the standard**	**Comments (e.g. limitation of use to specific products)**

GSFA food category

Food category No	**Name of the GSFA food category**
FC 13.1 **FC 13.2** **FC 13.3**	

Q1.3 Indicate and justify the range of the proposed use level of the food additive needed to accomplish the desired technological effect at the lowest possible use level

Proposed (range of) lowest possible use level to accomplish the desired effect (expressed on the final product as consumed)	**Justification of the level(s) proposed**
	BMC has an ADI of "not specified". It is used for its encapsulation capacity to encapsulate vitamin A palmitate (VAP) and protect it from external degradation effects. PFH-VAP has equal levels of BMC and VAP. The ratio of BMC to VAP will not change depending on the food vehicle. The VAP limits are all below the EFSA-defined BMC limit of 700mg/day in the EU. The toxicity of VAP is reached well before that of BMC. For example, the WHO recommended nutrient intake of Vitamin A for children ages 1-3 years old is 400 ug RE/day or 0.73 mg VAP/day. Considering the 1:1 ratio, PFH-VAP will only deliver 0.73mg of BMC/day, which is significantly below the 700mg/day limit. PFH-VAP will not exceed 10% of BMC in the total dietary limit. The VAP limits are well below the EFSA limits of 700mg/day for BMC.

Q2 COMPLIANCE WITH SECTION 3.2 OF THE PREAMBLE TO THE GSFA

Q2.1 Describe the technological function of the food additive relative to the CXG 36-1989 (include the functional class) and the advantage conferred by its use

Technological function relative to the CXG 36-1989: *Advantage from the use of the additive:* INS 1205 Méthacrylate copolymère, basique – Carrier – Encapsulation. - Protects nutrients from degradation by external environmental factors until they are delivered to the consumer; - Ensures better bioavailability of vitamin A
Q2.2 Does the use of the food additive serve one or more of the needs set out from (a) through **(d) of Section 3.2 of the Preamble to the GSFA? Indicate which one(s)**
a. To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet; b. To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
Q2.3 Cannot the objectives set out from (a) through (d) of Section 3.2 of the Preamble to the GSFA be achieved by other means that are economically and technologically practicable?
No, the objectives cannot be achieved with other economically and technologically applicable means because the use of BMC gives the best results in the current state of our knowledge.
Q2.4 Would the use of this food additive in the intended food(s) modify any characteristic of the food that might mislead the consumer? For example the nature, substance, quality or nutritional quality of the food, the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques by which the consumer might be misled**.**
No, BMC will not change the quality of the food. On the contrary, it will stabilize and improve its effectiveness through its greater bioavailability.
Q3 COMPLIANCE WITH THE APPROACH ON THE USE OF ADDITIVES IN FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN
Q3.1 Does the proposed food additive perform the same/similar technological purpose as other food additives that have already been authorized for use in the same product category? If not, what is the justification for the need for a food additive with a new functional class and/or technological purpose? If yes, what advantage(s) does the proposed food additive provide over currently permitted options?
BMC is a new additive that was approved by the CAC in 2021 after its evaluation by JECFA as ADI "not specified". Its INS is 1205 with a functional class Glazing Agent and Carrier. BMC has a technological purpose: carrier and encapsulating agent. BMC is used to encapsulate micronutrients, for example vitamin A palmitate (VAP), which will be added to GSFA vehicle foods in the fortification strategy/policy of African countries such as Senegal where climatic conditions (storage and exposure to light) are difficult and alter the bioavailability of vitamin A. Furthermore, BMC has no toxic effects.

Thailand

Matters for information / action

- **53rd Session of the Codex Committee on Food Additives**)**CCFA53**(

From our view, CXS 73-1981 should permit the use of the food additives listed in CXG 10-1979, Part D as nutrient carriers.

- **54th Session of the Codex Committee on Food Additives**)**CCFA54**(

We view that the technological need/justification of methacrylate copolymer, basic (BMC) under Agenda item **5** should be considered.

- **43rd Session of the Codex Committee on Methods of Analysis and Sampling**)**CCMAS43**(

the approach for the placement of nitrogen conversion factors **)**Nx**(**

1. We view that Nx values as described in footnote 1, a) protein under Section Essential composition and quality factors should be retained.

2. We agree to forward the document titled **"**Nitrogen to protein conversion factors**"** to 47th CAC for adoption as an Annex to CXS 234**-**1999 as proposed by 43rdCCMAS **)**REP24**/**MAS, Appendix II, Part 3**(.**

3. We have an observation that the wording related to Nx in the mentioned Annex is only reflected the wording from the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981) and in the current related footnote in CXS 234 which is different from that of the recently revised Standard for Follow-up formula for Older Infants and Product for Young Children (CXS 156-1987). Thus, its wording related to Nx as described in Footnote 1, should be added into the Annex.