

CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 5(d)

CX/FA 16/48/10 Add.1
March 2016

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-eighth Session

Xi'an, China, 14-18 March 2016

USES AND USE LEVELS OF PAPRIKA EXTRACT (INS 160C (II))

Replies to CL 2015/9-FA Part C, point 8 of Russian Federation, IACM and NATCOL

RUSSIAN FEDERATION

Russian Federation does not support the use of paprika extract (INS 160c (ii)) in the following food categories:

- 01.6.4.1 Plain processed cheese
- 02.2.1.1 Butter and concentrated butter
- 04.1.1.2 Surface-treated fresh fruit
- 04.1.2.2 Dried fruit
- 08.1 Fresh meat, poultry and game
- 08.1.1 Fresh meat, poultry and game, whole pieces or cuts
- 08.1.2 Fresh meat, poultry and game, comminuted
- 09.1 Fresh fish and fish products, including molluscs, crustaceans, and echinoderms,
- 10.1 Fresh eggs.

The use of food additives in these food categories can mislead the consumer on the product quality. It is necessary to give risk estimation and risk assessment of all proposed ML of paprika extract (INS 160c (ii)) because it is biological active food compound.

INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS (IACM) AND NATURAL FOOD COLOURS ASSOCIATION (NATCOL)

FORM FOR THE SUBMISSION OF PROPOSALS FOR NEW AND/OR REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA

In completing this form, only brief information is required. However, responsive information is required for each field. The form may be retyped if more space is needed under any one heading provided that the general format is maintained. A separate table should be completed for each food additive.

THE PROPOSAL IS SUBMITTED BY:	<i>International Association of Color Manufacturers (IACM) & Natural Food Colour Association (NATCOL)</i>
IDENTITY OF THE FOOD ADDITIVE:	
Name of the Additive <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	<i>Paprika extract</i>
INS Number	<i>160c(ii)</i>
Functional Class <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>	<i>colour</i>
PROPOSED USE(S) OF THE FOOD ADDITIVE (1):	The proposal for <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision <i>Please see original replies CX/FA 16/48/10 (USES AND</i>

	<i>USE LEVELS OF PAPRIKA EXTRACT (INS 160C (II)) Replies to CL 2015/9-FA Part C by IACM and NATCOL for this information; requesting consideration of maximum levels as submitted.</i>
EVALUATION BY JECFA:	
Evaluation by JECFA <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph).</i>	<i>Evaluation year: 2014, 79th Meeting ADI: 0–1.5 mg/kg bw, Expressed as total carotenoids Specification: FAO JECFA Monographs 16/49</i>
JUSTIFICATION:	
Justification for use and technological need <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>	<i>Serves a technological function as colour</i>
Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	<i>Table 3 additive: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Please provide information on dietary intake assessment below) As indicated in the 2014 JECFA evaluation (WHO Technical Report Series, No. 990, 2014), the assessment of dietary exposure to paprika extract used as a colour was based on exposure to total carotenoids in paprika extract. Based on survey data, the highest exposure at the 95th percentile was estimated to be 6.3–13.2 mg/day (equivalent to 0.1–0.2 mg/kg bw per day, based on a body weight of 60 kg), which is below the ADI. The Committee concluded that dietary exposure to paprika extract used as a food colour does not present a health concern.</i>
Justification that the use does not mislead consumer	<i>It is common practice that colour such as paprika extract is used in food. Any use of paprika extract in food would need to be labelled, thus informing the consumer. Other colours are already allowed in the food categories proposed so it would not be misleading to the consumer.</i>

- (1) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strikethrough~~ text, and changes or additions noted in **bold** font.
- (2) Food category number and name, as listed in Annex B of the GSFA.
- (3) For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g., “not-specified”).
- (4) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g., limitation of use to specific products in a food category).

NATURAL FOOD COLOURS ASSOCIATION (NATCOL)

NATCOL appreciates the opportunity to provide comments on CX/FA 16/48/10 (USES AND USE LEVELS OF PAPRIKA EXTRACT (INS 160C (II)) Replies to CL 2015/9-FA Part C) Natural Food Colour Association - is an international body acting on behalf of the natural food colour industry. NATCOL offers expertise on natural colours regarding their properties, use, and regulatory status. NATCOL is a non-profit organisation.

In particular, NATCOL wishes to highlight an error in the reporting in one of the provisions previously submitted in CX/FA 16/48/10 as Paprika Extract INS 160c(ii) i.e. the provisions for Food Category 08.4 (Edible casings), which should be listed on the weight basis of the casings themselves (not on the sausage basis as NATCOL submitted in October 2015). At this time, NATCOL wishes to submit our additional comment on Paprika Extract INS 160c(ii) as a comment to CX/FA 16/48/10 for inclusion as an addendum document or as a CRD on this Agenda item (5d).

General Comments:

After consultation with both the EU Codex representative and the US Codex representatives in order to get clarity on the reporting basis for the Food Category 08.4 (Edible casings), we have been advised as follows:

In the EU legislation the MPLs apply to the food as marketed, unless otherwise stated (see Article 11, (3) of Regulation (EC) No 1333/2008). In the GSFA the MPLs are set on the final product as consumed, unless otherwise specified (see Preamble to the GSFA, Section 6 (c)).

We understand that in both cases the meaning was to indicate that the MPLs are not related to intermediate products but to the final product (as marketed / consumed) of a given food category since the concentration of an additive could differ during the production process (e.g. due to dilution or concentration steps). There is a category 'casings' in the GSFA and indeed the final product of the category casings would be a casing (which can be marketed and consumed when used as a contained for sausages). Therefore, it is clear that in the case of the category 08.4 Edible casings the MPL relate to casings not to sausages.

Specific Comments on Provisions for Paprika Extracts in Food Category 08.4 (Edible Casings):

After internal discussions with the European paprika producers whose data we submitted to both the EU and CODEX, we would now propose use levels for Food Category 08.4 (Edible casings);

in the casing of 900 - 3900 - 9000 mg/kg (min – typical – max) to reflect levels

in the sausage as eaten of 9 - 39 - 90 mg/kg (min – typical – max).

For perspective typically a casing is 0.3% of a sausage but this depends on diameter so it can be up to 1.0%.

NATCOL appreciates the opportunity to provide comments on CX/FA 16/48/10 (USES AND USE LEVELS OF PAPRIKA EXTRACT (INS 160C (II)) Replies to CL 2015/9-FA Part C) Natural Food Colour Association - is an international body acting on behalf of the natural food colour industry. NATCOL offers expertise on natural colours regarding their properties, use, and regulatory status. NATCOL is a non-profit organisation.

In particular, NATCOL wishes to highlight an error in the reporting in one of the provisions previously submitted in CX/FA 16/48/10 as Paprika Extract INS 160c(ii) i.e. the provisions for Food Category 08.4 (Edible casings), which should be listed on the weight basis of the casings themselves (not on the sausage basis as NATCOL submitted in October 2015). At this time, NATCOL wishes to submit our additional comment on Paprika Extract INS 160c(ii) as a comment to CX/FA 16/48/10 for inclusion as an addendum document or as a CRD on this Agenda item (5d).

General Comments:

After consultation with both the EU Codex representative and the US Codex representatives in order to get clarity on the reporting basis for the Food Category 08.4 (Edible casings), we have been advised as follows:

In the EU legislation the MPLs apply to the food as marketed, unless otherwise stated (see Article 11, (3) of Regulation (EC) No 1333/2008). In the GSFA the MPLs are set on the final product as consumed, unless otherwise specified (see Preamble to the GSFA, Section 6 (c)).

We understand that in both cases the meaning was to indicate that the MPLs are not related to intermediate products but to the final product (as marketed / consumed) of a given food category since the concentration of an additive could differ during the production process (e.g. due to dilution or concentration steps). There is a category 'casings' in the GSFA and indeed the final product of the category casings would be a casing (which can be marketed and consumed when used as a contained for sausages). Therefore, it is clear that in the case of the category 08.4 Edible casings the MPL relate to casings not to sausages.

Specific Comments on Provisions for Paprika Extracts in Food Category 08.4 (Edible Casings):

After internal discussions with the European paprika producers whose data we submitted to both the EU and CODEX, we would now propose use levels for Food Category 08.4 (Edible casings);

In the casing of 900 - 3900 - 9000 mg/kg (min – typical – max) to reflect levels

In the sausage as eaten of 9 - 39 - 90 mg/kg (min – typical – max).

For perspective typically a casing is 0.3% of a sausage but this depends on diameter so it can be up to 1.0%.

Secondly, NATCOL wishes to highlight an error in the reporting in one of the provisions previously submitted in CX/FA 16/48/10 as Paprika Extract INS 160c(ii) i.e. the provisions for Food Category 01.6.2.3 (Cheese Powder), which should be listed on the weight basis of the pure Cheese Powder (not on the basis of the reconstituted sauce as consumed as NATCOL submitted in October 2015). At this time, NATCOL wishes to submit our additional comment on Paprika Extract INS 160c(ii) as a comment to CX/FA 16/48/10 for inclusion as an addendum document or as a CRD on this Agenda item (5d).

Specific Comments on Provisions for Paprika Extracts in Food Category 01.6.2.3 (Cheese Powder):

After internal discussions with the European paprika producers whose data we submitted to both the EU and CODEX, we would now propose use levels for Food Category 01.6.2.3 (Cheese powder);

In the Cheese powder (before reconstitution) of 15 - 100 - 250 mg/kg (min – typical – max) to reflect levels

In the sauce as eaten of 3 - 20 - 50 mg/kg (min – typical – max).

General Comments:

In addition, we would also like to make the following comment, regarding the presentation of the use levels of food additives in foods that form only part of the food as eaten (i.e. casings, coatings, decorations, fillings, etc.) and those where the food must be re-constituted with water (dried foods, powders, etc.). Indeed, we would greatly appreciate to have the pWG consider this issue, especially since maximum permitted levels are established on the final product as consumed at Codex level (unless otherwise specified). The products corresponding to the food categories at stake here would not normally be eaten as such. Consequently, it might be helpful if footnotes could be added to use conditions for such foods to indicate whether the concentration relates to the food as described or as presented for consumption in an entire food or after re-constitution. Examples of categories that require a footnote to clarify whether 'as eaten' or not include:

FCS No.	Title
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)
07.2	Fine bakery wares (sweet, salty, savoury) and mixes
08.4	Edible casings (e.g., sausage casings)
12.5.2	Mixes for soups and broths
12.6.3	Mixes for sauces and gravies
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa

We would propose that the working group consider these as examples and review the entire GSFA to identify all cases requiring a footnote. 07.2 Fine Bakery wares should have a sub-category for mixes as it is impossible to have the one category cover both fine bakery wares AND mixes.

Correlation between certain Food Categories in the GSFA and the List of GSFA Food Categories in which the use of Colours is justified

"GSFA Categories in which the use of one or more colors is justified" that was produced in 2007 (see appendix III, attached) was the basis for which the NATCOL data submitted in October 2015. However, it has been highlighted by the Chair of the pWG that the GSFA has been updated whereas the list does not appear to have been altered. In order to avoid recommending usage in categories for which use is not justified, NATCOL requested clarification from the pWG and to resolve the ambiguity.

Consequently, it was recommended that NATCOL support their amended provisions by stating that these are food categories that the Committee had previously recommended that the use of colors is technologically justified, and attach the list to our CRD (just the pertinent parts from the document). And as recommended, we have also included a table showing the correspondence between the old FCs and the FCs in the current GSFA.

Finally, NATCOL wishes to submit in Table format the proposed changes to the NATCOL use levels previously submitted in CX/FA 16/48/10 as Paprika Extract INS 160c(ii). These include: amended provisions for Food Category 01.6.2.3 (Cheese Powder); amended provisions for Food Category 08.4 (Edible casings); provisions for

Food Categories 12.9 converted to the corresponding food categories which are currently in the GSFA.

At this time, NATCOL wishes to submit our additional comment on Paprika Extract INS 160c(ii) as a comment to CX/FA 16/48/10 for inclusion as an addendum document or as a CRD on this Agenda item (5d).

NATCOL - GSFA paprika extract use levels

Proposed changes to NATCOL paprika extract use levels listed in CX/FA 16/48/10

GSFA Categories in which the use of one or more colors is justified		GSFA use levels			Notes
		mg/kg or mg/l			
FCS No.	Title	Paprika INS160c(ii) Use Levels*			Notes
		Low	Typical	Max	
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	15	100	250	Before reconstitution
01.6.2.3	Cheese powder (for reconstitution; e.g., for cheese sauces)	3	20	50	As reconstituted (in cheese sauce, etc. as consumed.) - original entry
06.8.1	Soybean-based beverages	1	5	30	New GSFA category added to colours list. Previously 12.9.1.1
06.8.2	Soybean-based beverage film	4	4	4	New GSFA category added to colours list. Previously 12.9.1.2
06.8.8	Other soybean protein products	4	4	4	New GSFA category added to colours list. Previously 12.9.1, 12.9.1.3 and 12.9.5
08.4	Edible casings (e.g., sausage casings)	900	3900	9000	In casing before filling
08.4	Edible casings (e.g., sausage casings)	5	39	90	In sausage, as consumed - original entry
12.9	<i>Protein products</i>	4	4	4	GSFA Category deleted from colours list
12.9.1	<i>Soybean protein products</i>	4	4	4	GSFA Category deleted from colours list
12.9.1.1	<i>Soybean beverage</i>	1	5	30	GSFA Category deleted from colours list
12.9.1.2	<i>Soybean milk film</i>	4	4	4	GSFA Category deleted from colours list
12.9.1.3	<i>Other soybean protein products (including non-fermented soy sauce)</i>	4	4	4	GSFA Category deleted from colours list
12.9.5	<i>Other protein products</i>	4	4	4	GSFA Category deleted from colours list

* mg/kg or mg/l, expressed as total carotenoids using the conversion factor of 100,000 colour units = 7.2% total carotenoids