CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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

Agenda Items 2, 3a, 3b, 4a, 4b, 5a, 5c, 5d, 6, 7, 8 CRD 36

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

Comments of Russian Federation

Item 2

Matters Referred By The Codex Alimentarius Commission and other Subsidiary Bodies

Others

1. Editorial amendments to the descriptors of FC 14.1.4.2 and FC 14.1.5

We support the introduction of changes to the description of food categories in terms of the listing of food categories in points FC 14.1.4.2 and FC 14.1.5. These changes indeed could clarify the difference between these food categories.

2. Sorbitol syrup (INS 420(ii)): safety evaluation

The Russian Federation supports inclusion of Sorbitol syrup (INS 420(ii)) in the JECFA priority list to provide data for its safety evaluation by CCFA52.

In the Russian Federation, the adequate level of consumption (15 g/per day per person) and the upper permissible level (40 g/per day per person) from all sources have been established for this food additive because of a likely laxative effect.

3. Carotenoids, chlorophylls and chlorophyllins, copper complexes and polysorbates

The Russian Federation proposes to consider an algorithm of combining food additives into groups not only in accordance with the ADI values **but also in accordance with their functional classes**.

Item 3a

Matters of interest arising from FAO/WHO and from the 84th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Actions required as a result of changes in acceptable daily intake (ADI) status and other toxicological recommendations from JECFA:

INS	Food additive	Required actions
133	Brilliant Blue FCF	The 84th JECFA established for INS133 an ADI of 0–6 mg/kg bw. The previous ADI of 0–12.5 mg/kg bw was withdrawn. In this regard, we believe that in all food categories in which this food additive is currently allowed MLs should be lowered accordingly
	β-Carotene-rich extract from Dunaliella salina	Beta-carotene is a provitamin A. Physiological requirement for adults is 5 mg/day per person The upper permissible intake level is 10 mg / day per person from all sources (natural content in food + biologically active additive + food additive)
	Yeast extracts containing mannoproteins	The information provided does not contain data on the species, GMM origin, and results of risk assessments of the strain-producer.

Item 3b

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 84TH JECFA MEETING

INS	Food additive	Required actions
551	Silicon dioxide, amorphous (R)	Unfortunately, the 84th JECFA did not consider of nanoparticles included in INS 551 and results of its risk estimation for consumers. We believe that the contents of nanoparticles needs to be included in the specification due to certain concerns of nanotoxicity. We consider this as the basis for further evaluation of INS 551 by JECFA.

Item 4a

REGIONAL STANDARD FOR DOOGH (at Step 5/8)

When considering the standard, please take into consideration the position of the Russian Federation regarding the use of food additives in the "DOOGH" drink. All proposals for changing MLs are based on the need to ensure the safe use of these food additives.

INS	Food additive	Proposed M**aximum Level**	ADI	Position of The Russian Federation (based on ADIs)
104*	Quinoline yellow	150 mg/kg	Temporary ADI of 0-3 mg/kg bw (82th JECFA, 2016)	ML should not be more than 10 mg/kg.
110*	Sunset yellow FCF	300 mg/kg	0-4 mg/kg bw (74th JECFA, 2011)	ML should not be more than 5 mg/kg.
122	Azorubine (Carmoisine)	150 mg/kg	0-4 mg/kg bw (27th JECFA, 1983)	ML should not be more than 5 mg/kg.
124	Ponceau 4R (Cochineal red A)	150 mg/kg	0-4 mg/kg bw (74th JECFA, 2011)	ML should not be more than 5 mg/kg.
~~151~~	~~Brilliant black (Black PN)~~	~~150 mg/kg~~	0-1 mg/kg bw (25th JECFA, 1981)	Not allowed in this FC in The Russian Federation
~~155~~	~~Brown HT~~	~~150 mg/kg~~	0-1.5 mg/kg bw (28th JECFA, 1984)	
160b(i)	Annatto extract, bixin-based	20 mg/kg	as bixin 0 – 12 mg/kg bw for bixin and 0 – 0.6 mg/kg for norbixin and its disodium and dipotassium salts (67th JECFA, 2006)	ML should not be more than 10 mg/kg.
160b(ii)	Annatto extract, norbixin-based	20 mg/kg		
432-436	Polysorbates	3000 mg/kg	0-25 mg/kg bw (17th JECFA, 1973)	ML should not be more than 1000 mg/kg.
~~900a~~	~~Polydimethylsiloxane~~	~~50 mg/kg~~	0–1.5 mg/kg bw (80th JECFA, 2011)	Proposal should be removed because it lacks technological justification. Not allowed in The Russian Federation
200-213	Sorbic acid — sorbates; Benzoic acid — benzoates	1000 mg/kg	Group ADI 0-25 mg/kg bw for sorbic acid and its Ca, K, & Na salts (17th JECFA, 1973)	ML should be no more than 300 mg/kg. Should be used only in non-heat-treated dairy-based desserts
~~234~~	~~Nisin~~	~~12 mg/kg~~	0–2 mg/kg bw (77th JECFA, 2013)	The Russian Federation does not agree with proposal. Antibiotics should not be used in food because a worldwide problem of the AMR.

INS	Food additive	Proposed M**aximum Level**	**ADI**	**Position of The Russian Federation (based on ADIs)**
961	Neotame	100 mg/kg	0-2 mg/kg bw (61st JECFA, 2003)	ML should not be more than 32 mg/kg. Should be used only in energy-reduced doogh or with no added sugar
*The total quantity of E 104, E 110, E 124 and the colours in Group III shall not exceed the maximum listed for Group III				

All sweeteners should be used only in energy-reduced doogh or with no added sugar.

Item 4b

Alignment of the Food Additive Provisions of Commodity Standards and relevant provisions of the General Standard For Food Additives (GSFA)

General Comments:

The Russian Federation supports the work on harmonization of requirements for the use of food additives in commodity standards on certain types of food products and the General Standard for Food Additives (CAC 192-1995).

The preamble of Agenda Item 4b contains a description of principles used for inclusion of food additives in Tables 1, 2 and 3 of CAC 192-1995. These principles are based on the safety and technological justification of food additive use in the manufacture of various food products, including non-standardized food products.

At the same time, the preamble of CAC 192-1995 states that the use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions.

We believe that proposals for expanding the scope of the use of food additives in certain categories of food products should account for **the level of consumption from all food categories** and, associated risks for human health. An example of this approach, leading to the need to review the list of food additives, were aluminum-containing food additives.

It is necessary to specify the rules for justifying the technological need in greater detail.

These principles should be reflected in the “Decision tree for the recommended approach to alignment of the GSFA and commodity standards food additive provisions” (Attachment 2 of Appendix 6).

Item 5a

Appendix 4: Food Category No. 01.1.1 (Fluid milk (plain))

General Comments:

The Russian Federation does not currently permit any additives for use in plain fluid milk products. The Russian Federation strongly opposes the use of food additives (with the exception of phosphates) in FC No. 01.1.1 (Fluid milk (plain)).

1. The Russian Federation does not agree with use of food additives in category «01.1.1 Milk (plain)» and sub-categories. Widely used ultra-high temperature (UHT) treatment or sterilization of milk do not require use of food additives (except phosphates) before or after. Moreover, the use of emulsifiers, fillers, stabilizers should not be tolerated in milk as they affect milk intrinsic properties.

2. The use of food additives in milk (plain) could mislead consumers and facilitate adulteration.

4. Milk (plain) is broadly used as an ingredient of baby foods and most of the food additives proposed are not allowed in foods for children under 3 years old (see Carry-over principles of food additives into foods).

5. No technological justifications were provided for the use of these FA in this FC.

Recommendations on the expression of the ML for Trisodium citrate (INS 331(iii)) in food category 01.1.1:

There is technological justification for to use of Trisodium citrate INS 331(iii) in case with only UHT goat milk.

Food Category No. 14.1.2 Fruit and vegetable juices

Food Category No. 14.1.3 Fruit and vegetable nectar

General Comments:

We believe that the proposals submitted for consideration by CCFA 50 on the use of food additives in fruit, vegetable juices and nectars **violate the basic principles of the use of food additives**, since the use of emulsifier, stabilizer, thickener and other food additives in fruit and vegetable juices and nectars could mislead consumers. The use of food additives in juices could change their organoleptic properties and **nutritional value**, contributing to the spread of alimentary diseases. In addition, we believe that the use of food additives in the production of juices and nectars is not technologically justified.

Item 5c

DISCUSSION PAPER ON THE USE OF NITRATES (INS 251, 252) AND NITRITES (INS 249, 250)

We believe that the working out MLs for nitrates and nitrites and drafting a list of foods in which these food additives could be used should be primary tasks of the CCFA.

In order to reduce risks of using nitrates (INS 251, INS 252) and nitrites (INS 249, INS 250) and the exposure to nitrosamines which are formed in nitrite and nitrate metabolism in the human body, countries need to provide data on possible levels of nitrate, nitrate and nitrosamine consumption from different sources (water, vegetables, fruits, meat and fish products) for different age and social groups of the population.

At the next stage, it is proposed to run a risk assessment and develop measures to prevent the risks (including the need to review the MLs of nitrites and nitrites in various categories of food). This work should be carried out in accordance with the basic principles of food safety risk assessment developed by FAO / WHO:

- Risk assessment (1995);

- Risk Management (1997);

- Risk Communication (1998).

This work will require an analysis of all available scientific data. In addition, it is not possible to analyze the situation and develop appropriate measures in this case without involving other Codex committees.

In the Russian Federation, nitrates (INS 251, INS 252) are used as food additives up to the following MLs (alone or in combination in terms of $NaNO_3$ - residual amounts): sausages and meat products salted, boiled, smoked and canned meat - not more than 250 mg / kg; cheeses hard, semisolid, soft - not more than 50 mg / kg; substitutes for cheeses on a milk basis - not more than 50 mg / kg; herring, sprat is salted and in marinade - no more than 200 mg / kg. Potassium nitrite (INS 249) and sodium nitrite (INS 250) are allowed as food additives in the following dosages (individually or in combination in terms of NaNO2 - residual amounts): sausages and meat products, smoked, salted, dried, boiled sausages and other boiled meat products, canned meat - not more than 50 mg / kg. In children's food products (canned meat, pasteurized sausages on a meat basis, meat and vegetable canned food (vegetable and meat canned food), meat semi-finished products, pates and culinary products) nitrites are not allowed (<0.5 mg / kg). These MLs completely (250 mg/kg for nitrates and 50 mg/kg for nitrites) ensure that the additives when used in foods provide sufficient protection for human health during the shelf life, including bacteriostatic effect on *Clostridium botulinum, Listeria monocytogenes, Salmonella spp. and* produce a pink colour of meat products already more than 20 years.

Our MLs are based on scientific evidence collected for nitrates and nitrites and their negative influence on human body from all sources (water, fruit and vegetables and food additives). The evidence was last re-evaluated in 2015 year. The MLs lfor nitrites and nitrites are achievable if HACCP is observed in food manufacturing and handling.

Recommendation 4:

08.2.1.1 Cured (including salted) non-heat treated processed meat, poultry, and game products in whole pieces or cuts							
Types of products or production processes	**Maximum Use Level**						**Are there alternatives to the proposed use of nitrites available?**
	Maximum ingoing amount on the total net content of the final product expressed as NO_2 ion			**Maximum residual amount on the total net content of the final product expressed as NO_2 ion**			
	Preservation	**Colour retention**	**Cured taste**	**Preservation**	**Colour retention**	**Cured taste**	
Meat and fish products and it's production process	*70-80* mg/kg	*70-80* mg/kg	*70-80* mg/kg	*30-50* mg/kg	*30-50 mg/kg (3-5 mg/kg gives a rosy tint)*	*30-50 mg/kg*	*strict adherence of GMP measures*

Item 5d

DISCUSSION PAPER ON THE USE OF THE TERMS "UNPROCESSED" AND "PLAIN" IN THE GSFA

The document was prepared by the Russian Federation describing requirements for the use of food additives in unprocessed food (food raw materials or fresh food) and minimally processed (plain) foods.

The paper proposes to:

- Consider the definitions of unprocessed (food raw materials or fresh food) and minimally processed (plain) foods for inclusion in the General Standard for Food Additives (CXS 192-1995)

- consider the proposal to ban the use of food additives in unprocessed foods and limited use of food additives in minimally processed foods.

In this regard, we propouse to establish an electronic working group to work on principles of technological justification for the use of food additives in minimally processed (plain) food.

Item 6

PROPOSED DRAFT AMENDMENTS TO THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES (CXG 36-1989)

1. Steviol glycosides from Steviol glycosides from fermentation (INS 960b) - Sweetener
2. Rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica (960b(i)) - Sweetener

   Evidence provided to justify the use of these additives needs to be supported by additional data, according to the Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms - CAC/GL 46-2003. Until then, we do not support inclusion of these additives in the INS list of food additives.

Item 7

ROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

1. Benzoates (INS 210-213)

At the request of CCFA at its Forty-sixth Session (2015), the Committee evaluated dietary exposure to benzoic acid salts (benzoates). An acceptable daily intake (ADI) of 0–5 mg/kg body weight (bw), expressed as benzoic acid (300 mg/per person with body mass 60 kg and 100 mg/per person with body mass 20 kg) was established.

CCFA 49 has not adopted ML of 250 mg/kg with Note 13 (as benzoic acid) and note "Except for use in cream sodas, root beers and similar types of products and concentrates used in frozen beverage at 500 mg/kg as consumed".

In the Russian Federation and the Eurasian Economic Union, the following levels have been established for benzoates (INS 210-213) for the use in non-alcoholic flavored beverages (water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks):

INS 210 Benzoic acid INS 211 Sodium benzoate INS 212 Potassium benzoate INS 213 Calcium benzoate Note 13 (As benzoic acid)	Non-alcoholic flavored beverages, ML =150 ppm

These MLs have been set to ensure the microbiological safety of beverages during their shelf life.

We consider it not advisable to include benzoates in the JECFA priority list.

2. **INS No 960 steviol glycosides - revision of specifications for Rebaudioside A from Multiple Gene Donors Expressed in Yarrowia Lipolytica, FAO JECFA Monograph 19 (2016)**

   Adenosine-5’-monophosphate deaminase (AMP deaminase) derived from Aspergillus melleus and Streptomyces murinus

Evidence provided to justify the use of these additives needs to be supported by additional data, according to the Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms - CAC/GL 46-2003.

Item 8

DISCUSSION PAPER ON “FUTURE STRATEGIES FOR CCFA”

In line with our comment that we cannot agree with the suggestion that the chairs of the eWG should be those giving the right to prioritize the topics, the Russian Federation added some important paragraphs in the proposed table. New paragraphs are **in bold.**

The draft criteria for CCFA to prioritize its work:

Question	Rating
1. Does the topic fall within the mandate of CCFA?	Yes/No If “yes” proceed to the following questions. If “no” discard the proposal.
2. Can the topic be addressed through one of the existing EWGs (EWG on GSFA, Alignment, INS, JECFA priority list)?	Yes/No If “yes” refer to ~~Chair of relevant EWG~~ **CCFA for prioritisation.** If “no” proceed to next question.
3. Is there a risk to public health?	Global Risk: 5 Regional Risk: 3 Small Risk: 0
4. Is the use technologically justified?	**Yes/No** **If “yes” proceed to the following questions.** **If “no” discard the proposal.**
5. Is there an advantage in the use of the additive?	**Yes: 10** **No : 0**
6. Could the use of the additive mislead consumers?	**Yes:0** **No:10**
7. Is there impact on international food trade?	Global Trade Impact: 5 Regional Trade Impact: 3 Little international trade impact: 0
8. Is the topic relevant to completing the GSFA to be the single authoritative Codex Standard for the use of food additives?	Yes: 10 No : 0