



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-Second Session

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): ADDITIVES INTENDED FOR USE AS A GLAZE OR IN A GLAZE/COATING OR WAX FOR SURFACE TREATMENT IN FOOD CATEGORIES 04.1.1.2 AND 04.2.1.2; ACESULFAME POTASSIUM (INS 950) IN FOOD CATEGORIES 14.1.4 AND 14.1.5 AND SACCHARINS (INS 954(I)-(IV)) IN SUBCATEGORIES OF FOOD CATEGORIES 14.1.4, AND ADDITIVES WITH THE FUNCTIONAL CLASS OF COLOUR IN FCS 14.1.4 AND ITS SUBCATEGORIES; PROVISIONS IN THE STEP PROCESS FOR TABLE 3 ADDITIVES WITH SWEETENER FUNCTION IN FOOD CATEGORY 14.1.5; AND PROVISIONS FOR COLOURS IN FOOD CATEGORIES 01.0 THROUGH 03.0 AND THEIR SUBCATEGORIES INCLUDING ADOPTED PROVISIONS FOR COLOURS WITH NOTE 161 ASSOCIATED WITH THEM AND DRAFT AND PROPOSED DRAFT PROVISIONS

Prepared by the United States of America with the assistance of Australia, Brazil, Canada, Chile, Costa Rica, Egypt, European Union (EU), Guatemala, India, Indonesia, Japan, Korea, Malaysia, Nicaragua, Nigeria, Russian Federation, Peru, Thailand, United Kingdom, Calorie Control Council (CCC), EU Specialty Food Ingredients, Food Industry Asia (FIA), International Association of Color Manufacturers (IACM), International Council of Beverages Associations (ICBA), International Dairy Federation (IDF), International Food Additives Council (IFAC), International Sweeteners Association (ISA), Natural Food Colours Association (NATCOL), Organisation des Fabricants de produits Cellulosiques Alimentaires (OFCA)

Introduction

1. In accordance with CL 2020/34-FA and an additional email from the Codex Secretariat, the EWG on the GSFA to CCFA52 was reconvened to continue previous discussions on the following topics:

- (i) Request further comment on the technological justification for the use of specific food additives as a glaze or for use in waxes, coatings or glazes in food categories 04.1.1.2 and 04.2.1.2 (Recirculation from Appendix 4 of CX/FA 20/52/7);
- (ii) Request further comment on adopted provisions for acesulfame potassium (INS 950) and saccharins (INS 954(i)-(iv)) in specific food categories (Recirculation from Annex 2 of Appendix 6 of CX/FA 20/52/7);
- (iii) Request further comment on provisions for Table 3 additives with sweetener function in food category 14.1.5 (Recirculation from Annex 3 of Appendix 6 of CX/FA 20/52/7); and
- (iv) Request further comment on the use of certain colours in food category 14.1.4 and its subcategories (Recirculation from Annex 2 of Appendix 7 of CX/FA 20/52/7).

In addition, the EWG on the GSFA to CCFA52 considered additional activities pertaining to:

- (v) Continuation of work on colours: Circulate for comment provisions for colours in Food Categories 01.0 - 03.0 and subcategories, including all provisions currently in the step process and those adopted with Note 161.

Working Documents

2. The working documents for the report of the EWG on the General Standard for Food Additives are presented as appendices to this document. The appendices provide background on the topic under discussion, collate comments on the topic from the EWG, and provide recommendations for each topic.

- Draft and proposed draft provisions that pertain to topic i are presented in Appendix A.

- Adopted provisions for acesulfame potassium (INS 950) and saccharins (INS 954(i)-(iv)) that pertain to topic ii as well as adopted provisions or draft and proposed draft provisions for certain colours in food category 14.1.4 and its subcategories that pertain to topic iv are combined into Appendix B.
- Draft and proposed draft provisions for Table 3 additives with sweetener function in food category 14.1.5 that pertain to topic iii are presented in Appendix C.
- Provisions for colours in Food Categories 01.0-0.30 and subcategories that pertain to topic v are presented in Appendix D.

Appendix A: Recirculation of specific draft and proposed draft provisions from Appendix 4 of CX/FA 20/52/7: additives intended for use as a glaze or in a glaze/coating or wax for surface treatment in food categories 04.1.1.2 and 04.2.1.2

1. Among several topics, CCFA51 requested the EWG on the GSFA to CCFA52 to¹:
 - request information on actual use levels and/or technological justification on the proposed food additive provisions held at the current step in Table 1 and 2 of the GSFA including provisions in food categories 04.1.1.2 and 04.2.1.2 for additives intended for use as a glaze or in a glaze/coating or wax for surface treatment.

Introduction:

2. CCFA50 requested the EWG on the GSFA to CCFA51 to provide recommendations on all remaining draft and proposed draft provisions in Table 1 and 2 of the GSFA in food categories 01.0 through 16.0, with the exception of those additives with technological functions of colour (excluding specific food categories where provisions for additives with colour function were considered) or sweetener, adipates, nitrites and nitrates, the provisions in food category 14.2.3 and its subcategories, and provisions awaiting a reply from CCSCHE, CCPFV or CCFO.² The EWG on the GSFA to CCFA51 provided recommendations³ which were discussed by the physical working group (PWG) on the GSFA to CCFA51.⁴ When consensus could not be reached on several of these provisions, CCFA51 requested that the EWG on the GSFA to CCFA52 re-circulate these provisions for further comment.

- Provisions in food categories 04.1.1.2 and 04.2.1.2 for additives intended for use as a glaze or in a glaze/coating or wax for surface treatment: During discussion by the PWG on the GSFA to CCFA51 on provisions in FCs 04.1.1.2 “Surface-treated fresh fruit” and 04.2.1.2 “Surface-treated fresh vegetables, (including mushrooms, and fungi, roots and tubers, pulses and legumes (including soybeans), and aloe vera, seaweeds and nuts and seeds)” the PWG noted that technological justification had not been provided for many of the draft provisions, and it was unclear if many of these additives were actually used in surface treatments for fresh produce. The Chair noted that the EWG on the GSFA to CCFA51 had focused on the horizontal approach on the use of additives in surface treatments in these food categories, and as such information on technological justification and actual use may not be available at that time even if an additive was currently used in such surface treatments. The Chair proposed that those provisions for which information had not been provided be held at their current step and circulated for comment on the technological justification and the actual use of those additives in surface treatment on fresh produce. CCFA51 agreed to hold these provisions and recirculate them for comment on technological justification and actual use in the surface treatment of fresh produce.

3. The EWG on the GSFA to CCFA52 issued two circulars for comment containing draft and proposed provisions in FCs 04.1.1.2 and 04.2.1.2. These circulars requested comments on actual use levels and/or technological and justification for the draft and proposed draft provisions under discussion. The EWG on the GSFA finalized a report with proposals for these provisions (CX/FA 20/52/7, Appendix 4). Subsequently, CCFA52 was postponed to 2021 due to issues related to COVID-19. The Codex Secretariat encouraged all the Codex Committees to explore different ways of maintaining the momentum of the Codex standard setting work and to minimize the impact of the pandemic on Codex work. Specific to CCFA, the Codex Secretariat issued a Circular Letter (CL 2020/34-FA) requesting comment on recommendations that, among other tasks, the EWG on the GSFA “continue their work as necessary under the terms of reference established by CCFA51.” Under this direction, the Chair of the EWG on the GSFA determined that recirculation of certain provisions for additives intended for use as a glaze or in a glaze/coating or wax for surface treatment in food categories 04.1.1.2 and 04.2.1.2 may help the EWG reach consensus on those provisions.

Working document:

4. The EWG circulated two documents for comment containing this Appendix. The current document contains proposals on draft and proposed draft provisions in FCs 04.1.1.2 “Surface-treated fresh fruit” and 04.2.1.2 “Surface-treated fresh vegetables, (including mushrooms, and fungi, roots and tubers, pulses and legumes (including soybeans), and aloe vera, seaweeds and nuts and seeds)” for which there is member support for adoption but for which technological justification had not been provided at the time of the final report of the EWG on the GSFA to CCFA52 (CX/FA 20/52/7, Appendix 4).

¹ REP 19/FA, para. 137.

² REP 18/FA, Para. 112.

³ CX/FA 19/51/7.

⁴ FA/19 CRD2.

5. This document presents the provisions under discussion in the format of the food categories listed in Table 2 of the GSFA. To assist the EWG's discussion, this document includes the following information:

- Information on corresponding Codex commodity standards and the use of food additives in those commodity standards is provided for each food category;
- The horizontal approach described in FA/45 CRD 2 Appendix IV, FA/46 CRD 2 Appendix II pertaining to the technological justification of food additives with "acidity regulator" or "emulsifier, stabilizer, and thickener" function in food categories listed in the Annex to Table 3; and
- Historical discussions on the provision in previous sessions of CCFA, and compilation of comments from EWG members in response to previous circulars on this subject.

6. The proposals are based on the "weight of evidence"; that is, comments containing justifications were given more weight than comments with no supporting justification. The proposals take into consideration information on corresponding Codex commodity standards and the use of food additives in those commodity standards is provided for each food category.

Draft and proposed draft provisions in the GSFA in FCs 04.1.1.2 “Surface-treated fresh fruit” and 04.2.1.2 “Surface-treated fresh vegetables, (including mushrooms, and fungi, roots and tubers, pulses and legumes (including soybeans), and aloe vera, seaweeds and nuts and seeds)”

Food Category No. 04.1.1.2 (Surface treated fresh fruit)

Descriptor: The surfaces of certain fresh fruit are coated with glazes or waxes or are treated with other food additives that act as protective coatings and/or help to preserve the freshness and quality of the fruit. Examples include apples, oranges, dates, and longans.

Horizontal approach (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): acidity regulators not horizontally justified - ES&T on hold until secondary additives discussion

Corresponding commodity standards: 143-1985: Standard does not address coatings.

General Note: CCFA45 discussed the horizontal approach to Table 3 ES&T and initially proposed that ES&T are horizontally justified in this FC with a note “for use in glaze, coating, and decoration only”. However, during discussion on FC 04.2.1.2 the Committee noted that the use of additives in coatings may be a secondary additive use and held the provisions for discussion at CCFA46 (REP13/FA paras 82-85). The PWG on the GSFA to CCFA46 held these provisions for further discussion on secondary additives (CCFA46 CRD2). CCFA49 discussed that secondary additives could be addressed by using notes within the current GSFA food category system (REP 16/FA).

CCFA51 discussed the horizontal approach to Table 3 ES&T. The Committee agreed to the horizontal application of a note that reads, as appropriate, either “For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits” or “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits” but noted that technological justification had not been provided for the draft and proposed draft provisions. The Committee agreed to recirculate the provisions to seek information on technological justification.

General comments by EWG members in response to 1st Recirculation request information on technological justification

Egypt: Many chemical physical changes during postharvest storage and handling. Formulated edible coatings to avoid many of the above challenges to extend shelf life, and maintaining both quality and nutritional value.

IFAC: endorses the comments submitted by Chile and Egypt on Appendix A, particularly the technological justification supporting the continued use of alginic acid, ammonium alginate, calcium alginate, and carrageenan in FCs 04.1.1.2 and 04.2.1.2.

General Comments by EWG members in response to 1st Circular request for information on technological justification:

Australia: The Australian comments provided below are for Australian permissions of the food additives as GMP food additives permitted to be added to the food category called “preparations of food additives”, which can then be used as emulsifiers or stabilisers in preparations of surface treatment preparations, being waxes or other glazing agents, used to treat both fruits and vegetables. In this situation they would be similar to what is being referred to as ‘secondary food additives’ in CCFA. They do not have permissions in their own right to be surface treat fruits or vegetables. It is also important to note, that these are permissions only; no information is available on whether these food additives are actually used for this purpose.

These comments apply to both fresh fruits and vegetables.

Canada: Canada is engaging industry on substances used in surface treatments for fresh fruits (FC 04.1.1.2) and fresh vegetables (FC 04.2.1.2), and we hope to provide input as part of a subsequent circular. We do, however, note that the lists of additives under consideration are largely similar but that there are some differences. We wonder if the working group considers it reasonable to apply the same list of additives for both food categories, as the use of additives in surface treatment formulations are likely to be the same. However, we also have no objection to continue considering the current lists as proposed. For reference, we note the following differences:

- The list for FC 04.1.1.2 additionally includes gum Arabic (INS 414);
- The list for FC 04.2.1.2 additionally includes calcium chloride (INS 509), calcium sulfate (INS 516), potassium dihydrogen citrate (INS 332(i)), and tripotassium citrate (INS 332(ii)).

IFAC: IFAC supports the application of a note that reads, as appropriate, either “For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits” and / or “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits” where technological justification exists for draft and proposed draft provisions in this FC.

IFAC has highlighted several draft and proposed draft provisions for this FC for which existing data exists to support the technological justification for the use of these additives in edible coatings. However, IFAC notes that continued innovation in the area of edible coatings is ongoing and it is likely that other additives under consideration in this FC also provide value in edible coating formulations.

IFAC's technological justification is as follows, with additional details on specific additives in the table below:

Fresh fruits undergo many physiological changes during postharvest storage and handling, including: tissue softening, increased sugar levels, decreases in organic acid levels, degradation of chlorophyll accompanied by the synthesis of anthocyanins or carotenoids upon maturation, production and losses of volatile flavor compounds, decreases in phenolic and amino acid contents, and breakdown of cell materials due to respiration. Appropriately formulated edible coatings can be utilized on fresh fruits with both edible and non-edible peels to meet the many of the above challenges associated with shelf life extension, and maintaining both quality and nutritional value.

For optimal effectiveness, edible glazing / coating formulations must be tailored to meet the unique biological demands of each type of fruit. For example, specific glazing / coating agents may be more suitable for certain types of fruits than others. Additionally, existing coatings in this FC are hydrophobic in nature, and are often delivered to the surface of fresh fruits using a water-based formulation. This requires the use of emulsifiers and stabilizers to allow the glazing / coating to be applied uniformly and completely, which enhances the effectiveness of the glazing / coating. Use of emulsifiers and stabilizers not only provide the clear advantage of improving the function of the glazing / coating, but are required for their effective use.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
ACETIC AND FATTY ACID ESTERS OF GLYCEROL	472a	GMP	16	7	Emulsifier, Sequestrant, Stabilizer	Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."
<p>2nd Recirculation Proposal: Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Supports chair's proposal. Technological justification: As emulsifier for glazing agents, the additive delivers two important properties:</p> <ul style="list-style-type: none"> - control of moisture loss, increasing the performance of regular coatings. (Guillard et al, JAOCS, Vol 81, no 11 (2004)). - improvement of the film forming properties of coatings (Guillard et al, JAOCS, Vol 81, no 11 (2004)). <p>Introduction of lipids food grade substances in regular coatings (i.e carnauba wax), increase the efficiency in film forming and, due to its hydrophobic nature, to control moisture loss. ADI is 'not limited' and application is at low dosis (technologically lower than 2% in the coating, considering a standard range of coating of 1 liter of glazing agent per tonn of fruit, means less than 20 ppm on the fresh fruit). Its properties as emulsifier are also known, and in this regard, can contribute to the emulsion of waxes, specially natural waxes like beewax and carnauba. That is also explained in Handbook of Food Preservation (M. Shafiur Rahman, 2007): Reduction of surface water activity at the water-oil interface helps to both form and stabilize emulsions, which is important for shelf-life properties of emulsion coatings.</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: could accept with the Note 454</p> <p>RU: There absent technological justification for to use INS 472a in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Brazil: does not support discontinuation. Acetic and fatty acid esters of glycerol deliver an excellent control of moisture loss, that combined with carnauba wax leads to preserve the freshness of fruits, especially those that have to be shipped far away. Additionally, its very good film forming properties helps to other glazing agents (i.e. carnauba) to a homogeneous spreading on the surface of the fruits, optimizing their coating performance, in a synergetic way.</p> <p>Chile: support the final report proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, as well as the need of refrigeration than in some cases consumer can interrupt, and long distance transportation between countries and continents. Additionally fruits are a fresh produce that maintain their physiological I process, just decelerated by refrigeration, and therefore they undergo many physiological changes during postharvest storage and handling. All those changes means the danger of loss of nutritive properties, loss of appearance making the produce non marketable and the bigger risk of loss of food.</p> <p>For to avoid those problems, the industry uses different coatings, that in some case require additives fro maintain its stability on storage or in order to facilitate a homogeneous application of the wax, coating or glazing, or to improve the resistance of the wax, coating or glazing to external conditions such as high or low humidity by example). At the end, the use of the proposed substances, that generally are food additives, will help in to reduce the loss of food.</p> <p>Egypt: supports use at GMP as Emulsifier, and Stabilizer. See general comment above</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>Indonesia: Supports discontinuation</p> <p>Nigeria: Supports adoption at GMP</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes “For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;” and “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, Indonesia, RU: Supports discontinuation</p> <p>Nigeria: Adopt food additives that are fully evaluated by JECFA</p> <p>USA: Authorized for use in Foods in General at GMP</p> <p>Zimbabwe: supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market.</p>						
ACETYLATED DISTARCH PHOSPHATE	1414	GMP	16	7	Emulsifier, Stabilizer, Thickener	Adopt with Note 454 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”
<p>2nd Recirculation Proposal: Adopt with Note 454 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 1414 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>Egypt: supports use at GMP. Ins 1414 is important for freshness and avoid chemical and physiological changes during postharvest storage and handling</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>Indonesia: Supports discontinuation</p> <p>Nigeria: Supports adoption at GMP</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes "For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits," and "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, Indonesia, RU: Supports discontinuation</p> <p>Nigeria: INS 1414 is a suitable emulsifier, stabilizer and thickener because it ensures viscosity without changing the food properties</p> <p>USA: Authorized for use in Foods in General at GMP</p> <p>Zimbabwe: supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market. supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market.</p>						
ALGINIC ACID	400	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant,	Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
					Sequestrant, Stabilizer, Thickener	
<p>2nd Recirculation Proposal: Adopt with Note 454 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Supports proposal</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 400 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Brazil: does not support discontinuation. Its film forming properties help to the better spreading of the glazing agent but, also, let a proper gas exchange which reduces problems of fermentation, mostly when fruits are shipped far away or commercialized / stored for a long time.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>Egypt: supports use at GMP as stabilizers, emulsifier and gelling agent, for surface treatment for fresh F&V that perishable to change</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes “For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;” and “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: Supports discontinuation</p> <p>Indonesia: Does not support discontinuation. Technologically justified and used in FC at GMP</p> <p>Nigeria: As stabilizers, thickener and emulsifier and gelling agent, it is stored with a compound package bag</p> <p>USA: GRAS for use in Foods in General at 0.1% as a humectant, stabilizer or thickener</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
AMMONIUM ALGINATE	403	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."
<p>2nd Recirculation Proposal: Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Supports proposal</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 403 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>1st Recirculation proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Brazil: does not support discontinuation. Its film forming properties help to the better spreading of the glazing agent but, also, let a proper gas exchange which reduces problems of fermentation, mostly when fruits are shipped far away or commercialized / stored for a long time.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>Egypt: supports use at GMP as stabilizers, emulsifier, gelling agent, Humectant, Sequestrant and glazing agent for surface treatment for fresh F&V that sensitive to chemical and physical changes</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes "For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;" and "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: Supports discontinuation</p> <p>Nigeria: As stabilizers, thickener and emulsifier and gelling agent, it is stored with a compound package bag</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>USA: GRAS for use in Foods in General at 0.1% as a humectant, stabilizer or thickener</p> <p>Zimbabwe: supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market.</p>						
CALCIUM ALGINATE	404	GMP		7	Antifoaming agent, Bulking agent, Carrier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."
<p>2nd Recirculation Proposal: Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Supports proposal</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 404 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Brazil: does not support discontinuation. Its film forming properties help to the better spreading of the glazing agent but, also, let a proper gas exchange which reduces problems of fermentation, mostly when fruits are shipped far away or commercialized / stored for a long time.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>Egypt: supports using at GMP as a thickening, stabilizing and gel forming agent, Glazing agent, Humectant and Sequestrant.</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes "For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;" and "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>2nd CL Proposal: Discontinue</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>Australia: GMP Food Additive</p> <p>Indonesia: Does not support discontinuation. Technologically justified and used in FC at GMP</p> <p>EU, RU: Supports discontinuation</p> <p>Nigeria: It is a powerful thickening, stabilizing and gel forming agent</p> <p>USA: GRAS for use in Foods in General at 0.3% as a stabilizer or thickener</p>						
CARRAGEENAN	407	GMP		7	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener	Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."
<p>2nd Recirculation Proposal: Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Supports proposal</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 407 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Brazil: does not support discontinuation. Its film forming properties help to the better spreading of the glazing agent but, also, let a proper gas exchange which reduces problems of fermentation, mostly when fruits are shipped far away or commercialized / stored for a long time.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>Egypt: supports using at GMP as a Carrier, Emulsifier, Gelling agent, Glazing agent, and Humectant</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes "For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;" and "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: Supports discontinuation</p> <p>Indonesia: Does not support discontinuation</p> <p>Nigeria: used to thicken, emulsify and preserve foods. Some evidence shows that it triggers inflammation and damages digestive system.</p> <p>Zimbabwe: supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market.</p>						
GUM ARABIC (ACACIA GUM)	414	GMP	16	7	Bulking agent, Carrier, Emulsifier, Glazing agent, Stabilizer, Thickener	Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."
<p>2nd Recirculation Proposal: Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 414 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>Egypt: supports using at GMP as a Carrier, Emulsifier, Gelling agent, Glazing agent, and Humectant</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes "For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;" and "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: Supports discontinuation</p> <p>USA: GRAS for use in Foods in General at 1.0% as a surface-finishing agent, emulsifier, stabilizer or thickener</p> <p>Zimbabwe: supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market.</p>						
HYDROXYPROPYL CELLULOSE	463	GMP	16	7	Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener	Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."
<p>2nd Recirculation Proposal: Adopt with Note 454 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Supports proposal</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: could accept with the Note 454</p> <p>RU: There absent technological justification for to use INS 463 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>OFCA/ICA: supports the proposal to adopt the provision with note 454</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia assumes that the Final Report proposal was meant to be the same as for the other food additives. That is: Final Report Proposal: Adopt with Notes "For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;" and "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits."</p> <p>If that is the case Australia's comments are the same as for other food additives.</p> <p>Australia supports the proposal (to adopt with use of notes, and not to discontinue). It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Brazil: does not support discontinuation. Its film forming properties help to the better spreading of the glazing agent but, also, let a proper gas exchange which reduces problems of fermentation, mostly when fruits are shipped far away or commercialized / stored for a long time.</p> <p>Chile: supports adoption with Note "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.". See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>OFCA: Supports continuation</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes “For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;” and “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: INS could be used in this FC in TF Glazing agent, Stabilizer, Thickener</p> <p>USA: Authorized for use in Foods in General at GMP as a Film Former, Protective Colloid, emulsifier, stabilizer, thickener</p> <p>Zimbabwe: supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market.</p>						
HYDROXYPROPYL METHYL CELLULOSE	464	GMP	16	7	Bulking agent, Emulsifier, Glazing agent, Stabilizer, Thickener	Adopt with Note 454 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”
<p>2nd Recirculation Proposal: Request further information on technological justification</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Technological justification: As all celluloses derivatives, it has been used as part of formulations of coating and glazes, as the film former, gas exchange actor, in combination with a lipidic part (fatty acid, fatty acid ester, waxes) when fruits are protected with coatings being hydroxypropyl methyl cellulose (HPMC) the most extensively used. In “Edible coating of fruits and vegetables: a review” (Raghav et al, IJSRME, 2016), in a classification of edible coatings, cellulose derivatives are included in the family of polysaccharides used in edible coatings, including hydroxypropyl cellulose. It is stated that all the family have good resistance properties and are partially permeable to moisture and gas transmission. Cellulose derivatives, depending of the technological need, can be formulated (page 191 in the same article) in the edible coatings as the hydrocolloid part jointly with the lipids or composites, of the edible coating. There are extensive literature on the application in edible coatings for fruits using HPMC as the polysaccharide part of the coating. As examples: 1.- Effect of antifungal hydroxypropyl methyl cellulose (HPMC)-lipid edible composite coatings on Postharvest decay development and quality attributes of cold-stored “Valencia” oranges. Valencia- Chamorro et al (Postharvest Biology and Technology 54 (2009) 72-79. 2.-Effect of three different Aloe vera Gel-Based edible coatings on the quality of fresh-cut “Hayward” kiwifruits. Passfiume et al (Foods 2020, 9, 939. 3.- Effect of hydroxypropyl cellulose-beewax composite edible coatings formulated with or without antifungal agents on physicochemical properties of plums during cold storage. Gunaydin et al Journal of Food Quality Volume 2017, Article ID 8573549. 4.- Effect of various additives on the properties of the films and cotaings derived from hydroxypropyl methyl cellulose- A review. Ghadermazi et al Food Sci Nutr 2019; 7: 3363-3377.</p> <p>Chile: Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, as well as the need of refrigeration than in some cases consumer can interrupt, and long distance transportation between countries and continents. Additionally fruits are a fresh produce that maintain their physiological I process, just decelerated by refrigeration, and therefore they undergo many physiological changes during postharvest storage and handling. All those changes means the danger of loss of nutritive properties, loss of appearance making the produce non marketable and the bigger risk of loss of food.</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>For to avoid those problems, the industry uses different coatings, that in some case require additives for maintain its stability on storage or in order to facilitate a homogeneous application of the wax, coating or glazing, or to improve the resistance of the wax, coating or glazing to external conditions such as high or low humidity by example). At the end, the use of the proposed substances, that generally are food additives, will help in to reduce the loss of food.</p> <p>EU: could accept with the Note 454</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC</p> <p>OFCA/ICA: support the continuation. However, we would recommend to obtain more information from the trade association covering those products (fresh fruits & vegetables)</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>OFCA: Supports continuation</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes “For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;” and “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: Supports discontinuation</p> <p>USA: Authorized for use in Foods in General at GMP as a Film Former, Protective Colloid, emulsifier, stabilizer, thickener</p> <p>Zimbabwe: supports use at GMP to preserve the freshness of commodity especially those that have to be transported long distances to the destination market</p>						
PECTINS	440	GMP		7	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	Adopt with Note 454 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”
<p>2nd Recirculation Proposal: Adopt with Note 454 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Brazil: Technological justification: Pectin has been used as part of formulations of coatings and glazes, as the film former, gas exchange actor, in combination with a lipidic part (fatty acid, fatty acid ester, waxes) when fruits are protected with coatings. Examples: 1.- Natural Pectin Polysaccharides as edible coatings. Valdes et al. Coatings 2015, 5, 865-886. 2.- Fruit preservation with an edible pectin gel with a low glycemic index. Spanish National Research Council (CSIC). leaflet-aj-044-2019-12-12</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
<p>Chile: support the proposal. Post harvest storage and trade of fresh fruits can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: could accept with the Note 454</p> <p>RU: There absent technological justification for to use INS 440 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol. ectins are naturally present in fruit, They are part of the cell wall and as a food additive its use must be under GMP.</p> <p>Egypt: supports use in Foods in General at GMP as an emulsifier, stabilizer, thickener and Glazing agent.</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>Indonesia: Pectins are natural carbohydrate polymers which can be applied on the surface of fruits.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes “For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruits;” and “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh fruits.”</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: Supports discontinuation</p> <p>Indonesia: Does not support discontinuation. Technologically justified, a natural carbohydrate polymer which can be applied on the surface of fruits</p> <p>Nigeria: used in food as a gelling agent, particularly in jams and jellies</p> <p>USA: GRAS for use in Foods in General at GMP as an emulsifier, stabilizer, thickener</p>						

Food Category No. 04.2.1.2 (Surface-treated fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes (including soybeans), and aloe vera), seaweeds and nuts and seeds)

Descriptor: The surfaces of certain fresh vegetables are coated with glazes or waxes or are treated with other food additives that act as protective coatings and/or help to preserve the freshness and quality of the vegetable. Examples include: avocados, cucumbers, green peppers and pistachio nuts.

Horizontal approach (FA/45 CRD2 Appendix FA/46 CRD 2 Appendix V): acidity regulators not horizontally justified, ES&T hold until secondary additives

Corresponding commodity standards: 330-2018: Does not address surface treatment

General Note: CCFA45 discussed the horizontal approach to Table 3 ES&T and initially proposed that ES&T are horizontally justified in this FC with a note “for use in glaze, coating, and decoration only”. However, during discussion on FC 04.2.1.2 the Committee noted that the use of additives in coatings may be a secondary additive use and held the provisions for discussion at CCFA46 (REP13/FA paras 82-85). The PWG on the GSFA to CCFA46 held these provisions for further discussion on secondary additives (CCFA46 CRD2). CCFA49 discussed that secondary additives could be addressed by using notes within the current GSFA food category system (REP 16/FA).

CCFA51 discussed the horizontal approach to Table 3 ES&T. The Committee agreed to the horizontal application of a note that reads, as appropriate, either “For use as a glaze where such surface treatment is allowed for application to the surface of fresh vegetables, seaweeds or nuts and seeds” or “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds, or nuts and seeds” but noted that technological justification had not been provided for the draft and proposed draft provisions. The Committee agreed to recirculate the provisions to seek information on technological justification.

General comments on the 1st Recirculation

Egypt: Many chemical physical changes during postharvest storage and handling. Formulated edible coatings to avoid many of the above challenges to extend shelf life, and maintaining both quality and nutritional value.

IFAC: endorses the comments submitted by Chile and Egypt on Appendix A, particularly the technological justification supporting the continued use of alginic acid, ammonium alginate, calcium alginate, and carrageenan in FCs 04.1.1.2 and 04.2.1.2.

General Comments 1st Circular Comments by EWG members to CCFA52 on Proposal (Request information on technological justification):

IFAC: supports the application of a note that reads, as appropriate, either “For use as a glaze where such surface treatment is allowed for application to the surface of fresh vegetables, seaweeds or nuts and seeds” and / or “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds” where technological justification exists for draft and proposed draft provisions in this FC.

IFAC has highlighted several draft and proposed draft provisions for this FC for which it has existing data to support the technological justification for the use of these additives in edible coatings; however, IFAC notes that continued innovation in the area of edible coatings is ongoing and it is likely that other additives under consideration in this FC also provide value in edible coating formulations.

IFAC’s technological justification is as follows, with additional details on specific additives in the table below:

Fresh vegetables undergo many physiological changes during postharvest storage and handling, including tissue softening, increase in sugar level, decrease in organic acid levels, degradation of chlorophyll accompanied by the synthesis of anthocyanins or carotenoids upon maturation, production and losses of volatile flavor compounds, decrease in phenolic and amino acid contents, and breakdown of cell materials due to respiration. Appropriately formulated edible coatings can be utilized on fresh vegetables with both edible and non-edible peels to meet the many challenges associated with shelf life extension, and maintaining both quality and nutritional value.

For optimal effectiveness, edible glazing / coating formulations must be tailored to meet the unique biological demands of each type of vegetable. For example, specific glazing / coating agents may be more suitable for certain types of vegetables over others. Additionally, existing coatings in this FC are hydrophobic in nature, and are often delivered to the surface of fresh vegetables using a water-based formulation. This requires the use of emulsifiers and stabilizers to allow the glazing / coating to be applied uniformly and completely, which enhances the effectiveness of the glazing / coating. Use of emulsifiers and stabilizers not only provide the clear advantage of improving the function of the glazing / coating, but are required for their effective use.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
ALGINIC ACID	400	GMP		7	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent,	Adopt with Note 456 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds.”

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
					Humectant, Sequestrant, Stabilizer, Thickener	
<p>2nd Recirculation Proposal: Adopt with Note 456 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds.”</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh vegetables can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 400 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds.</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol in FC 4.1.12</p> <p>Egypt: supports use in Foods in General at GMP as an emulsifier, stabilizer, thickener, Sequestrant, Humectant, and Glazing agent</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes ““For use as a glaze where such surface treatment is allowed for application to the surface of fresh vegetables, seaweeds or nuts and seeds” and “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds.”</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>EU, RU: Supports discontinuation</p> <p>Indonesia: Does not support discontinuation. Technologically justified, and used in FC at GMP</p>						
CALCIUM ALGINATE	404	GMP		7	Antifoaming agent, Bulking agent, Carrier, Foaming agent, Gelling	Adopt with Note 456 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds.”

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
					agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener	
<p>2nd Recirculation Proposal: Adopt with Note 456 “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds.”</p> <p>Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.</p> <p>Chile: support the proposal. Post harvest storage and trade of fresh vegetables can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.</p> <p>EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided</p> <p>RU: There absent technological justification for to use INS 404 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds</p> <p>1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided</p> <p>Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.</p> <p>Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol in FC 4.1.12</p> <p>Egypt: supports use in Foods in General at GMP as an emulsifier, stabilizer, thickener and Glazing agent</p> <p>EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided</p> <p>India: does not support adoption as currently not allowed in India.</p> <p>RU: Supports discontinuation. Technological justification is absent for this FC.</p> <p>Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes ““For use as a glaze where such surface treatment is allowed for application to the surface of fresh vegetables, seaweeds or nuts and seeds” and “For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds.”</p> <p>2nd CL Proposal: Discontinue</p> <p>Australia: GMP Food Additive</p> <p>Indonesia: Does not support discontinuation. Technologically justified and used in FC at GMP</p> <p>RU: Supports discontinuation</p> <p>USA: GRAS for use in Foods in General at 0.3% as a stabilizer or thickener</p>						

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopt.	INS Functional Class	Final EWG Proposal
PECTINS	440	GMP		7	Emulsifier, Gelling agent, Glazing agent, Stabilizer, Thickener	Adopt with Note 456 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds."

2nd Recirculation Proposal: Adopt with Note 456 "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds."

Australia: supports the proposal. It reiterates comments made earlier that it is a GMP food additive, that is able to be added to preparations of food additives, which can include waxes, coatings and glazes used to surface treat fresh fruits.

Chile: support the proposal. Post harvest storage and trade of fresh vegetables can be threatened by long time between harvest and consumer, and long distance transportation between countries and continents.

EU: discontinuation, as no specific justification for the proposed use of this additive and information on its actual use has been provided

RU: There absent technological justification for to use INS 440 in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds

1st Recirculation Proposal: Request technological justification. Discontinue if technological justification is not provided

Australia: supports the proposal. It reiterates comments made to the original EWG documents, that is it is a GMP food additive.

Chile: support the final report proposal. See detailed comments under Acetic and Fatty acid esters of glycerol in FC 4.1.12

Egypt: supports use in Foods in General at GMP as an emulsifier, stabilizer, thickener and Glazing agent

EU: strongly supports discontinuation, if no specific justification for the use in waxes, coatings, glazes or for use as a glaze in this food category is provided

India: does not support adoption as currently not allowed in India.

Indonesia: Pectins are natural carbohydrate polymers which can be applied on the surface of fruits.

RU: Supports discontinuation. Technological justification is absent for this FC

Final Report (CX/FA 20/52/7, Appendix 4) Proposal: Adopt with Notes ""For use as a glaze where such surface treatment is allowed for application to the surface of fresh vegetables, seaweeds or nuts and seeds" and "For use in waxes, coatings or glazes where these surface treatments are allowed for the application to the surface of fresh vegetables, seaweeds or nuts and seeds."

2nd CL Proposal: Discontinue

Australia: GMP Food Additive

EU, RU: Supports discontinuation

Indonesia: Does not support discontinuation. Technologically justified, a natural carbohydrate polymer which can be applied on the surface of fresh fruits

USA: GRAS for use in Foods in General at GMP as an emulsifier, stabilizer, thickener

Appendix B: Recirculation of draft and proposed draft provisions from Annex 2 of Appendix 6 of CX/FA 20/52/7 and Annex 2 of Appendix 7 of CX/FA 20/52/7: acesulfame potassium (INS 950) in food categories 14.1.4 and 14.1.5 and saccharins (INS 954(i)-(iv)) in subcategories of food categories 14.1.4, and additives with the functional class of colour in FCs 14.1.4 and its subcategories

Among several topics, CCFA51 requested the EWG on the GSFA to CCFA52 to consider¹:

- adopted provisions for acesulfame potassium (INS 950) in FCs 14.1.4 and 14.1.5 and saccharins (INS 954(i)-(iv)) in subcategories of food categories 14.1.4; and
- draft and proposed draft provisions for additives with the functional class of colour in FCs 14.1.4 and its subcategories.

Background: acesulfame potassium (INS 950) and saccharins (INS 954(i)-(iv))

1. CCFA50 established the EWG on Note 161 to consider the use of Note 161 related to the use of sweeteners and to review recommendations in a previous discussion paper (CX/FA 19/51/10) in the context of pending and adopted provisions in the GSFA.² The EWG on Note 161 to CCFA51 formulated recommendations³ for provisions in food categories under discussion. These recommendations included that:

- For adopted provisions: these provisions would be revised to replace Note 161 with a specific alternative note
- For provisions in the step process: these provisions would be revised to replace Note 161 with a specific alternative note and circulated for comment by the EWG on the GSFA to CCFA52.

When discussing these recommendations at CCFA51, one member expressed concern on the dietary intake corresponding to the maximum use levels for adopted provisions for acesulfame potassium (INS 950) in FCs 14.1.4 and 14.1.5 and saccharins (INS 954(i)-(iv)) in FC 14.1.4 or their subcategories. CCFA51 agreed to request the EWG on the GSFA to CCFA52 to consider adopted provisions for acesulfame potassium (INS 950) in FCs 14.1.4 and 14.1.5 and saccharins (INS 954(i)-(iv)) in subcategories of FC 14.1.4 for discussion on use level.⁴

Background: colours

2. To continue to advance provisions for colours through the step process, CCFA51 requested that the EWG on the GSFA to CCFA52 consider the provisions for colours, both adopted provisions with Note 161 associate with them and provisions in the step process, in various food categories including 14.0 (Beverages, excluding dairy products) and its subcategories (except FCs 14.1.2, 14.1.3, 14.2.3 and their subcategories).⁵

Introduction

3. In preparation for CCFA52's original scheduled date of March 2020, the EWG on the GSFA to CCFA52 issued three circulars requesting comment on the provisions under consideration and published a report with recommendations for those provisions based on comments submitted by EWG members.⁶ However, CCFA52 was rescheduled to 2021 due to the COVID-19 pandemic. To further progress the work of Codex Alimentarius the Codex Secretariat encouraged all the Codex Committees to explore different ways of maintaining the momentum of the Codex standard setting work and to minimize the impact of the pandemic on Codex work. Specific to CCFA, the Codex Secretariat issued a Circular Letter (CL 2020/34-FA) requesting comment on recommendations that, among other tasks, the EWG on the GSFA "continue their work as necessary under the terms of reference established by CCFA51." Under this direction, the Chair of the EWG on the GSFA determined that recirculation of certain provisions for further discussion by the EWG may help CCFA52 reach consensus on those provisions.

¹ REP 19/FA, paras. 138(xi)- (xiii)

² REP 18/FA, para. 142

³ CX/FA 19/51/10

⁴ REP 19/FA para 119

⁵ REP 19/FA, para. 138(i) - (ii)

⁶ CX/FA 20/52/7

4. Specific to the recirculation of the provisions for acesulfame potassium (INS 950) in food categories 14.1.4 and 14.1.5 and saccharins (INS 954(i)-(iv)) in subcategories of food categories 14.1.4, and additives with the functional class of colour in FCs 14.0 and its subcategories (except FCs 14.1.2, 14.1.3, 14.2.3 and their subcategories), the Chair of the EWG on the GSFA to CCFA52 noted that the EWG had not had time to fully discuss all information provided to the second and third circulars. Pertinent to safety, one EWG member provided dietary exposure estimates for the proposed maximum use levels for these additives based on a refined Budget Method. In addition, several EWG members provided information on the technological need for the proposed maximum use levels for several colours, including visual demonstrations of intensification of colour with increasing use level. However, other members had expressed concern that the proposed maximum use levels could result in exposure exceeding the JECFA ADI and lower maximum use levels were considered sufficient to address the technological need. Those comments in favor of lowering the maximum use level did not address the comments provided to the EWG in support of the safety or technological justification for the original proposed use levels. The full comment compilation for the first three circulars of the EWG on the GSFA to CCFA52 specific to the provisions for acesulfame potassium (INS 950) and saccharins (INS 954(i)-(iv)) can be found [here](#)⁷ while the comment compilation specific to colours in food category 14.0 or its subcategories can be found [here](#)⁸ on the CCFA52 webpage.

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5. The EWG issued two circulars for comment. The first recirculation presented the final EWG proposals in from Annex 2 of Appendix 6 of CX/FA 20/52/7 and Annex 2 of Appendix 7 of CX/FA 20/52/7 and requested comment on the use of: acesulfame potassium (INS 950) and saccharins (INS 954(i)-(iv)) in food categories 14.1.4 and 14.1.5, and additives with the functional class of colour in FCs 14.1.4 and its subcategories. The second recirculation contained the full comment submitted by one EWG member to the third circular applying a Refined Budget Method to calculate exposure from the uses under consideration, and contained general comments from EWG members to the first recirculation on the application of the Refined Budget Method to the provisions under discussion. The second recirculation also presented comments from EWG Members in regards to questions to seek comment from JECFA in regards to the suitability of the refined Budget Method and presented comments on the consensus proposals for additives with the functional class of colour in FC 14.1.4.

6. The current document contains 2 Annexes.

7. Annex 1 presents questions to seek comment from JECFA in regards to the suitability of the refined Budget Method and a request from JECFA on reevaluating dietary exposure to acesulfame potassium (INS 950) and saccharins (INS 954(i)-(iv)) in food categories 14.1.4 and 14.1.5.

8. Annex 2 presents proposals for additives with the functional class of colour in FCs 14.1.4 and its subcategories.

9. In the Annexes, the provisions are presented in the format of Table 2 of the GSFA. When a food additive provision from a parent food category is considered in the corresponding subcategories, the provision is indicated in the subcategory in bolded font with no Step indicated in the “Step/Adopted” column.

10. A full compilation of comments submitted for Appendix B to the two recirculations are available [here](#)⁹.

Conventions

⁷ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-52%252FLinks%252FAppendix6_Final_Proposals_with_Comment_Compilation_and_Attachments.pdf

⁸ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-52%252FLinks%252FAppendix6_Final_Proposals_with_Comment_Compilation_and_Attachments.pdf

⁹ <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-52%252FLinks%252FAppendix%20B%20-%20Comment%20Compilation.pdf>

11. These recommendations are based on the “weight of evidence”; that is, comments containing justifications were given more weight than comments with no supporting justification.

Annex 1: Provisions for acesulfame potassium (INS 950) in food categories 14.1.4 and 14.1.5 and saccharins (INS 954(i)-(iv)) in subcategories of food categories 14.1.4

Summary of the EWG on use of for acesulfame potassium (INS 950) and saccharins (INS 954(i)-(iv)) in food categories 14.1.4 and 14.1.5

A key argument in support of certain proposed maximum use levels for acesulfame potassium (INS 950) in FCs 14.1.4 and 14.1.5 and saccharins (INS 954(i)-(iv)) in subcategories of FC 14.1.4, was dietary exposure estimates for non-milk beverages provided by ICBA using a refined Budget Method. The EWG considered the use of the refined budget method, and determined that it would be helpful to obtain comments from JECFA regarding the application of this technique.

Proposals on the types of questions that should be posed to JECFA were received, and a consensus set of questions is posed, below, for consideration by the Committee.

Questions posed by CCFA for consideration by JECFA

Part 1: CCFA requests that JECFA perform a dietary exposure estimate for acesulfame potassium (INS 950) in food categories 14.1.4 and 14.1.5, and saccharins (INS 954(i)-(iv)) in food category 14.1.4.

While in general, lower levels of the food additives will be used, CCFA notes that a maximum level of 600 mg/kg for acesulfame potassium (INS 950) in food categories 14.1.4 and 14.1.5 and a maximum level of 300 mg/kg for saccharins (INS 954(i)-(iv)) in the subcategories of food category 14.1.4 are currently adopted. A proposal has been made to reduce the use level for saccharins (INS 954(i)-(iv)) to 230 mg/kg in food category 14.1.4. Any comments from JECFA on the safety of these maximum use levels would be helpful.

Part 2: CCFA requests JECFA to comment on and discuss the following questions regarding the refined Budget Method presented by ICBA:

- a. Is the refined Budget Method methodology proposed by the ICBA scientifically sound? How conservative is the dietary exposure assessment presented when applied to the sweeteners Acesulfame potassium and Saccharin?
- b. How appropriate is it to apply multiple refinement parameters (such as market share, the percentage of products containing the substance etc.) into a Budget Method calculation?
- c. Are there any limitations, uncertainties and applicability of the refined Budget Method that CCFA should be made aware of?
- d. Are the refined Budget Method and the tiered exposure estimates presented by ICBA suitable methods for determining dietary exposure to colours and sweeteners in non-milk beverages for the purpose of comparing against the JECFA ADI to determine if a proposed maximum use level is safe?
- e. Is it appropriate for CCFA to use dietary exposure estimates provided for non-milk beverages from the refined Budget Method as presented by ICBA to determine maximum use levels for sweeteners in GSFA Food Category 14.1.4 and 14.1.5 that would be below the established JECFA ADI?

Category No. 14.1.4 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks)

Corresponding commodity standards: None

Additive	INS	Max Level	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
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SACCHARINS	954(i)- (iv)	300	161	2008	Sweetener	Collapse this provision into the parent food category 14.1.4 and revise to a reduced ML of 230 mg/kg in FC 14.1.4; addition of Note 127, removal of Note 161 and replacement with the compromise alternative Note 477.	
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Category No. 14.1.4.3 (Concentrates (liquid or solid) for waterbased flavoured drinks)

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	PROVISION WILL BE CONSIDERED IN THE PARENT CATEGORY, FC 14.1.4
SACCHARINS	954(i)- (iv)	300	127 & 161	2008	Sweetener	Collapse this provision into the parent food category 14.1.4 and revise to a reduced ML of 230 mg/kg in FC 14.1.4; addition of Note 127, removal of Note 161 and replacement with the compromise alternative Note 477.	

Category No. 14.1.5 (Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa)

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
ACESULFAME POTASSIUM	950	600	161 & 188	2007	Flavour enhancer, Sweetener	Maintain existing use level of 600 mg/kg. Maintain Note 188, add Note 127, and replace Note 161 with compromise alternative Note 478.	See questions posed by CCFA for consideration by JECFA in summary comment box, above.

Annex 2: Proposals for additives with the functional class of colour in FCs 14.1.4 and its subcategories**Category No. 14.1.4 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks)**

Corresponding commodity standards: None

General Comments:

Australia: A general comment provided by the non-alcoholic beverage industry group was that the discussions and provisions should be limited to the parent food category, being 14.1.4, since similar levels should be, and are, required for the different subcategories.

Canada: Comments for FC 14.1.4 and subcategories: Industry provided comments to Canada during the revision of this first circular letter. The beverage industry would be in favour of provisions for food colours under the parent category FC 14.1.4 as the technological justification is the same for all beverages and drinks conforming to FC 14.1.4. Similar levels are required for each subcategory which would also justify having provisions under the parent category instead of individual provisions for each subcategory. This approach would also be consistent with the approach taken for other food colours already adopted within FC 14.1.4.

Industry has provided technological justification for the use of food colours in beverages. Food colours make beverages of FC 14.1.4 more appealing to the consumers. Synthetic colours are usually more acid- and heat-stable than their natural counterparts, and allow for standardization of colour hues across products. Synthetic colours are reported to be more reliable and versatile by the industry. According to the beverage industry, the use of food colours is not considered to mislead the consumer. Beverages and drinks conforming to FC 14.1.4 are expected to contain food colours, and food colours are labelled on the list of ingredients.

Canada would not object to the inclusion of provisions for the food colours under consideration in the Appendix to the parent category FC 14.1.4 if their use is technologically justified and safe, and if the max levels are similar in all subcategories.

Costa Rica: General Comment for 14.1.4 Parent Category: Discussions on color provisions should be limited to the parent GSFA 14.1.4. category. The GSFA 14.1.4. water-based flavored beverage category is unlike any other GSFA food category as non-alcoholic beverage products consist mostly of water, approximately 85 – 100% as noted by the European Hydration Institute.¹⁰ Technological justification for use of colors will be the same across carbonated and non-carbonated drinks and their corresponding concentrates/syrups. In our analysis across subcategories, we have found that similar levels are indeed required for each subcategory. As there is no meaningful difference across subcategories, color provisions should therefore be discussed at the GSFA 14.1.4. parent category level. This is the approach implemented for almost all other colors currently adopted within GSFA 14.1.4. (http://www.fao.org/gsfaonline/docs/CXS_192e.pdf, see pp. 426-428).

Category No. 14.1.4 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks)							
Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
ALLURA RED AC	129	300	127, 161	2009	Colour	Do not consider in subcategories; Revise adopted provision in parent category 14.1.4—250 mg/kg; Remove Note 161	Revise provision in parent category 14.1.4 to a ML of 150 mg/kg; Maintain Note 127 and remove Note 161.

¹⁰ https://www.europeanhydrationinstitute.org/nutrition_and_beverages Source: Holland B. et al (1991) McCance and Widdowson. The Composition of Foods 5th ed. The Royal Society of Chemistry Cambridge, UK

Category No. 14.1.4 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks)							
Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
AMARANTH	123	100		7	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 50 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 50 mg/kg; Add Note 127
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	50	8	4	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 30 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 30 mg/kg; Add Note 127
ANNATTO EXTRACTS, NORBIXIN BASED	160b(ii)	50	185	4	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 30 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 30 mg/kg; Add Note 127
AZORUBINE (CARMOISINE)	122	100		7	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 95 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 95 mg/kg; Add Note 127
BRILLIANT BLACK (BLACK PN)	151	100		7	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 10 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 10 mg/kg; Add Note 127
CURCUMIN	100(i)	100		7	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 60 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 60 mg/kg; Add Note 127
PAPRIKA EXTRACT	160c(ii)	30	39		Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 30 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 30 mg/kg; Add Notes 39 and 127
QUINOLINE YELLOW	104	100		7	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 120 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 70 mg/kg; Add Note 127
SUNSET YELLOW FCF	110	100	127, 161	2008	Colour	Do not consider in subcategories; Maintain adopted provision in parent category 14.1.4; Remove Note 161	Maintain adopted provision in parent category 14.1.4; Remove Note 161

Category No. 14.1.4 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks)							
Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
TARTRAZINE	102	300		7	Colour	Do not consider in subcategories; Adopt provision in parent category 14.1.4 at 100 mg/kg; Add Note 127	Adopt provision in parent category 14.1.4 at 100 mg/kg; Add Note 127

Category No. 14.1.4.1 (Carbonated water-based flavoured drinks)							
Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
PAPRIKA EXTRACT	160c(ii)	30	39	2	Colour	Do not consider in subcategories; Consider provision in parent category 14.1.4	Do not consider in subcategories; Consider provision in parent category 14.1.4
Category No. 14.1.4.2 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks)							
PAPRIKA EXTRACT	160c(ii)	30	39	2	Colour	Do not consider in subcategories; Consider provision in parent category 14.1.4	Do not consider in subcategories; Consider provision in parent category 14.1.4
Category No. 14.1.4.3 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks)							
PAPRIKA EXTRACT	160c(ii)	300	39	2	Colour	Do not consider in subcategories; Consider provision in parent category 14.1.4	Do not consider in subcategories; Consider provision in parent category 14.1.4

Appendix C: Recirculation of adopted provisions from Annex 3 of Appendix 6 of CX/FA 20/52/7: provisions in the step process for Table 3 additives with sweetener function in food category 14.1.5

Among several topics, CCFA51 requested the EWG on the GSFA to CCFA52 to consider:¹

- draft and proposed draft provisions for Table 3 additives with sweetener function in food category 14.1.5.

Background

1. CCFA50 established the EWG on Note 161 to consider the use of Note 161 related to the use of sweeteners and to review recommendations in a previous discussion paper (CX/FA 19/51/10) in the context of pending and adopted provisions in the GSFA.² The EWG on Note 161 to CCFA51 formulated recommendations³ for provisions in food categories under discussion. These recommendations included that:

- For adopted provisions: these provisions would be revised to replace Note 161 with a specific alternative note
- For provisions in the step process: these provisions would be revised to replace Note 161 with a specific alternative note and circulated for comment by the EWG on the GSFA to CCFA52.

2. In response to these recommendations CCFA51 agreed to request the EWG on the GSFA to CCFA52 to consider, among other topics, draft and proposed draft provisions for sweeteners in the food categories under discussion.⁴

3. In preparation for CCFA52's original scheduled date of March 2020, the EWG on the GSFA to CCFA52 issued three circulars requesting comment on the provisions under consideration and published a report with recommendations for those provisions based on comments submitted by EWG members.⁵ However, CCFA52 was rescheduled to March 2021 due to the COVID-19 pandemic. To further progress the work of Codex Alimentarius, the Codex Secretariat encouraged all the Codex Committees to explore different ways of maintaining the momentum of the Codex standard setting work and to minimize the impact of the pandemic on Codex work. Specific to CCFA, the Codex Secretariat issued a Circular Letter (CL 2020/34-FA) requesting comment on recommendations that, among other tasks, the EWG on the GSFA "continue their work as necessary under the terms of reference established by CCFA51." Under this direction, the Chair of the EWG on the GSFA determined that recirculation of certain provisions for further discussion by the EWG may help CCFA52 reach consensus on those provisions.

4. Specific to the recirculation of draft provisions for Table 3 additives with sweetener function in food category 14.1.5, the Chair of the EWG on the GSFA to CCFA52 noted that the EWG had not fully discussed the topic of a specific numeric use level or a use a level of Good Manufacturing Practice (GMP) in the context of whether the resultant use level could result in a laxative effect.

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5. The EWG issued two circulars for comment. The first recirculation presented the final EWG proposals in Annex 3 of Appendix 6 of CX/FA 20/52/7 and requested information on the technological justification and use levels for provisions for Table 3 additives with sweetener function in food category 14.1.5. The second recirculation sought comments on the consensus proposals for the provisions under discussion in the format of the food categories listed in Table 2 of the GSFA.

6. The current document contains 2 Annexes.

7. Annex 1 presents a summary of the comments from the first and second recirculations.

8. Annex 2 presents proposals for the draft and proposed draft provisions for Table 3 additives with sweetener function in food category 14.1.5.

¹ REP 19/FA, para. 138(x)

² REP 18/FA, para. 142

³ CX/FA 19/51/10

⁴ REP 19/FA para 119

⁵ CX/FA 20/52/7

9. In the Annexes, the provisions are presented in the format of Table 2 of the GSFA. When a food additive provision from a parent food category is considered in the corresponding subcategories, the provision is indicated in the subcategory in bolded font with no Step indicated in the “Step/Adopted” column.

10. A full compilation of comments submitted for Appendix C to the two recirculations are available [here](#)⁶.

Conventions

11. These recommendations are based on the “weight of evidence”; that is, comments containing justifications were given more weight than comments with no supporting justification.

⁶ <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-52%252FLinks%252FAppendix%20C%20-%20Comment%20Compilation.pdf>

Annex 1: Summary of comments from the first and second recirculations

Comments made to the first and second recirculations included support for the food additive provisions in food category 14.1.5 at a use level of GMP and support for the food additive provisions in food category 14.1.5 at a numerical use level.

Members supporting use of the food additive provisions at GMP indicate the following:

- 1) the food additives are Table 3 food additives that have a non-numerical ADI (i.e. usually “not specified”) and do not represent a health risk since they have very low toxicity according to the reviews carried out by JECFA;
- 2) evaluations have indicated that use of the additives at required levels would not result in the likelihood of laxative effects from the consumption of food under FC 14.1.5.;
- 3) the use of these food additives in products covered under FC 14.1.5 at levels not to exceed GMP is self-limiting and any unreasonable use level in the products would render the product unpalatable and will not be accepted by the consumer; and
- 4) the potential for any laxative effect is also addressed by labeling of the product as containing the specified additive.

Members not supporting use of the food additive provisions at GMP indicate the following:

- 1) the use of these food additives in products covered under FC 14.1.5 at GMP is not appropriate, due to concerns about laxative effect;
- 2) some of the food additives have technical affects other than sweetener and flavour enhancer; therefore, clarification from JECFA is needed whether the food additives were assessed by JECFA for their use as sweetener and flavour enhancer in general and in particular in beverages; and
- 3) the clarification provided by JECFA at its 87th meeting regarding the term “ADI ‘not specified’ (see CX/FA 20/52/3, paras 12-15) noted that JECFA endorsed Guideline 2 of the GSFA and recommended that it be applied by addition of appropriate qualifications in Table 3 of the GSFA.

Annex 2: Draft and proposed draft provisions for Table 3 additives with sweetener function in food category 14.1.5**Category No. 14.1.5 (Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa)**

Corresponding commodity standards: None

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
ERYTHRITOL	968	40000		4	Flavour enhancer, Humectant, Sweetener	Adopt at GMP (TABLE 3 ADDITIVE) with Notes 160 and 478.	Adopt at 16000 mg/kg with Notes 160 and 478
ISOMALT (HYDROGENATED ISOMALTULOSE)	953	300000		4	Anticaking agent, Bulking agent, Glazing agent, Stabilizer, Sweetener, Thickener	Adopt at GMP (TABLE 3 ADDITIVE); add Notes 160 and 477	Adopt at 400,000 mg/kg with Notes 160 and 477
LACTITOL	966	30000		4	Emulsifier, Sweetener, Thickener	Adopt at GMP (TABLE 3 ADDITIVE) with Notes 160 and 477	Adopt at 40,000 mg/kg with Notes 160 and 477
MALTITOL	965(i)	100000		4	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener, Thickener	Adopt at GMP (TABLE 3 ADDITIVE) ; Add Notes 160 and 477	Adopt at 2700 mg/kg with Notes 160 and 477
MALTITOL SYRUP	965(ii)	100000		4	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener, Thickener	Adopt at GMP (TABLE 3 ADDITIVE); add Notes 160 and 477	Adopt at 4800 mg/kg with Notes 160 and 477
SORBITOL	420(i)	GMP		4	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener, Thickener	Adopt at GMP (TABLE 3 ADDITIVE); Add Notes 160 and 477	Adopt at 400,000 mg/kg with Notes 160 and 477
SORBITOL SYRUP	420(ii)	GMP		4	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener, Thickener	Adopt at GMP (TABLE 3 ADDITIVE); Add Notes 160 and 477	Adopt at 400,000 mg/kg with Notes 160 and 477

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	CX/FA 20/52/7 Final EWG Proposal	Final Recirculation Proposal
THAUMATIN	957	GMP		4	Flavour enhancer, Sweetener	Adopt at GMP (TABLE 3 ADDITIVE); Add Notes 160 and 478	Adopt at 30 mg/kg with Notes 160 and 478
XYLITOL	967	30000		4	Emulsifier, Humectant, Stabilizer, Sweetener, Thickener	Adopt at GMP (Table 3 additive); Add Notes 160 and 477	Adopt at 40,000 mg/kg with Notes 160 and 477

Appendix D: Provisions for colours in FCs 01.0 through 03.0 and their subcategories including adopted provisions for colours with Note 161 and draft and proposed draft provisions

1. Among several topics, it was agreed that the EWG on the GSFA to CCFA52 would consider additional activities pertaining to the continuation of work on colours including¹:
 - adopted provisions for colours in FCs 01.0 through 03.0 and their subcategories with Note 161 associated with them; and
 - draft and proposed draft provisions for colours in FCs 01.0 through 03.0 and their subcategories.

Introduction:

2. To continue to advance provisions for colours through the step process, CCFA51 requested that the EWG on the GSFA to CCFA52 consider the provisions for colours, both adopted provisions with Note 161 associate with them and provisions in the step process, in food categories 13.6 (*Food supplements*) and 14.0 (*Beverages, excluding dairy products*) and its subcategories (except FCs 14.1.2, 14.1.3, 14.2.3 and their subcategories)². The EWG on the GSFA completed work on this topic and finalized a report with proposals for these provisions (CX/FA 20/52/7, Appendix 4). Subsequently, CCFA52 was postponed to 2021 due to issues related to COVID-19. The Codex Secretariat encouraged all the Codex Committees to explore different ways of maintaining the momentum of the Codex standard setting work and to minimize the impact of the pandemic on Codex work. Specific to CCFA, the Codex Secretariat issued a Circular Letter (CL 2020/34-FA) requesting comment on recommendations that, among other tasks, the EWG on the GSFA considered additional activities pertaining to continuation of work on colours. As a result of comments to this circular letter, it was agreed that the EWG on the GSFA to CCFA52 would continue work on provisions for colours, both adopted provisions with Note 161 associate with them and provisions in the step process, in food categories 01.0 (*Dairy products and analogues, excluding products of food category 02.0*), 02.0 (*Fats and oils, and fat emulsions*) and 03.0 (*Edible ices, including sherbet and sorbet*) and their subcategories.

Working Document:

3. The EWG on the GSFA issued two circulars for comment containing this Appendix. The current document contains proposals on the adopted, draft and proposed draft provisions with the functional class of colours in food categories 01.0 through 03.0 and their subcategories. The proposals are based upon a consensus approach taking into account comments on the first circular by members of the EWG. These recommendations are based on the “weight of evidence”; that is, comments containing justifications were given more weight than comments with no supporting justification. The proposals take into consideration corresponding Codex commodity standards and information on the use of food additives in those commodity standards is provided for each food category.

¹ CL 2020/34-FA

² CX/ FA 20/52/7, Appendix 7

Provisions in FCs 01.0, 02.0, and 03.0 and their subcategories for additives with the functional class of colour: Draft and Proposed Draft Provisions and Adopted Provisions with Note 161

GENERAL COMMENTS on 1st CIRCULAR:

Australia: as the chair of the Alignment EWG provides some comments below linked to the alignment work as appropriate. These relate to the earlier alignment work for the cancelled 2020 CCFA meeting, in CX/FA 20/52/6, as well as the additional alignment work in the current 1st circular of the continued Alignment EWG work (September 2020). This is because some of the food categories and related CCMP commodity standards in this document have been considered in the alignment work.

CANADA: Canada supports discontinuation of colouring provisions in all food categories marked as “plain”. Canada supports holding provisions for carotenoids pending further discussion.

EU: the EU refers in its comments to the typical and maximum reported use levels provided by the industry as a reply to the open calls for data organized by the European Food Safety Authority (EFSA) within a programme for the re-evaluation of approved food additives. The typical and maximum reported use levels are captures in the EFSA opinions publicly available at <http://www.efsa.europa.eu/>.

Category No. 01.1.2 (Other fluid milk (plain))

Corresponding commodity standards: None

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
LUTEIN ESTERS FROM TAGETES ERECTA	160b(i)	GMP		2	Colour	Discontinue
<u>1st and 2nd Circular Proposal:</u> Discontinue						
<u>EWG comments on Proposal:</u>						
Canada, EU, Indonesia, RU, USA, IDF, NATCOL: Supports discontinuation. Colours not normally used in plain food categories						
Australia: Australia can support the proposal and EWG comments that no colours are added to plain products. The Australian permission includes flavoured products which is different. Australia standards does not have this specific food category, but a combined category, “liquid milk products and flavoured liquid milk”. This category allows colourings to be added; at GMP for this colouring.						
PAPRIKA EXTRACT	160c(ii)	30	39	2	Colour	Discontinue
<u>1st and 2nd Circular Proposal:</u> Discontinue						
<u>EWG comments on Proposal:</u>						
Canada, EU, Indonesia, RU, USA, IDF, NATCOL: Supports discontinuation. Colours not normally used in plain food categories						

Australia: Australia can support the proposal and EWG comments that no colours are added to plain products. The Australian permission includes flavoured products which is different. Australia standards does not have this specific food category, but a combined category, "liquid milk products and flavoured liquid milk". This category allows colourings to be added; at GMP for this colouring..

Category No. 01.1.4 (Flavoured fluid milk drinks)

Corresponding commodity standards: CODEX STAN 243-2003 (colours are permitted in flavoured fermented milks and drinks based on fermented milk, including in those heat treated after fermentation), 332R-2017 (all food additives are still under discussions)

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC.

GENERAL COMMENT on 1st CIRCULAR:

Australia: The Alignment EWG is currently (additional circulars for 2021 meeting) considering CXS 243-2003, to align provisions into the GSFA. Australia is the chair of the EWG and so provides the comments below noting this work to date reflecting the 1st circular (September 2020).

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ALLURA RED AC	129	300	52, 161	2009	Colour	Revise Adopted to a ML of 100 mg/kg with a new note ""except for use at 300 mg/kg in products conforming to CODEX STAN 243-2003" Remove Note 161, Retain note 52

2nd Circular Proposal: Retain use level of 300 mg/kg to align with CODEX STAN 243-2003. Discuss if use level is lower in products not covered by the standard. Remove Note 161, Retain note 52

EWG comments on 2nd Circular:

Australia: supports the proposal to align. Accepts the chair's explanation that note 362 is not required for flavoured products. Agree to remove note 161.

EU: information on the appropriate ML should be sought as 300 ppm seems to be excessive.

Guatemala: Support in alignment to CODEX STAN 243- 2003

Indonesia: does not support the proposal. Currently, Allura Rec AC is permitted with maximum level at 70 mg/kg as consumed basis. The maximum level is technologically justified in Food Category 01.1.4.

KR: Not permitted to use in this category

RU: agrees with proposal only in ML=150 mg/kg. In another case ADI 0-7 mg/kg bw could be exided

IACM: supports the proposal.

IDF: supports the proposal. The EWG may consider a lower level of 100 mg/kg for products not covered by the standard.

1st Circular Proposal: Revise Adopted. Remove Note 161

EWG comments on 1st Circular:

Australia: The 1st circular for the Alignment EWG (Appendix 3) proposes to add the note 362 (Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)). Australia supports removal of note 161. – **Chair’s note:** FC 01.1.4 is “flavoured fluid milks”. CODEX STAN 243 has sections for “flavoured” and for “plain” so it is clear that STAN 243 does not consider flavoured products to be plain products. As note 362 is “excluding plain products” it is not appropriate for this FC.

EU: lower ML than 300 ppm should be sufficient. In the EU the industry reported 24ppm as the typical use level and 75ppm was the highest reported level (source: EFSA re-evaluation of allura red ac; 2015).

India: allows at 100 ppm with note 52 in products covered under this category

RU: agrees with proposal only in ML=150 mg/kg. In another case ADI 0-7 mg/kg bw could be exided

USA: Supports removal of Note 161 with addition of Note XS332R. Authorized for use at GMP in foods in general

FIA: Supports revision to remove Note 161.

IACM supports proposal to revise adopted provision to remove Note 161. In JECFA’s most recent safety evaluation, the highest intake of allura red from all foods was 2.9 mg/kg bw/day at the 95th % for children 3–9 years in Europe under the most conservative brand-loyal scenario; however more realistically the intake is up to 1.2 mg/kg bw/day at the 95th % in the non-brand loyal scenario, assuming that 100% products contain this color. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 2.2 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.22 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017). JECFA noted that the range of estimated dietary exposures to allura red from all foods and beverages were well below the ADI (0.4–41% of the ADI) including intake for children and including the conservative estimate by EFSA.

IDF: supports adoption with proposed revision. Allowed/use levels reported between 70 and 100 mg/kg.

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	150	52, XS243	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)

EWG comments on Proposal:

Australia, Canada, EU, Guatemala, Japan, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion

PAPRIKA EXTRACT	160c(ii)	10	39	2	Colour	Adopt at 10 mg/kg with note 39 “on a total carotenoid basis” and new note “Except for use in concentrates at 50 mg/kg”. Request comments on whether INS 160c(ii) is used in products covered by CODEX STAN 243 and if that CODEX STAN should be revised. INS160c(ii) was evaluated by JECFA after CODEX STAN 243-2003 was finalized.
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2nd Circular Proposal: INS160c(ii) was evaluated by JECFA after CODEX STAN 243-2003 was finalized. Request comments on whether INS 160c(ii) is used in products covered by CODEX STAN 243 and if CODEX STAN should be revised. Request comments on actual use levels as comments indicate ML range of 10 – 150 mg/kg. Use levels proposed should discuss safety with respect to JECFA ADI. Request information on specific products within FC utilizing higher use level up to 150 mg/kg.

EWG comments on 2nd Circular:

Australia: defers to others to address use levels

EU: EU does not have any specific information on the use of INS 160c(ii) in products conforming to CXS 243-2003. As regards safety of the ML, the EFSA opinion (EFSA Journal 2015;13(12):4320) shows the typical level of 4.9 ppm and the maximum level of 30ppm for these products based on the data reported by the industry (note: in the EU these products fall within the FC 14.1.4). The refined exposure assessment (brand-loyal scenario) is just at the ADI for high level (P95) consumers (toddlers and children) from all uses authorized in the EU.

Japan: INS 160c(ii) is used in products broadly across this food category to provide desirable colour. Maximum use level is 50 mg/kg on a total carotenoid basis in concentrates for milk-based drinks. Higher use level is necessary for this product only. This product is not covered by CXS 243. For foods conforming to CXS243, INS 160c(ii) is used in fruit-flavoured yoghurt drinks and lactic acid bacteria drinks. Maximum use level is 3 mg/kg on a total carotenoid basis.

RU: Supports proposal of EU and USA adoption at 10 mg/kg with Notes 39 and XS332R

IACM: IACM supports a use level of 150 mg/kg in this category. Typical use levels are between 30-70 mg/kg, but levels up to 150 mg/kg are needed to correspond with higher flavor drinks. See photo for a visual demonstration of drink with various levels of paprika extract included under NATCOL showing levels of 10, 30 and 150 ppm.

IDF: IDF received use levels of up to 2.85 mg/kg as total carotenoids for fruit yoghurt drink and drinks based on fermented milk which are covered by CODEX STAN 243 (the products in 2.3 and 2.4 respectively). CODEX STAN 243 allows for colours in flavoured products. IDF wonders whether the revision of the commodity standard is necessary since provisions will be removed from the standard with the alignment exercise.

NATCOL: Support proposal. 30 mg/kg is required for an orange tone but up to 150 mg/kg is required to reflect customer expectation for intense tropical flavours use level of paprika 10ppm – 150ppm. Shades of paprika at 10ppm, 15ppm, 20ppm, 30ppm and 150ppm:



1st Circular Proposal: Adopt at 10 with Notes 39 and XS332R

EWG Comments on 1st Circular

Australia: The Alignment EWG notes it is at step 2, but it proposed adding the note XS243. Australia wonders if the additional note XS332R (Regional Standard for Doogh) is too early, before food additive provisions have been finalised.

EU, USA: Supports adoption at 10 w Notes 39 and XS332R

India: Paprika extract is used in India since ages as a spice extracts which also contributes coloring properties to a food.

JAPAN: Supports the proposal.INS 160c(ii) is used in products broadly across this food category to provide desirable colour. Maximum use level is 2 mg/kg in fruit-flavoured yoghurt drinks and lactic acid bacteria drinks.

RU: agrees with hold discussion

IACM: supports adoption at 30 mg/kg. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

IDF: supports the proposal. Use levels reported: 20 mg/kg as Paprika Extract (1.68 mg/kg as total carotenoid) for fruit yoghurt drink and lactic acid bacteria drink.

NATCOL: considers that 10 mg/kg gives a pale orangish tone. Therefore, 35 mg/kg is needed to give a medium orange tone and 150 mg/kg for a deep orange tone. Revised Max Level in the draft provision to 150

PONCEAU 4R (COCHINEAL RED A)	124	150	52, 161	2008	Colour	Retain use level of 150 mg/kg to align with CODEX STAN 243-2003. Retain Note 52, Remove Note 161
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2nd Circular Proposal: Retain use level of 150 mg/kg to align with CODEX STAN 243-2003. Retain Note 52, Remove Note 161

Chair Note: Adopted provision max level is 150 with notes 52 and 161. 1st circular incorrectly stated adopted use level as 300 with Notes 161 and XS309R

EWG comments on 2nd Circular:

Australia: supports the amended proposal, which is consistent with the current alignment of CXS 243 (unchanged). Support removal of note 161.

EU: the feedback provided indicates that lower level than 150 would be sufficient to achieve the desired effect.

Guatemala: Support the new proposal to retain level of 150 mg/kg and proposed notes.

Indonesia: does not support the proposal. Currently, Ponceau 4R (Cochineal Red A) is permitted with maximum level at 70 mg/kg. the maximum level is technologically justified in Food Category 01.1.4.

KR: Not permitted to use in this category

RU: Supports proposal of EU and USA adoption at 5 mg/kg

IACM, IDF: Supports proposal

1st Circular Proposal: Revise Adopted. Remove Note 161.

EWG Comments on 1st Circular

Australia: The 1st circular for Alignment EWG (Appendix 3) proposes to add the note 362 (Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)). Australia supports removal of note 161. Australia questions the notes as listed (i.e. 161, XS309R), since from checking they appear to be 52, 161. The Alignment EWG proposes keeping note 52 (excluding chocolate milk).

EU: the use level is excessive. In the EU 10 ppm is considered sufficient also reflecting possible exposure concerns in the EU.

India: allows at 100 ppm with note 52 in products covered under this category

RU: agrees with proposal only in ML=5 mg/kg. In another case ADI 0-4 mg/kg bw could be exided. This quantity enaugh for technology aims.

FIA: Supports revision to remove Note 161.

IACM: supports proposal to revise provision to remove Note 161. In its most recent safety evaluation (2011), JECFA concluded that there is no concern for a likely exceedance of the JECFA ADI of 4 mg/kg bw based on realistic lifetime intake of 0.02 mg/kg bw/day in children in Australia/New Zealand at the 90th % from all foods and beverages.

IDF: supports adoption with proposed revision. Allowed/use levels reported between 70 and 100 mg/kg. Note XS309R (for Regional Standard for Halwa Tehenia) is not needed here.

Category No. 01.2 (Fermented and renneted milk products (plain))

Corresponding commodity standards: None

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC but have been adopted in the subcategories.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
LYCOPENE, BLAKESLEA TRISPORA	160d(iii)	100		4	Colour	Discontinue
LYCOPENE, SYNTHETIC	160d(i)	100		4	Colour	Discontinue
LYCOPENE, TOMATO	160d(ii)	100		4	Colour	Discontinue
ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Discontinue

Category No. 01.2.1 (Fermented milks (plain))

Corresponding commodity standards: CODEX STAN 243-2003 (does not permit colours in plain products)

GSFA: Parent FC is in the Annex to Table 3. One Colour has previously been adopted in this FC.

GENERAL COMMENTS on 1st CIRCULAR:

Australia: supports the proposal to discontinue since there are no provisions for colours in plain products in CXS 243. This was part of the Alignment EWG consideration for the one colour (caramel IV) in FC 01.2.1, so the alignment proposal is to add XS243 to this provision.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
LYCOPENE, BLAKESLEA TRISPIRA	160d(iii)	100			Colour	Do not move from FC 01.2
<p><u>2nd Circular Proposal:</u> Do not move from FC 01.2</p> <p><u>EWG comments on 2nd Circular:</u> Australia, EU, RU: Agree, discontinue</p> <p><u>1st Circular Proposal:</u> Discontinue</p> <p><u>EWG comments on 1st Circular:</u> EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories</p>						
LYCOPENE, SYNTHETIC	160d(i)	100			Colour	Do not move from FC 01.2
<p><u>2nd Circular Proposal:</u> Do not move from FC 01.2</p> <p><u>EWG comments on 2nd Circular:</u> Australia, EU, RU: Agree, discontinue</p> <p><u>1st Circular Proposal:</u> Discontinue</p> <p><u>EWG comments on 1st Circular:</u> EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories</p>						
LYCOPENE, TOMATO	160d(ii)	100			Colour	Do not move from FC 01.2
<p><u>2nd Circular Proposal:</u> Do not move from FC 01.2</p> <p><u>EWG comments on 2nd Circular:</u> Australia, EU, RU: Agree, discontinue</p> <p><u>1st Circular Proposal:</u> Discontinue</p> <p><u>EWG comments on 1st Circular:</u> EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories</p>						

ZEAXANTHIN, SYNTHETIC	161h(i)	100			Colour	Do not move from FC 01.2
2nd Circular Proposal: Do not move from FC 01.2						
EWG comments on 2nd Circular: Australia, EU, RU: Agree, discontinue						
1st Circular Proposal: Discontinue						
EWG comments on 1st Circular: EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories						

Category No. 01.2.2 (Renneted milk (plain))

Corresponding commodity standards: None (CODEX STAN 243-2003 applies to parent FC but does not cover renneted milk)

GSFA: Parent FC is in the Annex to Table 3. One Colour has previously been adopted in this FC.

GENERAL COMMENT:

Australia: notes that although CXS 243 does not apply to this FC, to be consistent with FC 01.2.1 above no provisions for colours should apply. Therefore Australia supports discontinuation.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
LYCOPENE, BLAKESLEA TRISPOA	160d(iii)	100			Colour	Do not move from FC 01.2
2nd Circular Proposal: Do not move from FC 01.2						
EWG comments on 2nd Circular: Australia, EU, RU: Agree, discontinue						
1st Circular Proposal: Discontinue						
EWG comments on 1st Circular: EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories						
LYCOPENE, SYNTHETIC	160d(i)	100			Colour	Do not move from FC 01.2
2nd Circular Proposal: Do not move from FC 01.2						
EWG comments on 2nd Circular: Australia, EU, RU: Agree, discontinue						
1st Circular Proposal: Discontinue						

EWG comments on 1st Circular:						
EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories						
LYCOPENE, TOMATO	160d(ii)	100			Colour	Do not move from FC 01.2
2nd Circular Proposal: Do not move from FC 01.2						
EWG comments on 2nd Circular:						
Australia, EU, RU: Agree, discontinue						
1st Circular Proposal: Discontinue						
EWG comments on 1st Circular:						
EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories						
TITANIUM DIOXIDE	171	GMP		7	Colour	Do not move from FC 01.2
2nd Circular Proposal: Do not move from FC 01.2						
EWG comments on 2nd Circular:						
Australia, EU, RU: Agree, discontinue						
1st Circular Proposal: Discontinue						
EWG comments on 1st Circular:						
EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories						
ZEAXANTHIN, SYNTHETIC	161h(j)	100			Colour	Do not move from FC 01.2
2nd Circular Proposal: Do not move from FC 01.2						
EWG comments on 2nd Circular:						
Australia, EU, RU: Agree, discontinue						
1st Circular Proposal: Discontinue						
EWG comments on 1st Circular:						
EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories						

Category No. 01.3.2 (Beverage whiteners)

Corresponding commodity standards: CODEX STAN 250-2006, 252-2006 (neither CODEX STAN permits the use of colours)

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENTS on 1st CIRCULAR:

Australia: The Alignment EWG aligned the food additives for CXS 250-2006 and CXS 252-2006 as part of CX/FA 20/52/6. The comments below relate to the alignment work.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	50	8	4	Colour	Adopt at 50 with Notes 8, XS250, XS252
<p>2nd Circular Proposal: Adopt at 50 with Notes 8, XS250, XS252. Request further information on use in products in this FC.</p> <p><u>EWG comments on 2nd Circular:</u> Australia: supports the proposal. No additional information on use, defer to others EU: supports requesting further information on the use and justification in this FC. Guatemala, IACM, IDF: Supports proposal RU: Supports discontinuation. Do not used in this FC NATCOL: Supports proposal. Colour shade suitable and stable in this application. 50mg/kg proposed is enough to reach the requested colours. 1st Circular Proposal: Adopt at 50 with Notes 8, XS250, XS252</p> <p><u>EWG comments on 1st Circular:</u> Australia: supports the proposal noting the Alignment EWG document added XS250 and XS252, but left it at step 4. EU: not permitted in the EU in this FC. USA: Supports adoption at 50 with Notes 8, XS250, XS252. Authorized for use at GMP in foods in general IACM: supports adoption at 50 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI. IDF: supports adoption, the maximum level corresponds to reported use level. NATCOL: Supports adoption at 50 mg/kg</p>						
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100	XS250, XS252	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
<p>1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)</p>						

EWG comments on Proposal: Australia, EU, Guatemala, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion						
LYCOPENE, TOMATO	160d(ii)	5000		3	Colour	Discontinue Use is already permitted in this FC under provision adopted in Table 3
1st and 2nd Circular Proposal: Discontinue. Use is already permitted in this FC under provision adopted in Table 3						
EWG comments on Proposal: Australia, EU, RU, USA, IACM: Supports discontinuation. Use is already permitted in this FC under provision adopted in Table 3						
IDF: agrees with the proposal if listing confirmed in table 3. It is used in the category, therefore it is important to keep it in Table 3, or adopt this provision in table 1 and 2.						
PAPRIKA EXTRACT	160c(ii)	5	39	2	Colour	Adopt at 5 with Notes 39, XS250, XS252
1st and 2nd Circular Proposal: Adopt at 5 with Notes 39, XS250, XS252						
EWG comments on Proposal: Australia: supports the proposal noting the Alignment EWG document added XS250 and XS252, but left it at step 2. EU, Guatemala, RU USA: Supports adoption at 5 with Notes 39, XS250, XS252 IACM: supports proposal to adopt at 5 mg/kg. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern. IDF: supports adoption, the maximum level corresponds to reported use level. NATCOL: Supports proposal.						
TARTRAZINE	102	300		7	Colour	Adopt at 300 with Notes XS250, XS252
2nd Circular Proposal: Adopt at 300 with Notes XS250, XS252. Request further information on use in products in this FC						
EWG comments on 2nd Circular: Australia: supports the proposal. No additional information on use, defer to others EU: supports requesting further information on the use and justification in this FC. RU: Supports adoption at 300 with Notes XS250, XS252 IACM, IDF: Supports proposal 1st Circular Proposal: Adopt at 300 with Notes XS250, XS252 EWG comments on 1st Circular: Australia: supports the proposal noting the Alignment EWG document added XS250 and XS252, but left it at step 7.						

EU: not permitted in the EU in this FC.

RU, USA: Supports adoption at 300 with Notes XS250, XS252. Authorized for use in foods in general

IACM: supports proposal to adopt at 300 mg/kg. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017).

IDF: supports adoption, the maximum level corresponds to reported use level.

Category No. 01.4.1 (Pasteurized cream (plain))

Corresponding commodity standards: CODEX STAN 288-1976 (colours are not permitted)

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT:

Australia: The Alignment EWG is currently (additional circulars for 2021 meeting) considering CXS 288-1976, to align provisions into the GSFA for the FC 01.4.1, 01.4.2. and 01.4.3, but not 01.4.4. Australia is the chair of the EWG and so provides the comments below noting this work to date reflecting the 1st circular (September 2020).

Australia supports not having provisions for colours in this FC, since there are no provisions in CXS 288-1976. The Alignment EWG has proposed XS288 for each of them, with no changes to the step number.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
BEET RED	162	GMP		7	Colour	Discontinue
<u>1st and 2nd Circular Proposal:</u> Discontinue						
<u>EWG comments on Proposal:</u>						
Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						
CARAMEL I- PLAIN CARAMEL	150a	GMP		7	Colour	Discontinue
<u>1st and 2nd Circular Proposal:</u> Discontinue						

EWG comments on Proposal:						
Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						
CHLOROPHYLLS	140	GMP		7	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
EWG comments on Proposal:						
Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						
TITANIUM DIOXIDE	171	GMP		7	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
EWG comments on Proposal:						
Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						

Category No. 01.4.2 (Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain))

Corresponding commodity standards: CODEX STAN 288-1976 (colours are not permitted)

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR:

Australia: supports not having provisions for colours in this FC, since there are no provisions in CXS 288-1976. The Alignment EWG has proposed XS288 for each of them, with no changes to the step number.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
BEET RED	162	GMP		7	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
EWG comments on Proposal:						
Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						
CARAMEL I- PLAIN CARAMEL	150a	GMP		7	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
EWG comments on Proposal:						
Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						
CHLOROPHYLLS	140	GMP		7	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						

EWG comments on Proposal: Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						
LYCOPENE, TOMATO	160d(ii)	5000		3	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
EWG comments on Proposal: Australia, EU, RU, USA, IACM, IDF: Supports discontinuation. Colours not normally used in plain food categories						
TITANIUM DIOXIDE	171	GMP		7	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
EWG comments on Proposal: Australia, EU, RU, USA, IDF: Supports discontinuation. Colours not normally used in plain food categories						

Category No. 01.4.4 (Cream analogues)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	20		2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						
EWG comments on Proposal: Australia, EU, Guatemala, JAPAN, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion						
LYCOPENE, TOMATO	160d(ii)	5000		3	Colour	Discontinue Use is already permitted in this FC under provision adopted in Table 3
1st and 2nd Circular Proposal: Discontinue. Use is already permitted in this FC under provision adopted in Table 3						
EWG comments on Proposal: Australia, EU, Guatemala, RU, USA, IACM, IDF, NATCOL: Supports discontinuation. Use is already permitted in this FC under provision adopted in Table 3						
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	100	8	4	Colour	Adopt at 100 with Note 8
2nd Circular Proposal: Adopt at 100 with Note 8. Request further information on use in products in this FC						

EWG comments on 2nd Circular:

Australia: No additional information on use. Defer to others.

EU: supports requesting further information on the use in this FC.

Guatemala, IACM, IDF: Supports proposal

RU: does not agree with the proposal. There not safety and technological justification

NATCOL: The use of bixin is suitable to give a colour shade associated with dairy products and stable in this application.

1st Circular Proposal: Adopt at 100 with Note 8

EWG comments on 1st Circular:

EU: not requested by the industry for use in this FC in the EU.

RU: does not agree with the proposal. There not safety and technological justification

USA: Supports adoption at 100 with Note 8. Authorized for use at GMP in foods in general. Note that there is a typo in the name. Correct name is Annatto extracts, bixin based.

IACM: supports proposal to adopt at 100 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

NATCOL: Supports adoption at 100 mg/kg

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	300	185	4	Colour	Further discussion on actual use and use levels
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2nd Circular Proposal: Request information on actual use and use levels

EWG comments on 2nd Circular:

Australia: No additional information on use. Defer to others.

EU: supports requesting further information on the use

RU: does not agree with the proposal. There not safety and technological justification

IACM: Supports 1st CL proposal to adopt

1st Circular Proposal: Adopt at 300 with Note 185

EWG comments on 1st Circular:

EU: EU does not support the adoption. Not requested by the industry for use in this FC in the EU. The use of ANNATTO EXTRACTS, NORBIXIN-BASED needs to be restricted due to its low ADI. In the EU the exposure to ANNATTO EXTRACTS, NORBIXIN-BASED is at the ADI, whilst this colour is not permitted for use in this FC. Colours with higher ADIs or ADIs not specified shall be used instead.

RU: does not agree with the proposal. There not safety and technological justification

USA: Supports adoption at 300 with Note 185. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 300 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI.

NATCOL: Supports adoption at 300 mg/kg

PAPRIKA EXTRACT	160c(ii)	5	39	2	Colour	Adopt at 5 with Note 39
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1st and 2nd Circular Proposal: Adopt at 5 with Note 39

EWG comments on Proposal:

Australia, EU, Guatemala, RU, USA: Supports proposal- adoption at 5 with Notes 39

IACM: supports proposal to adopt at 5 mg/kg. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

NATCOL: Supports proposal. considers that 5 mg/kg would be enough to obtain a cream shade

Category No. 01.5.2 (Milk and cream powder analogues)

Corresponding commodity standards: CODEX STAN 251-5006 (colours are not permitted)

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR:

Australia: The Alignment EWG aligned the food additives for CXS 251-2006 as part of CX/FA 20/52/6. The comments below relate to the alignment work.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100	XS251	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						

EWG comments on Proposal:**Australia, EU, Guatemala, RU, USA, IACM, IDF, NATCOL:** Supports holding pending carotenoid discussion

ANNATTO EXTRACTS, BIXIN- BASED	160b(i)	100	8	4	Colour	Adopt at 100 with Notes 8, 72 (On the ready-to-eat basis) and XS251
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2nd Circular Proposal: Adopt at 100 with Notes 8 and XS251. Request further information on use in products in this FC**EWG comments on 2nd Circular:****Australia:** supports the proposal. No additional information on use, defer to others**EU:** supports requesting further information on the use**Guatemala, IACM, IDF:** Supports proposal**RU:** does not agree with the proposal. There not safety and technological justification**NATCOL:** The dosage in on a “ready-to-eat” basis. The use of bixin is suitable to give a colour shade associated with dairy products and stable in this application.**1st Circular Proposal:** Adopt at 100 with Notes 8 and XS251**EWG comments on 1st Circular:****Australia:** supports the proposal noting the Alignment EWG document added XS251, but left it at step 4.**EU:** Not requested by the industry for use in this FC in the EU.**RU:** does not agree with the proposal. There not safety and technological justification**USA:** Supports adoption at 100 with Note 8 and XS251. Authorized for use at GMP in foods in general. Note that there is a typo in the name. Correct name is Annatto extracts, bixin based.**IACM:** supports proposal to adopt at 100 mg/kg Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.**IDF:** supports adoption, the maximum level corresponds to reported use level.**NATCOL:** Supports adoption at 100 mg.kg

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	55	185	4	Colour	Further discussion necessary on use in products in this FC. Available information indicates a use level of 55 mg/kg with Notes 185 and XS251
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2nd Circular Proposal: Adopt at 55 with Notes 185 and XS251. Request further information on use in products in this FC

EWG comments on 2nd Circular:

Australia: supports the proposal. No additional information on use, defer to others

EU: supports requesting further information on the use

Guatemala, IACM, IDF: Supports proposal

RU: does not agree with the proposal. There not safety and technological justification

NATCOL: Supports proposal. Suitable and stable in this application. Gives colour to analogue uncoloured bases.

1st Circular Proposal: Adopt at 55 with Notes 185 and XS251

EWG comments on 1st Circular:

Australia: supports the proposal noting the Alignment EWG document added XS251, but left it at step 4.

EU: EU does not support the adoption. Not requested by the industry for use in this FC in the EU. The use of ANNATTO EXTRACTS, NORBIXIN-BASED needs to be restricted due to its low ADI. In the EU the exposure to ANNATTO EXTRACTS, NORBIXIN-BASED is at the ADI, whilst this colour is not permitted for use in this FC. Colours with higher ADIs or ADIs not specified shall be used instead.

RU: does not agree with the proposal. There not safety and technological justification

USA: Supports adoption at 55 with Note 185 and XS251. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 55 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI.

IDF: supports adoption, the maximum level corresponds to reported use level.

NATCOL: Supports adoption at 55 mg/kg

PAPRIKA EXTRACT	160c(ii)	5	39	2	Colour	Adopt at 5 with Notes 39, 72 (On the ready-to-eat basis) and XS251
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2nd Circular Proposal: Adopt at 5 with Notes 39, 72 (On the ready-to-eat basis) and XS251.

EWG comments on 2nd Circular:

Australia, EU, Guatemala, RU, IACM, IDF, NATCOL: Supports proposal

1st Circular Proposal: Adopt at 5 with Note 29 and XS251

EWG comments on 1st Circular:

Australia: supports the proposal noting the Alignment EWG document added XS251, but left it at step 4.

EU, RU, USA: Supports 1st CL proposal- adoption at 5 with Notes 39, XS251

IACM: supports proposal to adopt at 5 mg/kg. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern

IDF: supports adoption, the maximum level corresponds to reported use level.

NATCOL: considers that 5 mg/kg (on a ready to eat basis) would be enough to obtain a cream shade

Category No. 01.6.1 (Unripened cheese)

Corresponding commodity standards: CODEX STAN 221-2001 (permits the use of specific colours); 283-1978 (refers to additives allowed in CODEX STAN 221-2001 for this FC), 262-2007 (permits the use of specific colours for specific purposes), 273-1968 (colours are not permitted), 275-1972 (permits the use of specific colours)

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC. This FC includes both standardized and non-standardized (Flavoured unripened cheese) products

GENERAL COMMENTS on 1st CIRCULAR:

Australia: The Alignment EWG aligned the food additives for CXS 221-2001, CXS 273-1968, CXS 275-1973 and CXS 283-1978 as part of CX/FA 20/52/6. The Alignment EWG is currently (additional circulars for 2021 meeting) considering CXS 262-2007. These are all to align provisions into the GSFA for the FC 01.6.1. Australia is the chair of the EWG and so provides the comments below, noting the work to date for CXS 262-2007 reflects the 1st circular (September 2020). Notes that CXS 275-1973 is a corresponding commodity standard.

RU: Only flavoured unripened cheese

USA: Commodity standard 275-1973 is a corresponding commodity standard which permits the use of specific colours

IDF: IDF notes that this category includes standards that have been aligned and refers to the comments made by the delegation of Australia for consistency, in particularly regarding notes.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, NORBIXIN BASED	160b(ii)	25	185	4	Colour	Adopt at 25 with Notes 185, XS262, XS273 Chair Note: allowed in CODEX STAN 221 and 275 (cheese mass only) a 25 mg/kg.
<u>1st and 2nd Circular Proposal:</u> Adopt at 25 with Notes 185, XS262, XS273						
<u>EWG comments on Proposal:</u>						
Australia: Australia supports the proposal which is consistent with the alignment work. But alignment has proposed one additional new note, as noted below. The EWGs for GSFA and Alignment need to coordinate proposed amendments. Australia notes the Alignment EWG proposed provisions consistent with						

proposal, but with additional new note “Only for use in products conforming to the Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001) and the cheese mass of products conforming to the Standard for Cream Cheese (CXS 275-1973)”.

EU: EU does not support the adoption. Not requested by the industry for use in this FC in the EU. The use of ANNATTO EXTRACTS, NORBIXIN-BASED needs to be restricted due to its low ADI. In the EU the exposure to ANNATTO EXTRACTS, NORBIXIN-BASED is at the ADI, whilst this colour is not permitted for use in this FC. Colours with higher ADIs or ADIs not specified shall be used instead.

Guatemala: Supports adoption

RU: does not agree with the proposal. There not safety and technological justification

USA: Supports adoption at 25 with Note 185, XS262, XS273. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 25 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI.

IDF: supports adoption as proposed. Reported use levels up to 50 mg/kg.

AZORUBINE (CARMOISINE)	122	GMP	3	7	Colour	Adopt at 150 with notes XS221, XS262, XS273, XS275 and Note 201 “For use in flavoured products only.”
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2nd Circular Proposal: This colour is not allowed in any of the corresponding commodity standards – add notes XS221, XS262, XS273, XS275. GMP is not appropriate as INS 122 has a numeric use level. Request info on actual use and use level.

EWG comments on 2nd Circular:

Australia: supports adding notes XS221, XS262, XS273 and XS275 as this colour is not allowed in these standards. Alignment added these exclusion notes, noting it is a proposed draft provision. It also agrees that GMP is not appropriate, but it has no information on use levels so defers to others.

EU: supports requesting further info. No use reported by the industry in the EU (EFSA Journal 2015;13(3):4072)

RU: Could not be used in GMP/. This FA have ADI 0-4 mg/kg bw. Do not use in this FC

IACM: suggests adoption at 150 mg/kg.

1st Circular Proposal: Provision was omitted from 1st CL.

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100	XS221, XS262, XS273, XS275, XS283	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)

EWG comments on Proposal:

Australia, EU, Guatemala, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion

BRILLIANT BLACK (BLACK PN)	151	GMP	3	7	Colour	Adopt at 150 with notes XS221, XS262, XS273, XS275 and Note 201 "For use in flavoured products only."
<p>2nd Circular Proposal: This colour is not allowed in any of the corresponding commodity standards – add notes XS221, XS262, XS273, XS275. GMP is not appropriate as INS 151 has a numeric use level. Request info on actual use and use level.</p> <p>EWG comments on 2nd Circular: Australia: supports adding notes XS221, XS262, XS273 and XS275 as this colour is not allowed in these standards. Alignment added these exclusion notes, noting it is a proposed draft provision. It also agrees that GMP is not appropriate, but it has no information on use levels so defers to others.</p> <p>EU: supports requesting further info. No use reported by the industry in the EU (EFSA Journal 2015;13(1):3960)</p> <p>RU: Could not be used in GMP/. This FA have ADI 0-1 mg/kg bw. Do not use in this FC</p> <p>IACM: suggests adoption at 150 mg/kg.</p> <p>1st Circular Proposal: Provision was omitted from 1st CL.</p>						
BROWN HT	155	GMP	3	7	Colour	Adopt at 150 with notes XS221, XS262, XS273, XS275 and Note 201 "For use in flavoured products only."
<p>2nd Circular Proposal: This colour is not allowed in any of the corresponding commodity standards – add notes XS221, XS262, XS273, XS275. GMP is not appropriate as INS 155 has a numeric use level. Request info on actual use and use level.</p> <p>EWG comments on 2nd Circular: Australia: supports adding notes XS221, XS262, XS273 and XS275 as this colour is not allowed in these standards. Alignment added these exclusion notes, noting it is a proposed draft provision. It also agrees that GMP is not appropriate, but it has no information on use levels so defers to others.</p> <p>EU: supports requesting further info. No use reported by the industry in the EU (EFSA Journal 2014;12(5):3719)</p> <p>RU: Do not use in this FC</p> <p>IACM: suggests adoption at 150 mg/kg.</p> <p>1st Circular Proposal: Provision was omitted from 1st CL.</p>						
CARAMEL II- SULFITE CARAMEL	150b	50000		4	Colour	Chair's Note: In this FC, INS 150c is adopted at 15000 and 150d at 50000 mg/kg both with Note 201 "For use in flavoured products only." Adopt at 50000 with Notes 201, XS221, XS262, XS273, XS275
<p>2nd Circular Proposal: Adopt with Notes XS 221, XS262, XS273, XS275</p> <p>Chair's Note: In this FC, INS 150c is adopted at 15000 and 150d at 50000 mg/kg both with Note 201 "For use in flavoured products only."</p> <p>EWG comments on 2nd Circular:</p>						

Australia: supports adding notes XS221, XS262, XS273 and XS275 as this colour is not allowed in these standards. Alignment added these exclusion notes, noting it is a proposed draft provision.

EU: can technological justification be provided, in particular for the ML suggested? Any example of product requiring 50000 ppm? In the EU the industry did not report any use of this colour in this FC (EFSA, 2011). The ML at 50000 ppm is excessive. Note 201 shall be added

Guatemala, IACM, IDF: Supports proposal

RU: Strongly opposite proposal!!!!!!!. All proposals for the use of the colour CARMEL II- SULFITE CARMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

1st Circular Proposal: Adopt at 50000 with Notes XS262, XS273

EWG comments on 1st Circular:

Australia: notes the Alignment EWG proposed provisions consistent with proposal, but with additional new note XS275, but left at step 4

EU: the industry did not report any use of this colour in this FC (EFSA, 2011). The ML at 50000 ppm is excessive.

RU: consider discontinuation. All proposals for the use of the colour CARMEL II- SULFITE CARMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 50000 with Notes XS262, XS273. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA’s most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. Therefore, the intake from this food category is expected to represent a small fraction of the most conservative intake of up to 38 mg/kg bw/day that was estimated to result from the primary use of the color (alcoholic beverages) at the 95% of consumers-only. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

IDF: supports adoption as proposed.

CHLOROPHYLLS AND CHLOROPHYLLINS, COPPER COMPLEXES	141(i), (ii)	50	161	2009	Colour	Chair’s Note: Proposal is consistent with food additives permitted in CXS 221 and 262 as specified in the proposed new notes Revise Adopted to remove Note 161 and add notes XS273, XS275 and new notes “Except for use in products conforming to the Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001) at 15 mg/kg” and “Except for use in products conforming to the Standard for Mozzarella (CXS 262-2006) at 5 mg/kg, in cheese mass only, to obtain the colour characteristics of the product”.
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2nd Circular Proposal: Revise Adopted to remove Note 161 and add notes XS273, XS275 and new notes “Except for use in products conforming to the Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001) at 15 mg/kg” and “Except for use in products conforming to the Standard for Mozzarella (CXS 262-2006) at 5 mg/kg, in cheese mass only, to obtain the colour characteristics of the product”.

Chair’s Note: Proposal is consistent with food additives permitted in CXS 221 and 262 as specified in the proposed new notes

EWG comments on 2nd Circular:

Australia: supports the proposal as it is consistent with the alignment work as noted. The EWGs for GSFA and Alignment need to coordinate proposed amendments, which is the situation here.

EU: the use is technologically justified only for flavoured unripened cheese.

RU: agrees with the proposal only for flavoured unripened cheese – not for Unripened Cheese including Fresh Cheese (CXS 221-2001) at 15 mg/kg” and “Except for use in products conforming to the Standard for Mozzarella (CXS 262-2006)) at 5 mg/kg, in cheese mass only, to obtain the colour characteristics of the product”.

IACM, IDF, NATCOL: Supports proposal.

1st Circular Proposal: Revise Adopted to remove Note 161

EWG comments on 1st Circular:

Australia: supports removal of note 161. Australia notes the Alignment EWG proposed provisions with additional notes “Except for use in products conforming to the Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001) at 15 mg/kg”, “Except for use in products conforming to the Standard for Mozzarella (CXS 262-2006) at 5 mg/kg, in cheese mass only, to obtain the colour characteristics of the product”, XS273 and XS275.

EU: the use is technologically justified only for flavoured unripened cheese.

RU: agrees with the proposal (only flavoured) unripened cheese

USA: Supports removal of Note 161 with addition of notes XS221, XS273, XS275 for consistency with commodity standards. Authorized for use at GMP for foods in general.

FIA: Supports revision to remove Note 161.

IACM: supports proposal to revise adopted provision to remove Note 161. The overall average daily intake from use in this category is a small fraction of the JECFA ADI of 15 mg/kg bw/day.

IDF: supports adoption as proposed. Reported use levels up to 50 mg/kg.

NATCOL: Supports adoption at level 50 mg/kg. Permitted at 15 mg/kg according to CXS 221 and 5 mg/kg in CXS 262 (mozzarella)

CURCUMIN	100(i)	500		3	Colour	Chair’s Note: Proposal is consistent with food additives permitted in CXS 221 as specified in the proposed new note
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						Adopt at 150 with Notes XS262, XS273, XS275 and new note “For use in products conforming to the Group Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001), for treatment of edible cheese rind only”
<p>2nd Circular Proposal: Adopt at 150 with Notes XS262, XS273, XS275 and new note “For use in products conforming to the Group Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001), for treatment of edible cheese rind only”</p> <p>Chair’s Note: Proposal is consistent with food additives permitted in CXS 221 as specified in the proposed new note</p> <p>EWG comments on 2nd Circular:</p> <p>Australia: supports the proposal as mainly consistent with alignment. However, it notes the different ML now proposed being 150 mg/kg, which is different to alignment in CXS 221. This is GMP, but only for use in edible cheese rind, ie the new note.</p> <p>EU: Supports</p> <p>RU: agrees with the proposal only in ML=150 mg/kg, only flavoured unripened cheese</p> <p>IACM, IDF: Supports proposal</p> <p>1st Circular Proposal: Adopt at 500 with Notes XS262, XS273</p> <p>EWG comments on 1st Circular:</p> <p>Australia: notes the Alignment EWG proposed provision at GMP with additional notes, “For use in products conforming to the Standard for Unripened Cheese including Fresh Cheese (CXS 221-2001), for treatment of edible cheese rind only”, XS273 and XS275.</p> <p>EU: the use is technologically justified only for flavoured unripened cheese. The industry reported 20-30 ppm as the typical use level and 150 ppm as the maximum use level. The use level is important as the exposure to curcumin is at the ADI in the EU (EFSA, 2014).</p> <p>RU: agrees with the proposal only in ML=150 mg/kg, only flavoured unripened cheese</p> <p>USA: Supports adoption at 500 with XS Notes. Authorized for use at GMP for foods in general</p> <p>IACM: supports proposal to adopt at 500 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.</p> <p>IDF: supports adoption as proposed.</p>						
LUTEIN FROM TAGETES ERECTA	161b(i)	GMP		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
<p>1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.</p> <p>EWG comments on Proposal:</p> <p>Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending discussion in Table 3</p>						
PAPRIKA EXTRACT	160c(ii)	15	39	2	Colour	Chair’s Note: Proposal does not include notes XS262, XS221 or XS275 as per comments from observers (See below). EWG

						members are requested to discuss the revision of these two commodity standards to include paprika extract (INS 160c(ii)). Adopt at 15 with Notes 39, XS273
<p>2nd Circular Proposal: Adopt at 15 with Notes 39, XS273, XS275</p> <p>Chair's Note: Proposal does not include notes XS262 or XS221 as per comments from observers (See below). EWG members are requested to discuss the revision of these two commodity standards to include paprika extract (INS 160c(ii)).</p> <p>EWG comments on 2nd Circular:</p> <p>Australia: notes the additional comments received, which is in addition to the current alignment proposal which is as indicated in Australia's comments to the 1st circular. It supports seeking additional views of the EWG on the comments received and current proposal. As noted earlier the EWGs for GSFA and Alignment need to coordinate proposed amendments, especially if in this case the proposed amendments are different.</p> <p>EU: justification for the need of INS160c(ii) in XS 262 and 221 shall be provided. In the EU's view use of colours in this FC is justified only for flavoured products.</p> <p>RU: agrees with proposal adopt at 15 with Notes 39 and XS262, only flavoured unripened cheese. Notes XS273, XS275, XS221 are absent in GSFA</p> <p>IACM: supports EWG proposal to adopt at 15 mg/kg with notes XS262 and XS273. IACM asks whether note XS275 is appropriate.</p> <p>IDF: Supports the proposal. IDF wonders whether the revision of the commodity standard is necessary since provisions will be removed from the standard with the alignment exercise.</p> <p>NATCOL: Supports adoption at 15ppm with Notes XS262 (mozzarella, which allows no yellow-red colors at present and gives no obvious justification for these colors) and XS273 (cottage cheese, no colors permitted). With respect for JECFA assessment of paprika extract, remove note XS275 (cream cheese, where carotenes and norbixin are already permitted) and refer approval for alignment with this standard.</p> <p>1st Circular Proposal: Adopt at 15 with Notes 39, XS262, and XS273</p> <p>EWG comments on 1st Circular:</p> <p>AUSTRALIA: notes the Alignment EWG proposed provisions consistent with proposal, but with additional exclusion notes, XS221 and XS275.</p> <p>EU: the use is technologically justified only for flavoured unripened cheese. The EU can accept the adoption at 15ppm restricted to flavoured unripened cheese.</p> <p>GUATEMALA: > 320 mg/kg</p> <p>RU: agrees with the 1st CL proposal, only flavoured unripened cheese</p> <p>USA: Supports adoption at 15 with Notes 39, XS262, XS273. Authorized for use in foods at GMP.</p> <p>FIA: At the sixth session of the Codex Committee on Milk and Milk Products (CCMMP6), paprika oleoresin was listed in the proposed draft Standard for mozzarella at GMP. However at CCMMP7 all provisions for paprika oleoresin were removed from individual cheese standards as paprika oleoresin had only been evaluated by JECFA as a spice.</p>						

The intention was that, following a positive outcome of the JECFA evaluation of paprika extract/paprika oleoresin for use as a colour, the provisions for the use of paprika extract/paprika oleoresin would be re-included in the relevant cheese standards.

Paprika extract has now been assessed by JECFA as a colour. Since it has an ADI, a numerical ML is appropriate rather than GMP.: At the sixth session of the Codex Committee on Milk and Milk Products (CCMMP6), paprika oleoresin was listed in the proposed draft Standard for mozzarella at GMP. However at CCMMP7 all provisions for paprika oleoresin were removed from individual cheese standards as paprika oleoresin had only been evaluated by JECFA as a spice.

The intention was that, following a positive outcome of the JECFA evaluation of paprika extract/paprika oleoresin for use as a colour, the provisions for the use of paprika extract/paprika oleoresin would be re-included in the relevant cheese standards.

Paprika extract has now been assessed by JECFA as a colour. Since it has an ADI, a numerical ML is appropriate rather than GMP.

IACM: supports proposal to adopt at 15 mg/kg. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

IDF: supports adoption. Notes action at CCMMP6 and CCMMP7 as discussed by FIA above. Paprika extract has now been assessed by JECFA as a colour. Since it has an ADI, a numerical ML is appropriate rather than GMP. IDF wonders if the note XS262 could be therefore removed by the EWG.

PONCEAU 4R (COCHINEAL RED A)	124	100	3, 161	2008	Colour	Revise Adopted to remove Note 161, maintain note 3, and add notes XS221, XS262, XS273 and XS275 and note 201 "for use in flavoured products only".
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2nd Circular Proposal: Revise adopted to remove Note 161, maintain note 3, and add notes XS221, XS262, XS273 and XS275

EWG comments on 2nd Circular:

Australia, IDF: Supports proposal

EU: not permitted in the EU in this FC. The use of this colour is restricted due to its low ADI in the EU. Is it used in this FC? At what level?

RU: does not agree with proposal. There not safety and technological justification.

1st Circular Proposal: Revise Adopted to remove Note 161.

EWG comments on 1st Circular:

Australia: supports removal of note 161. Australia notes the Alignment EWG proposed provisions with additional notes, XS221, XS262, XS273 and XS275.

EU: not permitted in the EU in this FC. The use of this colour is restricted due to its low ADI in the EU.

RU: does not agree with proposal. There not safety and technological justification.

USA: If adopted Notes XS221, XS262, XS272, XS275, XS283 should be added for consistency with commodity standard

FIA, IDF: Supports revision to remove Note 161.

IACM: supports proposal to revise provision to remove Note 161. In its most recent safety evaluation (2011), JECFA concluded that there is no concern for a likely exceedance of the JECFA ADI of 4 mg/kg bw based on realistic lifetime intake of 0.02 mg/kg bw/day in children in Australia/New Zealand at the 90th % from all foods and beverages.						
QUINOLINE YELLOW	104	GMP	3	7	Colour	Discontinue
2nd Circular Proposal: This colour is not allowed in any of the corresponding commodity standards – add notes XS221, XS262, XS273, XS275. GMP is not appropriate as it has a numeric ADI. Request information on actual use and use level						
EWG comments on 2nd Circular: Australia supports adding notes XS221, XS262, XS273 and XS275 as this colour is not allowed in these standards. Alignment added these exclusion notes, noting it is a proposed draft provision. It also agrees that GMP is not appropriate, but it has no information on use levels so defers to others. EU: not permitted in the EU in this FC RU: Could not be used in GMP. This FA have ADI 0-3 mg/kg bw. Do not use in this FC 1st Circular Proposal: Provision was omitted from 1 st CL.						
TARTRAZINE	102	300	3	4	Colour	Adopt at 150 with Notes 3, XS221, XS262, XS273, and XS275 and note 201 “for use in flavoured products only”
2nd Circular Proposal: Request information on actual use level in this food category. Adopt at 150 with Notes 3, XS221, XS262, XS273, and XS275						
EWG comments on 2nd Circular: Australia: supports the proposal as consistent with alignment, ie use of XS221, XS262, XS273 and XS275. It has no information on use levels so defers to others. EU: The EU supports requesting further info. KR: Not permitted to use in this category RU: agrees with proposal only for flavoured unripened cheese IACM: Supports proposal 1st Circular Proposal: Adopt at 300 with Notes 3, XS262, XS273 EWG comments on 1st Circular: Australia: notes the Alignment EWG proposed provisions consistent with proposal, but with additional exclusion note XS275 EU: the use is technologically justified only for flavoured unripened cheese. The ML is excessive. The maximum level reported by industry was 30 ppm (EFSA, 2009) RU: agrees with the proposal only in ML=150 mg/kg, only flavoured unripened cheese						

USA: Supports adoption. Authorized for use in foods in general

IACM: supports proposal to adopt at 300 mg/kg. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017).

IDF: Supports 1st CL proposal for adoption

ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

Category No. 01.6.2 (Ripened cheese)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENTS on 1st CIRCULAR:

Australia: Alignment EWG document CX/FA 20/52/6 did make some recommendations for FC 01.6.2, and more importantly for 01.6.2.1 (noted below). But Australia is comfortable in considering provisions in subcategories if EWG agree.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
CAMEL II - SULFITE CAMEL	150b	50000		4	Colour	Discuss in subcategories
CURCUMIN	100(i)	500		4	Colour	Discuss in subcategories
LUTEIN FROM TAGETES ERECTA	161b(i)	GMP		4	Colour	Discuss in subcategories
ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Discuss in subcategories

Category No. 01.6.2.1 (Ripened cheese, includes rind)

Corresponding commodity standards: CODEX STAN 208-1999, 278-1978 (colours are not permitted); 263-1966, 264-1966, 265-1966, 266-1966, 267-1966, 268-1966, 269-1967, 270-1968, 271-1968, 272-1968, 274-1969, 276-1973, 277-1973 (colours in Tables 1 and 2 are permitted in the cheese mass for specific purposes), 278-1978 (does not discuss food additives), 283-1978 (Permits use of specific colours)

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENTS on 1st CIRCULAR:

Australia: The Alignment EWG considered this FC and these commodity standards in two documents.

At the 2019 CCFA meeting; CX/FA 19/51/6, that aligned CXS 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 274, 276 and 277.

CX/FA 20/52/6, for cancelled 2020 meeting, to be considered at 2021 meeting, CXS 208, 278 and 283. Suggest reference to CXS 279-1975 above is incorrect as it should be CXS 278-1978.

Australia as chair of the Alignment EWG therefore provides these comments from those documents and the alignment work undertaken.

IDF: notes that this category includes standards that have been aligned and refers to the comments made by the delegation of Australia for consistency, in particularly regarding notes, unless IDF has commented otherwise.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100	XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						
EWG comments on Proposal:						

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion						
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	25	185	4	Colour	Chair's Note: Provision adopted with Notes 185 and 463 at 25 mg/kg in 2019 as part of alignment. Adopt at 25 with Notes 185, 463, XS208, XS278, and new note "Except for use in products conforming to the General Standard for Cheeses (CXS 283-1978) at 50 mg/kg".
2nd Circular Proposal: Revise Adopted at 25 with Notes 185, 463, XS208, XS278, and new note "Except for use in products conforming to the General Standard for Cheeses (CXS 283-1978) at 50 mg/kg". Chair's Note: Provision adopted with Notes 185 and 463 at 25 mg/kg in 2019 as part of alignment.						
EWG comments on 2nd Circular: Australia: supports the proposal as it is consistent with the alignment work as indicated in Australia's comments to the 1st circular. RU: agrees with proposal in ML=15 mg/kg only for ripened orange, yellow and broken-white cheese and red and green pesto cheese. ADI is only 0-0.6 mg/kg bw IACM, IDF, NATCOL: Supports proposal 1st Circular Proposal: Adopt at 25 with Notes 185, XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283 EWG comments on 1st Circular: Australia: Alignment 2020 document CX/FA 20/52/6, recommended adopting at 25 mg/kg, with notes 185 and 463 (For use in cheese mass only for products conforming to the Standards for Cheddar (CXS 263-1966), Danbo (CXS 264-1966) Edam (CXS 265-1966), Gouda (CXS 266-1966), Havarti (CXS 267-1966), Samsø (CXS 268-1966), Emmental (CXS 269-1967), Tilsiter (CXS 270-1968), Saint-Paulin (CXS 271-1968), Provolone (CXS 272-1968), Coulommiers (CXS 274-1969), Camembert (CXS 276-1973) and Brie (CXS 277-1973)), but with additional notes XS208 and XS278, as well as new note "Except for use in products conforming to the General Standard for Cheeses (CXS 283-1978) at 50 mg/kg". Alignment 2019 document CX/FA 19/51/6 did not recommend XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277. Checking confirmed provisions for the colour at 25 mg/kg for use in the cheese mass only, which relates to note 463. Australia's comment is to suggest removing XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, add note 463 (already in GSFA) and new note due to alignment work and to adopt and not to leave at step 4. EU: as the use of colours is restricted in many commodity standards, the EU considers that a possible permission (in non-standardised products) should be for specific types of cheese only. The EU is aware of the need for this colour in ripened orange, yellow and broken-white cheese, red and green pesto cheese, mimolette cheese and red Leicester cheese RU: agrees with proposal in ML=15 mg/kg only for ripened orange, yellow and broken-white cheese and red and green pesto cheese USA: Supports adoption at 25 with proposed notes. Authorized for use at GMP in foods in general IACM: supports proposal to adopt at 25 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI.						

IDF: supports Australia's comment requesting removing notes XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, add note 463 (already in GSFA) and new note I283 due to alignment work and to adopt and not to leave at step 4.

NATCOL: Supports adoption at 25 mg/kg

CARAMEL II - SULFITE CARAMEL	150b	50000		Colour	Chair's Note: INS150d is adopted at 50000 and INS 150c is adopted at 15000 in this FC both with Notes 201 "For use in flavoured products only" Adopt at 50000 with Notes XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283
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2nd Circular Proposal: Adopt at 50000 with Notes XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283

Chair's Note: INS150d is adopted at 50000 and INS 150c is adopted at 15000 in this FC both with Notes 201 "For use in flavoured products only"

EWG comments on 2nd Circular:

Australia, IACM, IDF: Supports proposal

EU: can the technological need be clarified? What are the non-standardised products in which this colour is used? Could examples of products using this colour be provided?

RU: Strongly opposite proposal!!!!!!!. All proposals for the use of the colour CARAMEL II- SULFITE CARAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient. There are not technological need for this colour in any type of cheese falling under this FC

1st Circular Proposal: Adopt at 50000 with Notes XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG only dealt with caramel IV (INS 150d), which did propose adding the exclusion notes XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283. If EWG agrees the two forms of caramel are similar then Australia could support the same provisions and exclusion notes.

EU: the EU is not aware of the technological need for this colour in any type of cheese falling under this FC

RU: consider discontinuation. All proposals for the use of the colour CARAMEL II- SULFITE CARAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 50000 with XS Notes. Authorized for use at GMP for foods in general

IACM supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. Therefore, the intake from this food category is expected to represent a small fraction of the most conservative intake of up to 38 mg/kg bw/day that was estimated to result from the primary use of the color (alcoholic beverages) at the 95% of consumers-only. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

CURCUMIN	100(i)	500			Colour	Adopt at 500 with Notes XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283
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1st and 2nd Circular Proposal: Adopt at 500 with Notes XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283

EWG comments on Proposal:

Australia: Supports proposal, notes that the Alignment EWG did not deal with this colour, so it cannot provide any comment on the proposed ML. However, the exclusions notes are appropriate since there are no provisions for this colour in these standards.

EU: can the technological need be clarified? What are the non-standardised products in which this colour is used? Could examples of products using this colour be provided? The EU is not aware of the technological need for this colour in any type of cheese falling under this FC

RU: does not agree with proposal. There not safety justification. ADI 0-3 mg/kg bw

USA: Supports adoption at 500 with XS Notes. Authorized for use at GMP for foods in general

IACM supports proposal to adopt at 500 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003

IDF: Supports proposal

LUTEIN FROM TAGETES ERECTA	161b(i)	GMP			Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending discussion of inclusion in Table 3

PAPRIKA EXTRACT	160c(ii)	30	39	2	Colour	Chair's Note: Proposal does not include XS notes per comments from observers (See below) Adopt at 30 with notes 39, XS208, XS278
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2nd Circular Proposal: Adopt at 30 with notes 39, XS208, XS278

Chair's Note: Proposal does not include XS notes per comments from observers (See below)

EWG comments on 2nd Circular:

Australia supports the proposal if that is the view of the EWG. The exclusion notes (XS208, XS278 and XS283) were added due to alignment. It also supported the additional exclusion notes as its comment to the 1st circular since there are no provisions for the additive in these standards. It notes other comments to the 1st circular.

EU: justification for the need of INS160c(ii) in XS 262 and 221 shall be provided. In the EU's view use of colours in this FC is justified only for flavoured products.

RU: agrees with proposal only for ripened orange, yellow and broken-white cheese and red pesto cheese. There not clear for what need these notes:
Note 208 For use in dried and dehydrated products only. Note 278 For use in whipped cream and cream packed under pressure only.

IACM, IDF: Supports proposal

NATCOL: Supports. Only in ripened orange, yellow and broken-white and red pesto cheese.

1st Circular Proposal: Adopt at 30 with Notes 39, XS208, XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277, XS278, XS283.

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG document CX/FA 20/52/6 did deal with this colour for CXS 208, CXS 278 and CXS 283, where it added exclusion notes XS208, XS278 and XS283 and the recommendation to remain at step 2. However, the additional exclusions notes are appropriate since there are no provisions for this colour in these other standards. Australia also notes that the alignment work dealt with the colour paprika oleoresin (INS 160c) with a recommendation for the ML of GMP due to the provision in CXS 283, with XS208 and XS278, and added note 39.

EU: as the use of colours is restricted in many commodity standards, the EU considers that a possible permission (in non-standardised products) should be for specific types of cheese only. The EU is aware of the need for this colour in ripened orange, yellow and broken-white cheese and red pesto cheese at 30 ppm.

RU: agrees with proposal only for ripened orange, yellow and broken-white cheese and red pesto cheese

USA: Supports adoption at 30 with Notes. Permitted for use in foods at GMP

FIA: At the sixth session of the Codex Committee on Milk and Milk Products (CCMMP6), paprika oleoresin was listed in the proposed draft Standards Cheddar; Danbo; Edam; Gouda; Havarti; Samsø; Emmentaler; Tilsiter; Saint-Paulin; Provolone; Coulommiers; Camembert; and Brie at GMP.

However at CCMMP7 all provisions for paprika oleoresin were removed from individual cheese standards as paprika oleoresin had only been evaluated by JECFA as a spice.

The intention was that, following a positive outcome of the JECFA evaluation of paprika extract/paprika oleoresin for use as a colour, the provisions for the use of paprika extract/paprika oleoresin would be re-included in the relevant cheese standards.

Paprika extract has now been assessed by JECFA as a colour. Since it has an ADI, a numerical ML is appropriate rather than GMP.

IACM: supports proposal to adopt at 30 mg/kg. Paprika extract is used provide a light stable "orange" color to standardize the color of ripened cheeses, with use level needed to meet consumer expectations. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

IDF: supports adoption. Notes action by CCMMP6 and CCMMP7 as described by FIA above. Paprika extract has now been assessed by JECFA as a colour. Since it has an ADI, a numerical ML is appropriate rather than GMP. IDF wonders if the notes XS263, XS264, XS265, XS266, XS267, XS268, XS269, XS270, XS271, XS272, XS274, XS276, XS277 could therefore be removed by the EWG.

NATCOL: Supports adoption						
ZEAXANTHIN, SYNTHETIC	161h(i)	100			Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.						
EWG comments on Proposal						
Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.						

Category No. 01.6.2.2 (Rind of ripened cheese)**Corresponding commodity standards:** None**GSFA:** FC is not in the Annex to Table 3. Colours have previously been adopted in this FC**GENERAL COMMENT on 1st CIRCULAR**

Australia: The Alignment EWG has not considered any provisions for this FC, noting there are no corresponding commodity standards, though some standards do have provisions in their functional class table for surface/rind treatment. Australia therefore has limited comments for this FC. Australia does not separate provisions for food additives on cheese rind in its food additive regulations. In Australia various colours are permitted in the food category 'cheese and cheese products', some at GMP, some with a numerical ML.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
AMARANTH	123	100		7	Colour	Discontinue
2nd Circular Proposal: Discontinue						
EWG comments on 2nd Circular:						
Australia, EU, RU: Supports proposal						
NATCOL: Support IDF position that up to 100 mg/kg can be used.						
1st Circular Proposal: Adopt						
EWG comments on 1st Circular:						
EU: amaranth has a very low ADI. Other colours with higher ADIs or ADI not specified should be used instead.						
RU: does not agree with proposal. There not safety justification. Do not use in RU and Eurasian economy union						
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	1000	8	4	Colour	Adopt at 100 with Note 8

2nd Circular Proposal: Adopt at 100 with Note 8

EWG comments on 2nd Circular:

Australia: supports the proposal with lowered ML due to IDF use level

EU, IACM, IDF: Supports proposal

RU: does not agrees with proposal. ML should be not more 20 mg/kg

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: the ML is excessive. In the EU the uses and use levels of annatto extracts have been recently reviewed. The EU industry requested 20 ppm for this FC.

RU: does not agree with proposal. There not safety justification. There are possible only ML=20 mg/kg

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt. Based on JECFA’s refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

IDF: supports adoption. Reported use level up to 100 mg/kg reported uses at 100 mg/kg as a common color used in rind ripened cheese.

NATCOL: considers that the typical use is 20 mg/kg but also recognizes that exceptions are possible.

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	50	185	4	Colour	Adopt at 20 with Note 185 and new note “except for use in orange colored rinds at up to 50 mgkg”
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2nd Circular Proposal: Adopt at 20 with Note 185

EWG comments on 2nd Circular:

Australia: supports the proposal with lowered ML due to EU comment and industry request

EU, IACM: Supports proposal

RU: does not agrees with proposal. ML should be not more 20 mg/kg

IDF: Reported use levels up to 50 mg/kg in several countries. Darker shade of orange is a common color used for rind of ripened cheese.

NATCOL: Supports. However 50 mg/kg would allow more deep yellow colour.

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: in the EU the uses and use levels of annatto extracts have been recently reviewed. The EU industry requested 20 ppm for this FC. The ML for ANNATTO EXTRACTS, NORBIXIN-BASED has to be carefully considered due to the low ADI for this colour.

RU: does not agree with proposal. There not safety justification.

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI.

IDF: supports adoption. Reported use level aligns with maximum level as a common color used in rind ripened cheese.

NATCOL: considers that the typical use is 20 mg/kg but also recognizes that exceptions are possible.

AZORUBINE (CARMOSINE)	122	GMP		7	Colour	Discontinue
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2nd Circular Proposal: GMP is not appropriate as INS122 has a numeric ADI. Request information on actual use and use level.

EWG comments on 2nd Circular:

Australia: Supports proposal

EU: no use was reported by the industry in this FC (EFSA, 2015).

RU: Could not be used in GMP. This FA have ADI. 0-4 mg/kg bw. Do not use in this FC

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: no use was reported by the industry in this FC (EFSA, 2015).

RU: Supports 1st CL proposal

IACM: supports proposal to adopt. The JECFA ADI for azorubine is 4 mg/kg bw/day (1983).

β-CAROTENE- RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	500		2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)

EWG comments on 1st Circular:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion

BRILLIANT BLACK (BLACK PN)	151	GMP		7	Colour	Discontinue. No information on use specific to this FC provided.
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2nd Circular Proposal: GMP is not appropriate as it has a numeric ADI. Request information on actual use and use level

EWG comments on 2nd Circular:

Australia: supports the proposal with lowered ML due to IDF use level

EU: no use reported by the industry for this FC (EFSA, 2015).

RU: Numerical FA can't be used as GMP. ADI only 0-1 mg/kg bw . Do not use in this FC

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: no use reported by the industry for this FC (EFSA, 2015).

RU: does not agree with proposal. Numerical FA can't be used as GMP. ADI only 0-1 mg/kg bw

IACM: supports proposal to adopt. JECFA ADI of 1 mg/kg bw/day in 2019. Considering that only a fraction of products in this category contain this particular color, no concern is raised of potential average daily intake exceedance of the JECFA ADI. JECFA's summary report (2019) notes that the dietary intake of brilliant black from all reported sources does not present a safety concern.

BROWN HT	155	GMP		7	Colour	Discontinue. No information on use specific to this FC provided.
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2nd Circular Proposal: GMP is not appropriate as it has a numeric ADI. Request information on actual use and use level

EWG comments on 2nd Circular:

Australia: Supports proposal

EU: no use reported by the industry for this FC (EFSA, 2014). If needed, other colours with higher ADIs or ADI not specified should be used instead.

RU: Numerical FA can't be used as GMP. ADI only 0-1,5 mg/kg bw. Do not use in this FC

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: no use reported by the industry for this FC (EFSA, 2014). If needed, other colours with higher ADIs or ADI not specified should be used instead.

RU: does not agree with proposal. Numerical FA can't be used as GMP. ADI only 0-1,5 mg/kg bw

IACM: supports proposal to adopt. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 1.5 mg/kg bw set in 1984.

CARAMEL II - SULFITE CARAMEL	150b	50000			Colour	Chair's Note: INS 150c and 150d are adopted in this FC at 50000 mg/kg with no notes Adopt
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2nd Circular Proposal: Adopt

Chair's Note: INS 150c and 150d are adopted in this FC at 50000 mg/kg with no notes

EWG comments on 2nd Circular:

Australia: Supports proposal

EU: the industry reported the maximum level of 100 ppm for use in this FC (EFSA, 2011). Justification for the proposed ML is needed.

RU: Strongly opposite proposal!!!!!!!. All proposals for the use of the colour CARMEL II- SULFITE CARMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

IACM, IDF: supports proposal

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: the industry reported the maximum level of 100 ppm for use in this FC (EFSA, 2011).

RU: consider discontinuation. All proposals for the use of the colour CARMEL II- SULFITE CARMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 50000. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

CURCUMIN	100(i)	500		Colour	Do not move from parent FC. No information specific to use in this FC provided.
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2nd Circular Proposal: Request information on actual use and use level

EWG comments on 2nd Circular:

Australia: Supports proposal

EU: no use was reported in this food category (EFSA, 2014).

RU: Does not agree with proposal. ADI only 0-1,5 mg/kg bw. Do not use in this FC

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: no use was reported in this food category (EFSA, 2014).

RU: does not agree with proposal. There not safety justification.

USA: Supports adoption at 500. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 500 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.

LUTEIN FROM TAGETES ERECTA	161b(i)	GMP			Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Do not move from Parent FC if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on 1st Circular:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending discussion of inclusion in Table 3

PAPRIKA EXTRACT	160c(ii)	30	39	2	Colour	Adopt
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal:

Australia, EU, RU, USA: Supports adoption at 30 with Note 39

FIA: At the sixth session of the Codex Committee on Milk and Milk Products (CCMMP6), paprika oleoresin was listed in the proposed draft Standards Cheddar; Danbo; Edam; Gouda; Havarti; Samsø; Emmentaler; Tilsiter; Saint-Paulin; Provolone; Coulommiers; Camembert; and Brie at GMP.

However at CCMMP7 all provisions for paprika oleoresin were removed from individual cheese standards as paprika oleoresin had only been evaluated by JECFA as a spice.

The intention was that, following a positive outcome of the JECFA evaluation of paprika extract/paprika oleoresin for use as a colour, the provisions for the use of paprika extract/paprika oleoresin would be re-included in the relevant cheese standards.

Paprika extract has now been assessed by JECFA as a colour. Since it has an ADI, a numerical ML is appropriate rather than GMP.

It should be borne in mind that the level of the colour required for Cheddar may be higher than that for the other cheeses

IACM: supports proposal to adopt at 30 mg/kg. Use level needed to standardize the color of the rind of ripened cheeses to meet consumer expectations. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

NATCOL: Supports adoption at 30 mg/kg.

QUINOLINE YELLOW	104	GMP		7	Colour	Discontinue. No information on use specific to this FC provided.
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2nd Circular Proposal: GMP is not appropriate as INS 104 has a numeric ADI. Request information on actual use level.

EWG comments on 2nd Circular:

Australia: supports the proposal to seek use level. It has no information on use levels so defers to others.

EU: no use reported by the industry for this FC (EFSA, 2015).

RU: Numerical FA can't be used as GMP. ADI 0-3 mg/kg bw. Do not use in this FC

IACM: suggests use level of 10 mg/kg

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: no use reported by the industry for this FC (EFSA, 2015).

RU: does not agree with proposal. Numerical FA can't be used as GMP. ADI 0-3 mg/kg bw

IACM: supports adoption. The proposed maximum level should not raise any concerns as the refined average daily intake is below the ADI (0.3 – 10%) of 3 mg/kg bw, which was reaffirmed by JECFA in 2016. In JECFA's most recent safety evaluation, the most conservative intake of quinoline yellow from all foods and beverages was 4 mg/kg bw/day at the 95th % for children in Europe using maximum reported use levels; however JECFA recognized that the FSANZ estimate of 0.01 mg/kg bw per day, for children at the 95th %, is a more realistic dietary exposure, assuming that 100% products contain this color. JECFA noted that the more realistic FSANZ intake was well below the ADI and concluded that there is no health concern for quinoline yellow intake as a color additive.

TARTRAZINE	102	100		7	Colour	Adopt
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2nd Circular Proposal: Adopt

EWG comments on 2nd Circular:

Australia, EU, IACM, IDF: Supports proposal

RU: Does not agree with proposal. There is not technological justification for to use this FA in this FC

1st Circular Proposal: Adopt (Original proposal indicated use level at GMP- draft provision is actually at 100)

EWG comments on 1st Circular:

EU: GMP not appropriate. The industry suggested 100 ppm for edible cheese rinds (EFSA, 2009).

RU: does not agree with proposal. Numerical FA can't be used as GMP. ADI 0-10 mg/kg bw

USA: Supports adoption. Authorized for use in foods in general

IACM: supports adoption. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017)

ZEAXANTHIN, SYNTHETIC	161h(i)	100			Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Do not move from Parent FC if Table 3 provision is adopted.
1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.						
EWG comments on Proposal: Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.						

Category No. 01.6.2.3 (Cheese powder (for reconstitution; e.g. for cheese sauces))**Corresponding commodity standards:** None**GSFA:** FC is not in the Annex to Table 3. Colours have previously been adopted in this FC**GENERAL COMMENT on 1st Circular****Australia:** No Alignment work on this FC. Also Australian regulations do not have this food category, therefore Australia has provided limited comments.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN-BASED	160b(i)	50	8	4	Colour	Adopt
2nd Circular Proposal: Request information on technological justification for colours. Is use to restore colour lost during production?						
EWG comments on 2nd Circular: Australia: supports the proposal to request technological justification EU: supports requesting further information. KR: Used for colours in this category RU: Does not agree with proposal. There not technological justification for to use this FA in this FC IACM: IACM supports adoption at 50 mg/kg. This color is needed to match color expected by consumers for use in dishes such as macaroni and cheese or cheese dips. IDF: Reported use is justified by consumer preference. Coloring is intended to represent the expected/demanded product (vibrant orange). IDF supports adoption at level of 50 mg/kg.						

NATCOL: We understand that this FC is not necessarily made from already coloured cheese. The justification to add colour is the same as for processed cheese. If this FC is made from uncoloured cheese, we support 50mg/Kg

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: would like to learn more about the technological justification for the use of colours in this FC. Is the use of colours needed in this FC when it covers dehydrated product prepared from a variety or processed cheese in which colours are permitted as appropriate? Is it related to the production process of dehydrated products?

RU: does not agree with proposal. There not safety justification.

USA: Supports adoption at 50 with Note 8. Authorized for use at GMP in foods in general

IACM supports proposal to adopt at 50 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

IDF: supports adoption, the maximum level corresponds to reported use level.

NATCOL: Supports adoption at 50 mg/kg

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	50	185	4	Colour	Adopt
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2nd Circular Proposal: Request information on technological justification for colours. Is use to restore colour lost during production?

EWG comments on 2nd Circular:

Australia: supports the proposal to request technological justification

EU: supports requesting further information.

KR: Used for colours in this category

RU: Does not agree with proposal. There not technological justification for to use this FA in this FC

IACM: IACM supports adoption at 50 mg/kg. This color is needed to match color expected by consumers for use in dishes such as macaroni and cheese or cheese dips.

IDF: Reported use was justified by consumer preference. Coloring is intended to respond to consumer's expectations (vibrant orange).

NATCOL: We understand that this FC is not necessarily made from already coloured cheese. The justification to add colour is the same as for processed cheese. If this FC is made from uncoloured cheese, we support 50mg/Kg.

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: would like to learn more about the technological justification for the use of colours in this FC. Is the use of colours needed in this FC when it covers dehydrated product prepared from a variety or processed cheese in which colours are permitted as appropriate? Is it related to the production process of dehydrated products?

RU: does not agree with proposal. There not safety justification.

USA: Supports adoption at 50 with Note 185. Authorized for use at GMP in foods in general

IACM supports proposal to adopt at 50 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI.

IDF: supports adoption, the maximum level corresponds to reported use level.

NATCOL: Supports adoption at 50 mg/kg

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100		2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1).

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion

CARAMEL II - SULFITE CARAMEL	150b	50000			Colour	Adopt
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2nd Circular Proposal: Request information on technological justification for colours. Is use to restore colour lost during production?

EWG comments on 2nd Circular:

Australia: supports the proposal to request technological justification

EU: supports requesting further information.

KR: Used for colours in this category

RU: Does not agree with proposal. There not technological justification for to use this FA in this FC

IDF: Reported use is justified by consumer preference. Coloring is intended to respond to consumer's expectations..

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: would like to learn more about the technological justification for the use of colours in this FC. Is the use of colours needed in this FC when it covers dehydrated product prepared from a variety or processed cheese in which colours are permitted as appropriate? Is it related to the production process of dehydrated products? The ML is excessive. Is the ML expressed on cheese powder? By default the ML in the GSFA should be expressed “as consumed”.

RU: consider discontinuation. All proposals for the use of the colour CAMEL II- SULFITE CAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 50000. Authorized for use at GMP for foods in general

IACM supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA’s most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. The overall average daily intake from this category is therefore a small fraction of the JECFA ADI of 160 mg/kg bw/day.

IDF: supports adoption, the maximum level corresponds to reported use level.

CURCUMIN	100(i)	500		Colour	Adopt
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2nd Circular Proposal: Request information on technological justification for colours. Is use to restore colour lost during production?

EWG comments on 2nd Circular:

Australia: supports the proposal to request technological justification

EU: supports requesting further information.

KR: Used for colours in this category

RU: Does not agree with proposal. There not technological justification for to use this FA in this FC

IACM: supports 1st circular proposal to adopt

IDF: Reported use was justified by consumer preference. Coloring is intended to represent the expected/demanded product.

NATCOL: We understand that this FC is not necessarily made from already coloured cheese. The justification to add colour is the same as for processed cheese. If this FC is made from uncoloured cheese, we support 500 mg/Kg

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: would like to learn more about the technological justification for the use of colours in this FC. Is the use of colours needed in this FC when it covers dehydrated product prepared from a variety or processed cheese in which colours are permitted as appropriate? Is it related to the production process of dehydrated products? The ML is excessive. Is the ML expressed on cheese powder? By default the ML in the GSFA should be expressed “as consumed”.

RU: does not agree with proposal. There not safety justification. ADI 0-10 mg/kg bw

USA: Supports adoption at 500. Authorized for use at GMP for foods in general

IACM supports proposal at adopt at 500 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.

IDF: supports adoption, the maximum level corresponds to reported use level.

NATCOL: Supports adoption at 500 mg/kg

LUTEIN FROM TAGETES ERECTA	161b(i)	GMP			Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Do not move from Parent FC if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending discussion on inclusion in Table 3

PAPRIKA EXTRACT	160c(ii)	600	39	2	Colour	Adopt at 140 mg/kg with Note 39 provided confirmation reported use levels are on a total careotenoid basis (see note 39) and not on an extract basis.
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2nd Circular Proposal: Adopt at 140 with Note 39. Request information on technological justification for colours. Is use to restore colour lost during production?

EWG comments on 2nd Circular:

Australia: supports the proposal to request technological justification

EU: supports requesting further information.

KR: Used for colours in this category

RU: Does not agree with proposal . ML so higher because ADI only 0–1.5 mg/kg bw. There not technological justification for to use this FA in this FC

IACM: supports EWG proposal to adopt. This color is needed to match color expected by consumers for use in dishes such as macaroni and cheese or cheese dips. Please see photos of cheese powder and reconstituted cheese sauce from these powders (ration 1 part powder to 4 parts butter and milk) or five fold dilution. (provided same images as seen in NATCOL reponse below)

IDF: Supports the proposal. Reported use is justified by consumer preference. Coloring is intended to respond to consumer's expectations (vibrant orange).

NATCOL: Supports proposal. We understand it is on a "ready-to-eat" basis. It is used to add colour when uncoloured cheese is used.

Pictures of Cheese powder at 600ppm, 300ppm and 150ppm:



Pictures of Cheese powder (reconstituted as cheese sauce) from plated cheese powder at 30ppm, 60ppm and 120ppm:



1st Circular Proposal: Adopt at 140 mg/kg. (Draft provision should have stated use level at 600)

EWG comments on 1st Circular:

EU: EU would like to learn more about the technological justification for the use of colours in this FC. the proposed ML seems to be high and shall be verified. Is the ML expressed on cheese powder? By default the ML in the GSFA should be expressed “as consumed”.

RU, USA: Supports 1st CL proposal- adoption at 150 with Note 39

IACM: supports proposal to adopt at 140 mg/kg. Needed to standardize the color of cheese powders for which cheddar cheese may be used as an ingredient. In JECFA’s 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern

IDF: supports adoption, the maximum level corresponds to reported use level.

ZEAXANTHIN, SYNTHETIC	161h(i)	100		Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Do not move from Parent FC if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

Category No. 01.6.3 (Whey cheese)

Corresponding commodity standards: CODEX STAN 284-1981 (contains general reference to food additives included in Tables 1 and 2)

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: No Alignment EWG work on this commodity standard, but appears to have been aligned earlier. Also Australian regulations do not have this food category, therefore Australia has provided no comments.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	50	8	4	Colour	Discontinue
<u>1st and 2nd Circular Proposal:</u> Discontinue						
<u>EWG comments on Proposal:</u> Australia, EU, RU, IDF: Supports discontinuation						
ANNATTO EXTRACTS, NORBIXIN BASED	160b(ii)	10	185	4	Colour	Discontinue
<u>1st and 2nd Circular Proposal:</u> Discontinue						
<u>EWG comments on Proposal:</u> Australia, EU, RU, IDF: Supports discontinuation						

Category No. 01.6.4 (Processed cheese)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: No Alignment work on this FC. Also Australian regulations do not have this specific food category, therefore Australia has provided limited comments on the subcategories.

Additive	INS	Max Level	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
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		(mg/kg)				
ALLURA RED AC	129	100	161	2009	Colour	Discuss in subcategories
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	25	185	4	Colour	Discuss in subcategories
AZORUBINE (CARMOSINE)	122	200		7	Colour	Discuss in subcategories
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100		2	Colour	Discuss in subcategories
BRILLIANT BLACK (BLACK PN)	151	200		7	Colour	Discuss in subcategories
BROWN HT	155	200		7	Colour	Discuss in subcategories
CAMEL II - SULFITE CAMEL	150b	50000		4	Colour	Discuss in subcategories
CURCUMIN	100(i)	200		4	Colour	Discuss in subcategories
LYCOPENE, TOMATO	160d(ii)	1500		3	Colour	Discontinue Use is already permitted in this FC under provision adopted in Table 3
PAPRIKA EXTRACT	160c(ii)	140	39	2	Colour	Discuss in subcategories
QUINOLINE YELLOW	104	200		4	Colour	Discuss in subcategories
TARTRAZINE	102	200		7	Colour	Discuss in subcategories
ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Discuss in subcategories

Category No. 01.6.4.1 (Plain processed cheese)

Descriptor: Processed cheese product that does not contain added flavours, seasonings, fruit, vegetables and/or meat. Examples include: American cheese, requeson.

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in the parent FC

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ALLURA RED AC	129	100	161		Colour	Adopt at 100 without Note 161. Revise in parent FC 1.6.4 if note removed in both subcategories.
2nd Circular Proposal: Adopt at 100 without Note 161. Revise in parent FC 1.6.4 if note removed in both subcategories.						
EWG comments on 2nd Circular:						

Australia: supports the proposal. It seems reasonable to expect colours needed for plain processed cheese, similar to unripened and ripened cheeses, to ensure products are comparable in colour, noting comments to 1st circular.

EU: is of the view that the justification is limited to flavoured products only. The EU would like to learn more about the technological justification for products falling within this FC.

KR: Not permitted to use in this category

RU: Does not agree with proposal. There is general decision of GSFA not use of FA in plain products. It could mislead consumers about quality of food product.

IACM, IDF: Supports proposal

1st Circular Proposal: Adopt at 100 without Note 161

EWG comments on 1st Circular:

EU: technological justification shall be provided. The EU wonders why colours are needed in plain products?

RU: does not agree with proposal. There not safety justification. ADI 0-7 mg/kg bw

USA: Supports removal of Note 161. Authorized for use at GMP in foods in general. FC 01.6.4.1 is not a traditional “plain” food category in that “plain” is not listed as a parenthetical in the title - for this food category plain only excludes flavouring substances as per the descriptor. Many processed cheese products do not exist that do not contain added colour. See the descriptor and examples – “American cheese” requires the use of colour.

FIA: Supports revision to remove Note 161.

IACM: supports proposal to revise provision to remove Note 161. In JECFA’s most recent safety evaluation, the highest intake of allura red from all foods was 2.9 mg/kg bw/day at the 95th % for children 3–9 years in Europe under the most conservative brand-loyal scenario; however more realistically the intake is up to 1.2 mg/kg bw/day at the 95th % in the non-brand loyal scenario, assuming that 100% products contain this color. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 2.2 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.22 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017). JECFA noted that the range of estimated dietary exposures to Allura Red AC from all foods and beverages were well below the ADI (0.4–41% of the ADI) including intake for children and including the conservative estimate by EFSA

IDF: supports adoption. Use was confirmed although no use level was provided.

ANNATTO EXTRACTS, BIXIN BASED	160b(i)	60	8	4	Colour	Adopt with note 8 and new note “Except for use at 100 mg/kg in sliced processed cheeses”.
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2nd Circular Proposal: Adopt with new note “Except for use at 100 mg/kg in sliced processed cheeses”.

EWG comments on 2nd Circular:

Australia: supports the proposal, noting the comment from the IDF that instigated the additional note.

EU: is of the view that the justification is limited to flavoured products only. The EU would like to learn more about the technological justification for products falling within this FC.

JAPAN: Japan supports the proposal. INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetizing. Maximum use level is 10 mg/kg as bixin.

RU: Does not agree with proposal. There is general decision of GSFA not use of FA in plain products. It could mislead consumers about quality of food product.

FIA, IACM: Supports proposal

IDF: Supports the proposal. Reported use is justified by consumer preference. Coloring is intended to respond to consumer's expectations (vibrant orange).

NATCOL: Annatto colours are traditionally used to impart appealing colour to white/greyish cheese. Stable when used in this FC under normal conditions.

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: technological justification shall be provided. The EU wonders why colours are needed in plain products?

GUATEMALA: > 120 mg/kg

JAPAN: INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavour.. Japan would like to provide information on maximum use level in next circular.

RU: does not agree with proposal. There not safety justification. Use INS 160b(i) could mislead consumers about quality of PLAIN cheese

USA: Supports adoption. Authorized for use at GMP in foods in general. FC 01.6.4.1 is not a traditional "plain" food category in that "plain" is not listed as a parenthetical in the title - for this food category plain only excludes flavouring substances as per the descriptor. Many processed cheese products do not exist that do not contain added colour. See the descriptor and examples – "American cheese" requires the use of colour.

IACM: supports proposal to adopt. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

IDF: would support adoption with a new note "for use at 100 mg/kg in sliced processed cheeses only". The usage level reported of 100 mg/kg is needed for more vibrant yellows and oranges desired, particularly in sliced cheeses packed in clear or transparent packaging. Studies show that pigment loss can occur within just a few hours if the cheese is exposed to high-intensity fluorescent light (> 160 footcandles). The pigment loss will generally present as a pink tone but if the cheese continues to be exposed to intense lighting, a complete loss of pigment is possible which can lead to bleaching.

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	25	185	Colour	Adopt at 70 mg/kg with Note 185 "As norbixin".
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal:

Australia: Supports proposal

EU: is of the view that the justification is limited to flavoured products only. The EU would like to learn more about the technological justification for products falling within this FC.

JAPAN: INS 160b(ii) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavour. Japan proposes the maximum level be replaced with 70 mg/kg. INS 160b(ii) is used in foods broadly across this food category to make the food visually appealing and appetizing. Maximum use level is 70 mg/kg as norbixin.

RU: does not agree with proposal. There not safety justification. Use INS 160b(ii) could mislead consumers about quality of PLAIN cheese

USA: Supports adoption. Authorized for use at GMP in foods in general. FC 01.6.4.1 is not a traditional “plain” food category in that “plain” is not listed as a parenthetical in the title - for this food category plain only excludes flavouring substances as per the descriptor. Many processed cheese products do not exist that do not contain added colour. See the descriptor and examples – “American cheese” requires the use of colour.

FIA: Annatto extracts, norbixin-based is currently used as part of the colouring for both unflavoured and flavoured (e.g. smoked flavour) sliced processed cheese for international trade. Usage level up to 25mg/kg as norbixin. It is used to provide a yellow to orange hue and may be used in combination with other colours.

Annatto, sometimes in combination with other colours, is often needed to achieve the colour specifications set by foodservice customers purchasing processed cheese (e.g. global fast food chains). The level and type of each individual colour is therefore variable, depending on customer specifications.

IACM: supports proposal to adopt. Based on JECFA’s refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI

IDF: supports adoption. Plain processed cheeses are not necessarily white, even if not flavored, but vary from pale white to dark orange mostly due to consumer preferences. In addition, when mixed with Natural cheese(s) as a raw material and other high moisture content ingredients, the color of the mixture becomes thinner due to high moisture, it is necessary to add a lot of Norbixin in advance to thicken the color to obtain an appropriate color of the final product. Reported use is up to 66 mg/kg. Therefore IDF would suggest a maximum level of 70 mg/kg.

NATCOL: Annatto colours are traditionally used to impart appealing colour to white/greyish cheese.

AZORUBINE (CARMOSINE)	122	200		Colour	Do not move from Parent FC
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2nd Circular Proposal: Discontinue

EWG comments on 2nd Circular:

Australia, EU, RU: supports the proposal

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: technological justification shall be provided. The EU wonders why colours are needed in plain products?

RU: does not agree with proposal. Use could mislead consumers about quality of PLAIN cheese

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100			Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						
EWG comments on Proposal: Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion						
BRILLIANT BLACK (BLACK PN)	151	200			Colour	Do not move from Parent FC
2nd Circular Proposal: Discontinue						
EWG comments on 2nd Circular: Australia, EU, RU, IDF: Supports proposal						
1st Circular Proposal: Adopt						
EWG comments on 1st Circular: EU: technological justification shall be provided. The EU wonders why colours are needed in plain products? RU: does not agree with proposal. Use could mislead consumers about quality of PLAIN cheese						
BROWN HT	155	200			Colour	Do not move from Parent FC
2nd Circular Proposal: Discontinue						
EWG comments on 2nd Circular: Australia, EU, RU, IDF: Supports proposal						
1st Circular Proposal: Adopt						
EWG comments on 1st Circular: EU: technological justification shall be provided. The EU wonders why colours are needed in plain products? RU: does not agree with proposal. Use could mislead consumers about quality of PLAIN cheese						
CARAMEL II - SULFITE CARAMEL	150b	50000			Colour	Request information on actual use and use level. Provisions for INS 150c and 150d are adopted in FC 01.6.4.2, not 01.6.4.1.
2nd Circular Proposal: Request information on actual use and use level						
EWG comments on 2nd Circular: Australia: supports the proposal to seek use level. It has no information on use levels so defers to others. EU: supports requesting further information						

RU: Does not agree with proposal. There is general decision of GSFA not use of FA in plain products. It could mislead consumers about quality of food product. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

IDF: Plain processed cheeses are not necessarily white, even if not flavored, but vary from pale white to dark orange mostly due to consumer preferences. These products are traded internationally.

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: technological justification shall be provided. The EU wonders why colours are needed in plain products?

RU: consider discontinuation. All proposals for the use of the colour CAMEL II- SULFITE CAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 50000. Authorized for use at GMP for foods in general. FC 01.6.4.1 is not a traditional “plain” food category in that “plain” is not listed as a parenthetical in the title - for this food category plain only excludes flavouring substances as per the descriptor. Many processed cheese products do not exist that do not contain added colour. See the descriptor and examples – “American cheese” requires the use of colour.

IACM: supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA’s most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

CURCUMIN	100(i)	200			Colour	Adopt
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal

Australia: Supports proposal

EU: EU is of the view that the justification is limited to flavoured products only. The EU would like to learn more about the technological justification for products falling within this FC.

RU: does not agree with proposal. Use could mislead consumers about quality of PLAIN cheese

USA: Supports adoption at 200. Authorized for use at GMP for foods in general. FC 01.6.4.1 is not a traditional “plain” food category in that “plain” is not listed as a parenthetical in the title - for this food category plain only excludes flavouring substances as per the descriptor. Many processed cheese products do not exist that do not contain added colour. See the descriptor and examples – “American cheese” requires the use of colour.

IACM supports proposal to adopt at 200 mg/kg. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.

IDF: Supports proposal

LUTEIN FROM TAGETES ERECTA	161b(i)	GMP		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: old pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, USA, IACM, IDF, NATCOL: Supports holding pending discussion of inclusion in Table 3

RU: does not agree with proposal. Use could mislead consumers about quality of PLAIN food product. There needs to be discontinuation of proposal

PAPRIKA EXTRACT	160c(ii)	140	39	Colour	Adopt at 70 mg/kg with Note 39 "on a total carotenoid basis".
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2nd Circular Proposal: Request further information on products requiring higher use levels (400-750 mg/kg).

EWG comments on 2nd Circular:

Australia: supports the proposal to seek use level. It has no information on use levels so defers to others.

EU: Supports requesting further information

JAPAN: INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetising. The use level is 25 mg/kg on a total carotenoid in processed cheese containing cheddar cheese as an ingredients (spreadable, sliced, cube-shaped and block).

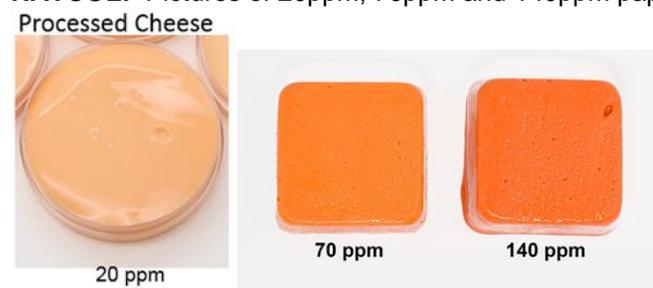
RU: Does not agree with proposal. There is general decision of GSFA not use of FA in plain products. It could mislead consumers about quality of food product.

FIA: The use levels of 400-750 mg/kg provided previously by other respondents were as paprika and convert to about 33.6 - 63 mg/kg as total carotenoids. Note 39 is "On a total carotenoid basis" and therefore these use levels are within the proposed ML of 140mg/kg on a total carotenoid basis.

IACM: Supports proposal. IACM confirms max levels of 140 mg/kg needed for plain (i.e. non-flavored, processed cheese, such as American cheese slices. (provided same image as seen below in NATCOL comment showing 70 and 140 ppm examples)

IDF: The use levels of 400-750 mg/kg are as paprika and convert to about 33.6 - 63 mg/kg as total carotenoids. Note 39 is "On a total carotenoid basis" and therefore these use levels are within the proposed ML of 140mg/kg on a total carotenoid basis. Plain processed cheeses are not necessarily white, even if not flavored, but vary from pale white to dark orange mostly due to consumer preferences. These products are traded internationally.

NATCOL: Pictures of 20ppm, 70ppm and 140ppm paprika in processed cheese:



1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: technological justification shall be provided. The EU wonders why colours are needed in plain products?

GUATEMALA: >400 mg/kg

JAPAN: Japan supports the proposal. INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Maximum use level is 70 mg/kg.

RU: does not agree with proposal. Use could mislead consumers about quality of PLAIN cheese

USA: Supports adoption at 140 with Note 39. Authorized for use in food at GMP. FC 01.6.4.1 is not a traditional “plain” food category in that “plain” is not listed as a parenthetical in the title - for this food category plain only excludes flavouring substances as per the descriptor. Many processed cheese products do not exist that do not contain added colour. See the descriptor and examples – “American cheese” requires the use of colour.

FIA: In processed cheese (and related products) paprika extract is used and has particular benefits due to the potential for “pinking” from the use of annatto. In the old Codex standards for processed cheese “oleoresin from paprika” was permitted.

Paprika is used as a colour in unflavoured sliced processed cheese for international trade to provide an orange to salmon hue, often in combination with other colours (e.g. a paprika and annatto mixture, or paprika and beta-carotene mixture). The level of use is variable, depending on the customer requirements.

IACM: support proposal to adopt. Needed to standardize the color of plain processed cheese for which cheddar cheese is used as ingredient. In JECFA’s 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

IDF: supports adoption, the maximum level corresponds to reported use level. In processed cheese (and related products) paprika extract is used and has particular benefits due to the potential for “pinking” from the use of annatto. In the old Codex standards for processed cheese “oleoresin from paprika” was permitted.

Paprika is used as a colour in unflavoured sliced processed cheese in NZ and for export out of NZ to provide an orange to salmon hue, often in combination with other colours (e.g. a paprika and annatto mixture, or paprika and beta-carotene mixture). The level of use is variable, depending on the customer requirements.

400-750 mg/kg as Paprika Extract (33.6 - 63 mg/kg as total carotenoid) for Processed cheese in Japan

QUINOLINE YELLOW	104	200		Colour	Do not move from Parent FC
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1st and 2nd Circular Proposal: Discontinue

EWG comments on Proposal:

Australia, EU, RU: supports the proposal

EU: technological justification shall be provided. The EU wonders why colours are needed in plain products?

TARTRAZINE	102	200		Colour	Adopt
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal:

Australia: Supports proposal

EU: EU is of the view that the justification is limited to flavoured products only. The EU would like to learn more about the technological justification for products falling within this FC.

KR: Not permitted to use in this category

RU: does not agree with proposal. Use could mislead consumers about quality of PLAIN food product

USA: Supports adoption. Authorized for use in foods in general. FC 01.6.4.1 is not a traditional “plain” food category in that “plain” is not listed as a parenthetical in the title - for this food category plain only excludes flavouring substances as per the descriptor. Many processed cheese products do not exist that do not contain added colour. See the descriptor and examples – “American cheese” requires the use of colour.

IACM: supports proposal to adopt at 200 mg/kg. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA’s most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017).

IDF: supports adoption, the maximum level corresponds to reported use level. Usage is for certain processed cheeses where target color is yellow versus orange. The technological justification here is specific to certain processed cheeses where the yellow color is the target. This is very common among certain varieties of block and sliced processed cheeses intended for melting, particularly when such cheeses are intended to be incorporated into sauces, including those used in macaroni and cheese preparations.

ZEAXANTHIN, SYNTHETIC	161h(i)	100		Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Do not move from Parent FC if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

RU: Does not agree with proposal. There is general decision of GSFA not use of FA in plain products. It could mislead consumers about quality of food product. There needs to be a discontinuation

Category No. 01.6.4.2 (Flavoured processed cheese, including containing fruit, vegetables, meat, etc.)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC and in the parent FC

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ALLURA RED AC	129	100	161		Colour	Adopt at 100 without Note 161. Revise in parent FC 1.6.4 if note removed in both subcategories.
<p>2nd Circular Proposal: Adopt at 100 without Note 161. Revise in parent FC 1.6.4 if note removed in both subcategories.</p> <p>EWG comments on 2nd Circular: Australia, EU, IACM, IDF: Supports proposal</p> <p>RU: agrees with proposal. Does not use in this FC in RU and a number countries too. So on does not agree with remove Note 161. ADI 0-7 mg/kg bw</p> <p>1st Circular Proposal: Adopt at 100 without Note 161</p> <p>EWG comments on 1st Circular: EU: this colour is not permitted in processed cheese in the EU</p> <p>RU: agrees with 1st CL proposal</p> <p>USA: Supports removal of Note 161. Authorized for use at GMP in foods in general</p> <p>FIA: Supports revision to remove Note 161.</p> <p>IACM supports proposal to revise provision to remove Note 161. In JECFA's most recent safety evaluation, the highest intake of allura red from all foods was 2.9 mg/kg bw/day at the 95th % for children 3–9 years in Europe under the most conservative brand-loyal scenario; however more realistically the intake is up to 1.2 mg/kg bw/day at the 95th % in the non-brand loyal scenario, assuming that 100% products contain this color. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 2.2 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.22 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017). JECFA noted that the range of estimated dietary exposures to Allura Red AC from all foods and beverages were well below the ADI (0.4–41% of the ADI) including intake for children and including the conservative estimate by EFSA</p> <p>IDF: supports adoption. The maximum level corresponds to reported use level in certain spreadable processed cheeses. This includes fruit flavored cream cheese spreads like products as well as certain savory spreadable cheeses flavored with ports, wines, dates and olives. The technological justification is to standardize differences in red colors expected by the consumers in these products.</p>						
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	60	8	4	Colour	Adopt at 15 mg/kg with note 8 and new note "Except for use at 100 mg/kg in sliced processed cheeses".
<p>2nd Circular Proposal: Adopt at 15 mg/kg with note 8 and new note "Except for use at 100 mg/kg in sliced processed cheeses".</p>						
<p>EWG comments on 2nd Circular: Australia: supports the proposal, noting EU and IDF comments that justify the changed ML and new note</p>						

EU, IACM, IDF: Supports proposal

JAPAN: Japan supports the proposal. INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavour. Maximum use level is 10 mg/kg as bixin.

RU: Agrees with adoption in ML=15 mg/kg with Note 8. However there not technological justification for to use new Note “Except for use at 100 mg/kg in sliced processed cheeses”.

NATCOL: Supports. Stable when used in this FC under normal conditions.

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: in the EU the uses of annatto extracts have been recently reviewed. The industry requested MPL of 15 ppm for bixin based annatto extracts in this FC.

JAPAN: INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Japan would like to provide information on maximum use level in next circular.

RU: agrees with 1st CL proposal

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt. Based on JECFA’s refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

IDF: would support adoption with a new note “for use at 100 mg/kg in sliced processed cheeses only”. The usage level reported of 100 mg/kg is needed for more vibrant yellows and oranges desired, particularly in sliced cheeses packed in clear or transparent packaging. Studies show that pigment loss can occur within just a few hours if the cheese is exposed to high-intensity fluorescent light (> 160 footcandles). The pigment loss will generally present as a pink tone but if the cheese continues to be exposed to intense lighting, a complete loss of pigment is possible which can lead to bleaching.

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	25	185	Colour	Adopt at 70 mg/kg with Note 185.
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal:

Australia: Supports proposal

EU: in the EU the uses of annatto extracts have been recently reviewed. The industry requested MPL of 8 ppm for norbixin based annatto extracts in this FC. The exposure to norbixin based annatto extracts is at the ADI in the EU, therefore the ML has to be carefully considered.

JAPAN: INS 160b(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Japan proposes the maximum level be replaced with 70 mg/kg. Maximum use level is 70 mg/kg as norbixin.

RU: Agrees with adoption in ML=15 mg/kg. ADI only 0-0.6 mg/kg bw

USA: Supports. Authorized for use at GMP in foods in general

FIA: Support proposal. Annatto extracts, norbixin-based is currently used as part of the colouring for both unflavoured and flavoured (e.g. smoked flavour) sliced processed cheese for international trade. Usage level up to 25mg/kg as norbixin. It is used to provide a yellow to orange hue and may be used in combination with other colours.

Annatto, sometimes in combination with other colours, is often needed to achieve the colour specifications set by foodservice customers purchasing processed cheese (e.g. global fast food chains). The level and type of each individual colour is therefore variable, depending on customer specifications.

IACM supports proposal to adopt. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI.

IDF: supports adoption, the maximum level corresponds to reported use level. Annatto extracts, norbixin-based is currently used as part of the colouring for both unflavoured and flavoured (e.g. smoked flavour) sliced processed cheese in national markets and for global export. It is used to provide a yellow to orange hue and may be used in combination with other colours. Reported use is up to 66 mg/kg. Justification is as follows: When mixed with Natural cheese(s) as a raw material and other high moisture content ingredients, the color of the mixture becomes thinner due to high moisture, it is necessary to add a lot of Norbixin in advance to thicken the color to obtain an appropriate color of the final product. Therefore IDF would suggest a maximum level of 70 mg/kg.

NATCOL: We consider that 8ppm is the typical use level in EU but confirm that higher levels are used in other parts of the world.

AZORUBINE (CARMOSINE)	122	200			Colour	Adopt at 10 mg/kg
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2nd Circular Proposal: Request further information on use and use level in this FC

EWG comments on 2nd Circular:

Australia: supports the proposal to request information on its use and also use level

EU: supports requesting further information.

RU: Agrees with adoption in ML=10 mg/kg/ This quantity for technology of flavoured processed cheese production. ADI (0-4 mg/kg bw)

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: analytical results show maximum 10 ppm (EFSA, 2015).

RU: agrees with proposal in ML=150 mg/kg

IACM: supports proposal to adopt. The JECFA ADI is 4 mg/kg bw/day (1983).

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100			Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion

BRILLIANT BLACK (BLACK PN)	151	200			Colour	Do not move from Parent FC
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2nd Circular Proposal: Request further information on use and use level in this FC

EWG comments on 2nd Circular:

Australia: supports the proposal to request information on its use and also use level

EU: supports requesting further information.

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161. ADI only 0-1 mg/kg bw!!!! Proposed ML is so higher!!!

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: no use reported by the industry for this FC (EFSA, 2015).

RU: agrees with proposal in ML=150 mg/kg

BROWN HT	155	200			Colour	Do not move from Parent FC
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2nd Circular Proposal: Request further information on use and use level in this FC

EWG comments on 2nd Circular:

Australia: supports the proposal to request information on its use and also use level

EU: supports requesting further information.

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161. ADI only 0-1,5 mg/kg bw!!!! Proposed ML is so higher!!!

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: no use was reported by the industry for this FC (EFSA, 2014). If needed, other colours with higher ADIs or ADI not specified should be used instead.

RU: agrees with proposal in ML=150 mg/kg

CARAMEL II - SULFITE CARAMEL	150b	50000			Colour	Chair's Note: INS 150c and 150d are adopted in this FC at 50000 mg/kg. 150d includes note 72 "On the ready-to-eat basis." Adopt
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2nd Circular Proposal: Adopt

Chair's Note: INS 150c and 150d are adopted in this FC at 50000 mg/kg. 150d includes note 72 "On the ready-to-eat basis."

EWG comments on 2nd Circular:

Australia, IACM, IDF: Supports proposal

EU: no use was reported by the industry (EFSA, 2011). The proposed ML is excessive. Technological justification and examples of products should be provided.

JAPAN: Japan would like to withdraw our comment provided in the 1st circular since no information are provided by industry.

RU: Strongly opposite proposal!!!!!!!. All proposals for the use of the colour CARMEL II- SULFITE CARMEL INS 150b should be reviewed from the position of safety and tecnological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: for flavoured processed cheese, no use was reported by the industry (EFSA, 2011). The proposed ML is excessive.

JAPAN: INS 150b is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Japan would like to provide information on maximum use level in next circular.

RU: consider discontinuation. All proposals for the use of the colour CARMEL II- SULFITE CARMEL INS 150b should be reviewed from the position of safety and tecnological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 50000. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day

CURCUMIN	100(i)	200			Colour	Adopt at 100 mg/kg
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2nd Circular Proposal: Adopt at 100 mg/kg

EWG comments on 2nd Circular:

EU: Accepts

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161. ADI only 0-3 mg/kg bw!!!! Proposed ML is so higher!!!

IACM, IDF: Supports proposal

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: the industry reported 10-30 ppm as the typical use level and 100 ppm as the maximum use level. The use level is important as the exposure to curcumin is at the ADI in the EU (EFSA, 2014).

RU: agrees with proposal in ML=150 mg/kg

USA: Supports adoption at 200. Authorized for use at GMP for foods in general

IACM supports proposal to adopt at 200 mg/kg. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003

LUTEIN FROM TAGETES ERECTA	161b(i)	100		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending discussion of inclusion in Table 3

PAPRIKA EXTRACT	160c(ii)	140	39		Colour	Adopt at 100 mg/kg with Note 39.
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2nd Circular Proposal: Request comments on actual use levels as comments indicate ML range of 35 – 750 mg/kg. Use levels proposed should discuss safety with respect to JECFA ADI. Request information on specific products within FC utilizing higher use level up to 750 mg/kg.

EWG comments on 2nd Circular:

Australia: supports the proposal to request information on its use and also use level

EU: in the EU the industry reported 35 ppm as the typical use level and 100 ppm as the ML (EFSA 2015). As regards safety of the ML, the refined exposure assessment (brand-loyal scenario) is just at the ADI for high level (P95) consumers (toddlers and children) from all uses authorized in the EU (EFSA Journal 2015;13(12):4320).

JAPAN: INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. The use level is 25 mg/kg on a total carotenoid in spreadable processed cheese and processed cheese block.

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161. ADI only 0-1,5 mg/kg bw!!!! Proposed ML is so higher!!!

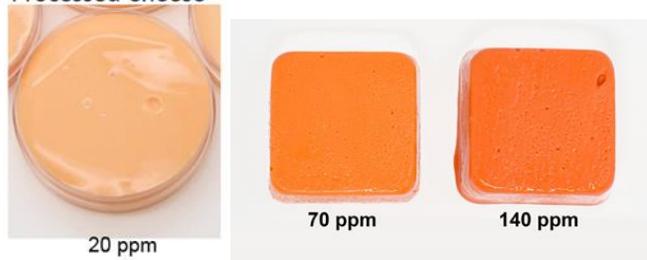
FIA: The use levels of 400-750 mg/kg provided previously by other respondents were as paprika and convert to about 33.6 - 63 mg/kg as total carotenoids. Note 39 is "On a total carotenoid basis" and therefore these use levels are within the proposed ML of 140mg/kg on a total carotenoid basis.

IACM: confirms max levels of 140 mg/kg needed for flavored, processed cheese. See previously submitted safety information with respect to JECFA ADI. (included same graphic as seen in NATCOL comment below showing levels of 70 and 140 ppm)

IDF: Supports proposal

NATCOL: Supports. 70ppm as normal level. The proposed values from IDF (36 – 63 mg/kg) are appropriate to achieve an acceptable colour shade. Picture at 20ppm, 70ppm and 140ppm:

Processed Cheese



1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: in the EU the industry reported 35 ppm as the typical use level and 100 ppm as the ML (EFSA 2015)

GUATEMALA: > 320ppm

JAPAN: supports the proposal. INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Maximum use level is 70 mg/kg.

RU, USA: Supports 1st CL proposal- adoption at 140 with Note 39. Authorized for use in foods at GMP

FIA: In processed cheese (and related products) paprika extract is used and has particular benefits due to the potential for “pinking” from the use of annatto. In the old Codex standards for processed cheese “oleoresin from paprika” was permitted.

IACM: supports proposal to adopt. Needed to standardize the color of processed cheese for which cheddar cheese is used as ingredient. In JECFA’s 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

IDF: In processed cheese (and related products) paprika extract is used and has particular benefits due to the potential for “pinking” from the use of annatto. In the old Codex standards for processed cheese “oleoresin from paprika” was permitted. Reported use level: 420-750 mg/kg as Paprika Extract (35.28 - 63 mg/kg as total carotenoid) for Processed cheese.

QUINOLINE YELLOW	104	200			Colour	Do not move from Parent FC
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2nd Circular Proposal: Discontinue

EWG comments on 2nd Circular:

Australia, EU, RU: supports the proposal

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: no use reported by the industry for this FC (EFSA, 2015).

RU: does not agree with proposal. There not safety justification.

TARTRAZINE	102	200			Colour	Adopt
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal:

Australia, EU: supports the proposal

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161. ADI only 0-10 mg/kg bw!!!! Proposed ML is so higher!!!

USA: Supports adoption. Authorized for use in foods in general

IACM: supports proposal to adopt. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017).

IDF: supports adoption. Reported use levels corresponds to the maximum level. Usage is for certain processed cheeses where target color is yellow versus orange. The technological justification here is specific to certain processed cheeses where the yellow color is the target. This is very common among certain varieties of block and sliced processed cheeses intended for melting, particularly when such cheeses are intended to be incorporated into sauces, including those used in macaroni and cheese preparations.

ZEAXANTHIN, SYNTHETIC	161h(i)	100			Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Do not move from Parent FC if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

Category No. 01.6.5 (Cheese analogues)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: No Alignment work on this FC since no relevant commodity standard. Also Australian regulations do not have this specific food category, therefore Australia has provided limited comments.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	50	8	4	Colour	Adopt at 100 mg/kg with Note 8
<p>2nd Circular Proposal: Adopt at 100 with Note 8</p> <p><u>EWG comments on 2nd Circular:</u> Australia, Guatemala, IACM: Supports proposal</p> <p>EU: what is the rationale for the ML of 100ppm?</p> <p>JAPAN: Japan supports the proposal. INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavour. Maximum use level is 10 mg/kg.</p> <p>RU: does not agree with proposal. There not safety justification. Does no used in this FC in RU</p> <p>IDF: IDF supports adoption. Higher usage level is needed for more vibrant yellows and oranges desired, particularly in sliced cheeses.</p> <p>NATCOL: The reasons to colour cheese analogues are the same as for processed cheeses: to impart appealing colour to white/greyish cheese.</p> <p>1st Circular Proposal: Adopt</p> <p><u>EWG comments on 1st Circular:</u> EU: no use reported by the industry for this FC.</p> <p>JAPAN: INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Japan would like to provide information on maximum use level in next circular.</p> <p>RU: does not agree with proposal. There not safety justification. Does no used in this FC in RU</p> <p>USA: Supports adoption. Authorized for use at GMP in foods in general</p> <p>IACM: supports proposal to adopt. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.</p> <p>IDF: supports adoption. Maximum usage level reported 100 mg/kg. Higher usage level is needed for more vibrant yellows and oranges desired, particularly in sliced cheeses.</p>						
AZORUBINE (CARMOISINE)	122	GMP	3	7	Colour	NOTE: INS 122 has a numeric ADI of 0-4 mg/kg bw. Use level of GMP is not appropriate

						Adopt at 100 mg/kg with Note 3 "surface treatment only"
<p>2nd Circular Proposal: Adopt at 100 with Note 3. NOTE: INS 122 has a numeric ADI of 0-4 mg/kg bw. Use level of GMP is not appropriate</p> <p>EWG comments on 2nd Circular: Australia, Guatemala, IACM: Supports proposal</p> <p>EU: what is the rationale for the ML of 100ppm? Any examples of products in which it is used?</p> <p>1st Circular Proposal: Request information on actual use levels. NOTE: INS 122 has a numeric ADI of 0-4 mg/kg bw. Use level of GMP is not appropriate</p> <p>EWG comments on 1st Circular: EU: no use reported by the industry for this FC (EFSA, 2015).</p> <p>RU: does not agree with proposal. There not safety justification. Does no used in this FC in RU</p> <p>IACM: supports a use level of 100 mg/kg. The JECFA ADI is 4 mg/kg bw/day (1983).</p>						
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	200		2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
<p>1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1).</p> <p>EWG comments on Proposal: Australia, EU, Guatemala, JAPAN, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion</p>						
BRILLIANT BLACK (BLACK PN)	151	GMP	3	7	Colour	NOTE: INS 151 has a numeric ADI of 0-1 mg/kg bw. Use level of GMP is not appropriate Adopt at 100 mg/kg with Note 3
<p>2nd Circular Proposal: Adopt at 100 with Note 3. NOTE: INS 151 has a numeric ADI of 0-1 mg/kg bw. Use level of GMP is not appropriate</p> <p>EWG comments on 2nd Circular: Australia, Guatemala: Supports proposal</p> <p>EU: does not support. No use reported by the industry for this FC (EFSA, 2015). What is the rationale for the ML of 100ppm? Any examples of products in which it is used? The ADI is only 1 mg/kg bw/d.</p> <p>1st Circular Proposal: Request information on actual use levels. NOTE: INS 155 has a numeric ADI of 0-1.5 mg/kg bw. Use level of GMP is not appropriate</p> <p>EWG comments on 1st Circular: EU: no use was reported by the industry for this FC (EFSA, 2015).</p> <p>RU: does not agree with proposal. There not safety justification. Does no used in this FC in RU . ADI only 0-1 mg/kg bw</p>						

IACM: supports a use level of 100 mg/kg. JECFA ADI of 1 mg/kg bw/day in 2019. Considering that only a fraction of products in this category contain this particular color, no concern is raised of potential average daily intake exceedance of the JECFA ADI. JECFA's summary report (2019) notes that the dietary intake of brilliant black from all reported sources does not present a safety concern.

BROWN HT	155	GMP	3	7	Colour	NOTE: INS 155 has a numeric ADI of 0-1.5 mg/kg bw. Use level of GMP is not appropriate Adopt at 100 mg/kg with Note 3
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2nd Circular Proposal: Adopt at 100 with Note 3. NOTE: INS 155 has a numeric ADI of 0-1 mg/kg bw. Use level of GMP is not appropriate

EWG comments on 2nd Circular:

EU: does not support. No use reported by the industry for this FC (EFSA, 2014). What is the rationale for the ML of 100ppm? Any examples of products in which it is used? The ADI is only 1.5 mg/kg bw/d.

Guatemala: Supports proposal

RU: does not agree with proposal. There not safety justification. Does no used in this FC in RU . ADI only 0-1,5 mg/kg bw

1st Circular Proposal: Request information on actual use levels. NOTE: INS 155 has a numeric ADI of 0-1.5 mg/kg bw. Use level of GMP is not appropriate

EWG comments on 1st Circular:

EU: no use was reported by the industry for this FC (EFSA, 2014). If needed, other colours with higher ADIs or ADI not specified should be used instead.

RU: does not agrre with proposal. Numerical FA can't be used as GMP. ADI only 0-1,5 mg/kg bw

IACM: supports a use level of 100 mg/kg. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 1.5 mg/kg bw set in 1984.

CARAMEL II - SULFITE CARAMEL	150b	50000		4	Colour	Chair's Note: INS 150c and 150d are adopted in this FC at 50000. INS150d includes Note 201. Adopt
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2nd Circular Proposal: Adopt

Chair's Note: INS 150c and 150d are adopted in this FC at 50000. INS150d includes Note 201.

EWG comments on 2nd Circular:

Australia, Guatemala, IACM: Supports proposal

EU: use in cheese analogue was not reported by the industry (EFSA, 2011). The ML is excessive.

RU: Strongly opposite proposal!!!!!!!. All proposals for the use of the colour CARAMEL II- SULFITE CARAMEL INS 150b should be reviewed from the position of safety and tecnolojical justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: use in cheese analogue was not reported by the industry (EFSA, 2011). The ML is excessive.

RU: consider discontinuation. All proposals for the use of the colour CAMEL II- SULFITE CAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 50000. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. The intake from this food category is not expected to result in overall average daily intake exceeding the ADI of 160 mg/kg bw set by JECFA in 2000

CURCUMIN	100(i)	500		4	Colour	Adopt
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal:

Australia, Guatemala: Supports proposal

EU: EU does not support adoption at this ML. No use was reported in the EU for this FC (EFSA, 2014). Despite that (i.e. using only the reported use levels in the refined exposure estimates) the estimates for high consumers toddlers and children were at the ADI with exceedance of the ADI in one survey each. The EU could accept the ML of 100ppm

RU: does not agree with proposal. There not safety justification. Does no used in this FC in RU . ADI only 0-3 mg/kg bw

USA: Supports adoption at 500. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 500 mg/kg. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003

INDIGOTINE (INDIGO CARMINE)	132	200	3, 161	2009	Colour	Revise Adopted to remove Note 161
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1st and 2nd Circular Proposal: Revise Adopted to remove Note 161

EWG comments on Proposal:

Australia: supports the proposal

EU: use in cheese analogue was not reported by the industry (EFSA, 2014). any information supporting the use and ML?

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161

USA: Supports removal of Note 161. Authorized for use at GMP for foods in general

FIA, IACM: supports proposal to revise provision to remove Note 161

LUTEIN FROM TAGETES ERECTA	161b(i)	GMP		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending discussion of inclusion in Table 3

PAPRIKA EXTRACT	160c(ii)	50	39	2	Colour	Adopt at 70 mg/kg with Note 39 “on a total carotenoid basis”
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2nd Circular Proposal: Request comments on actual use levels as comments indicate ML range of 14 – 750 mg/kg. Use levels proposed should discuss safety with respect to JECFA ADI. Request information on specific products within FC utilizing higher use level up to 750 mg/kg

EWG comments on 2nd Circular:

Australia: supports the proposal to request information on its use and also use level

EU: in the EU the industry reported 14 ppm as the typical use level and 35 ppm as the ML (EFSA 2015). As regards safety of the ML, the refined exposure assessment (brand-loyal scenario) is just at the ADI for high level (P95) consumers (toddlers and children) from all uses authorized in the EU (EFSA Journal 2015;13(12):4320).

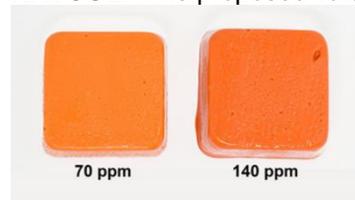
JAPAN: INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Maximum use level is 25 mg/kg on a total carotenoid in imitation cheese for further processing and other cheese analogues (spreadable, shredded, block and cube-shaped).

RU: Does not use in this FC in RU

IACM: IACM confirms max levels of 140 mg/kg needed for cheese analogues. See previously submitted safety information with respect to JECFA ADI. (Provided graphic seen below in NATCOL comments)

IDF: The reported use levels of 400-750 mg/kg are as paprika and convert to about 33.6 - 63 mg/kg as total carotenoids. Note 39 is “On a total carotenoid basis”. IDF suggests a maximum level of 70 mg/kg

NATCOL: The proposed values from IDF (36 – 63 mg/kg) are appropriate to achieve an acceptable colour shade. Pictures at 70ppm and 140ppm:



1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: in the EU the industry reported 14 ppm as the typical use level and 35 ppm as the ML (EFSA 2015)

GUATEMALA: > 320ppm

JAPAN: proposes the Max Level be replaced with 70 mg/kg. INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavour. Maximum use level is 70 mg/kg.

RU: does not agree with proposal. Numerical FA can't be used as GMP. ADI only 0-5 mg/kg bw

USA: Supports adoption at 50 with Note 39. Authorized for use in foods at GMP

IACM: supports proposal to adopt at 50 mg/kg to standardize the color of cheese analogues for which cheddar cheese may be used as an ingredient. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern

IDF: supports adoption. Paprika extract is used and has particular benefits due to the potential for "pinking" from the use of annatto. Reported use levels: 400 - 750 mg/kg as Paprika Extract (33.6 - 63 mg/kg as total carotenoid) for Cheese analogues.

QUINOLINE YELLOW	104	GMP	3	7	Colour	Discontinue
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2nd Circular Proposal: Discontinue

EWG comments on 2nd Circular:

Australia, EU, RU, IDF: Supports proposal

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: use in cheese analogue was not reported by the industry (EFSA, 2015).

RU: does not agree with proposal. Numerical FA can't be used as GMP. ADI only 0-3 mg/kg bw

TARTRAZINE	102	300	3	4	Colour	Adopt
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1st and 2nd Circular Proposal: Adopt

EWG comments on Proposal:

Australia: supports the proposal

EU: not permitted in the EU in this FC. any information on the technological justification and use of this colour in this FC? Any information supporting the ML?

RU: does not agree with proposal. There not safety justification. ADI only 0-10 mg/kg bw

USA: Supports adoption. Authorized for use in foods in general

IACM: supports proposal to adopt. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of

tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017).

IDF: Supports proposal

ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

Category No. 01.6.6 (Whey protein cheese)

Corresponding commodity standards: CODEX STAN 284-1971 (contains general reference to food additives in Tables 1 and 2 of the GSFA)

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: No Alignment EWG work on this commodity standard, but appears to have been aligned earlier. Also Australian regulations do not have this food category, therefore Australia has provided no comments.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	50	8	4	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
<u>EWG comments on Proposal:</u>						
Australia, EU, RU, IDF: Supports discontinuation						
ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	10	185	4	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue.						
<u>EWG comments on Proposal:</u>						
Australia, EU, RU, IDF: Supports discontinuation						

Category No. 01.7 (Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt))

Corresponding commodity standards: CODEX STAN 243-2003 (colours are permitted in flavoured fermented milks and drinks based on fermented milk, including in those heat treated after fermentation)

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENTS on 2ND CIRCULAR:

Australia: additional, amended comments due to EWG on Alignment, 2nd circular (currently out for EWG comment). Comments to the 1st circular of the EWG on Alignment received indicated that FC 01.7 specifically does not capture plain products, so it was considered that note 362 (excluding plain products conforming to CXS 243), was not required. This is explained in the comments to issue 12 (page 13) within Appendix 1 of the 2nd circular of the EWG for Alignment. Therefore note 362 was removed from the colour provisions proposed in the 2nd Alignment circular Appendix 3. This is a change to the Alignment 1st circular and Australia's earlier comments.

GENERAL COMMENTS on 1st CIRCULAR:

Australia: The Alignment EWG is currently (additional circulars for 2021 meeting) considering CXS 243-2003, to align provisions into the GSFA. Australia is the chair of the EWG and so provides the comments below noting this work to date reflecting the 1st circular (September 2020) relating specifically to FC 01.7.

The Alignment EWG has proposed adding note 362 (Excluding plain products conforming to the Standard for Fermented Milks (CXS 243-2003)) as part of the alignment work as noted in individual comments below.

USA: Notes that colours have previously been adopted in this FC.

IDF: notes that this category includes standards that have been aligned and refers to the comments made by the delegation of Australia for consistency, in particularly regarding notes, unless IDF has commented otherwise.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ALLURA RED AC	129	300	161	2009	Colour	Revise Adopted. Adopt at 300 to align with CXS 243-2003. Remove Note 161.
<u>2nd Circular Proposal:</u> Revise Adopted. Adopt at 300 to align with CXS 243-2003. Remove Note 161. Add Note 362 (Excluding plain products conforming to the Standard for Fermented Milks (CXS 243-2003))						
<u>EWG comments on 2nd Circular:</u>						
Australia: supports the proposal. However noting above general comment that it believes note 362 is not required for FC 01.7, due to 2nd circular of EWG on Alignment comments.						
Guatemala, FIA, IACM, IDF: Supports proposal						

1st Circular Proposal: Revise Adopted. Remove Note 161.

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding note 362 (Excluding plain products conforming to the Standard for Fermented Milks (CXS 243-2003)) and adopting at ML 300 mg/kg. Australia supports removal of note 161.

EU: lower ML than 300 should be sufficient. In the EU, the industry did not report the use in desserts However, analytical results provided by EUMS showed some limited presence of INS 129 in desserts up to 66 ppm. The ML shall not be higher than 150 ppm.

India: allows the use of this colour at 100 ppm in this category.

RU: agrees with proposal. Already in the GSFA, no need for Note 161

USA: Supports removal of Note 161 for consistency with commodity standard. Authorized for use at GMP in foods in general

FIA, IDF: Supports revision to remove Note 161.

IACM supports proposal to revise provision to remove Note 161. In JECFA's most recent safety evaluation, the highest intake of allura red from all foods was 2.9 mg/kg bw/day at the 95th % for children 3–9 years in Europe under the most conservative brand-loyal scenario; however more realistically the intake is up to 1.2 mg/kg bw/day at the 95th % in the non-brand loyal scenario, assuming that 100% products contain this color. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 2.2 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.22 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017). JECFA noted that the range of estimated dietary exposures to Allura Red AC from all foods and beverages were well below the ADI (0.4–41% of the ADI) including intake for children and including the conservative estimate by EFSA.

AMARANTH	123	300		7	Colour	Discontinue
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2nd Circular Proposal: Adopt

EWG comments on 2nd Circular:

Australia: notes the Alignment EWG proposed XS243, since there is no provision in CXS 243 for the colour

EU: strongly opposes the adoption due to possible safety (exposure) concerns. The ADI is very low (0.5 mg/kg bw/d), the use of this colours in this FC is not necessary. Colours with higher ADIs or ADI not specified should be used instead.

1st Circular Proposal: Provision was omitted from 1st CL.

ANNATTO EXTRACTS, BIXIN BASED	160b(i)	500	8	4	Colour	Adopt at 100 mg/kg with Note 8 new note " Except for use in non-plain products conforming to the Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg"
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2nd Circular Proposal: Adopt at 100 mg/kg with Note 362 and new note " Except for use in products conforming to the Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg"

EWG comments on 2nd Circular:

Australia: supports the proposal, noting consistency of the new note with alignment proposal. Considers note 362 not required

EU: for any ML higher than 20ppm technological justification should be provided. EU wonders what is the justification and what are the products for which higher ML than 20ppm is needed? As noted, in the EU the industry requested the ML at 15ppm.

Guatemala, FIA, IACM: Supports proposal

Japan: supports the proposal. INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetising. Maximum use level is 75 mg/kg in cheese-flavoured dairy-based fillings.

RU: Support EU proposal - The industry requested MPL of 15 ppm for bixin based annatto extracts in this FC. Not support link with Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg”

IDF: IDF supports the proposal but wonders whether the two notes are confusing: Notes 362 (Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)) and the new note (“ Except for use in products conforming to the Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg”) , and shall not be replaced by a new note: “Except for use in non-plain products conforming to the Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg”

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding note 362, and new note “ Except for use in products conforming to the Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg”, and leaving at step 4. Australia supports adoption, but with new notes, at ML of 500 mg/kg.

EU: the ML is excessive. In the EU the uses of annatto extracts have been recently reviewed. The industry requested MPL of 15 ppm for bixin based annatto extracts in this FC.

India: allows the use of this colour at 100 ppm in this category.

JAPAN: supports the proposal. INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetising. Maximum use level is 75 mg/kg in cheese-flavoured dairy-based fillings.

RU: agrees with 1st CL proposal

USA: Supports adoption. Authorized for use at GMP in foods in general

FIA, IDF: Supports the 1st CL proposal

IACM: supports proposal to adopt at 500 mg/kg. Based on JECFA’s refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

NATCOL: considers that the typical use is 15 mg/kg but also recognizes that exceptions are possible.

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	20	185	4	Colour	Adopt at 100 with Note 185 and new note " Except for use in non-plain products conforming to the Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg"
<p>2nd Circular Proposal: Adopt at 100 with Note 362 and new note " Except for use in products conforming to the Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg"</p> <p>EWG comments on 2nd Circular: Australia: supports the proposal, noting consistency of the new note with alignment proposal. Considers note 362 not required</p> <p>EU: opposes due to possible exposure concerns. In the EU industry requested MPL of 7.5 ppm for norbixin based annatto extracts in this FC. The exposure to norbixin based annatto extracts is at the ADI in the EU, therefore, the ML has to be carefully considered.</p> <p>Guatemala, FIA, IACM, IDF: Supports proposal</p> <p>JAPAN: Japan supports the proposal. INS 160b(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavor. Maximum use level is 20 mg/kg in puddings containing pumpkin as an ingredients.</p> <p>RU: Support EU proposal - The industry requested MPL of 7,5 ppm for bixin based annatto extracts in this FC. Not support link with Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg"</p> <p>1st Circular Proposal: Adopt</p> <p>EWG comments on 1st Circular: Australia: notes that the Alignment EWG has proposed adding note 362, and leaving at step 4. Australia supports adoption, but with new notes, at ML of 20 mg/kg.</p> <p>EU: in the EU the uses of annatto extracts have been recently reviewed. The industry requested MPL of 7.5 ppm for norbixin based annatto extracts in this FC. The exposure to norbixin based annatto extracts is at the ADI in the EU, therefore, the ML has to be carefully considered.</p> <p>India: allows the use of this colour at 100 ppm in this category.</p> <p>JAPAN: supports the proposal. INS 160b(ii) is used in foods broadly across this food category to make the food visually appealing and appetising and to associate the colour with the flavor. Maximum use level is 20 mg/kg in puddings containing pumpkin as an ingredients.</p> <p>RU: agrees with 1st CL proposal in ML =10 mg/kg</p> <p>USA: Supports adoption. Authorized for use at GMP in foods in general</p> <p>FIA: Supports the 1st CL proposal</p> <p>IACM: supports proposal to adopt at 20 mg/kg. ECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI</p>						

IDF: supports adoption. Annatto extract norbixin based is used in flavoured yoghurt to give the yoghurt a yellow/orange hue that is a suitable colour for the flavour of the yoghurt (e.g. flavours such as but not limited to lemon, apricot, custard, etc). It may be used in combination with other colours to achieve the final colour profile so usage levels of the annatto component varies between products. The level of annatto used is up to 90 mg/kg. The annatto in this particular case has 2.6% norbixin, therefore it is 2.34 mg/kg “as norbixin”.						
AZORUBINE (CARMOSINE)	122	150		7	Colour	Adopt – proposal aligns with CXS 243-2003
2nd Circular Proposal: Adopt with Note 362 – proposal aligns with CXS 243-2003						
EWG comments on 2nd Circular:						
Australia: supports the proposal, noting consistency of the new note with alignment proposal. Considers note 362 not required						
EU, Guatemala, IACM, IDF: Supports proposal						
RU: Proposed ML is so higher. Not support link with Standard for Fermented Milks (CXS 243-2003) at 20 mg/kg						
1st Circular Proposal: Adopt						
EWG comments on 1st Circular:						
Australia notes that the Alignment EWG has proposed adding note 362, with ML of 150 mg/kg as part of the alignment with CXS 243. Australia supports adoption but with addition of note 362.						
EU: accepts. The mean analytical value 15 ppm, the maximum 136 ppm (EFSA, 2015).						
India: allows the use of this colour at 100 ppm in this category.						
RU: agrees with 1 st CL proposal						
IACM: supports proposal to adopt at 150mg/kg. The JECFA ADI for azorubine is 4 mg/kg bw/day (1983).						
IDF: supports adoption, same level as in CXS 243.						
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	100	XS243	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						
EWG comments on Proposal:						
Australia, EU, JAPAN, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion						
BRILLIANT BLACK (BLACK PN)	151	150		7	Colour	Adopt– proposal aligns with CXS 243-2003
2nd Circular Proposal: Adopt with Note 362						
EWG comments on 2nd Circular:						
Australia: supports the proposal, noting consistency of the new note with alignment proposal. Considers note 362 not required						

EU, Guatemala, IACM, IDF: Supports proposal

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161. ADI only 0-1 mg/kg bw!!!! Proposed ML is so higher!!!

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding note 362, with ML of 150 mg/kg as part of the alignment with CXS 243. Australia supports adoption but with addition of note 362.

EU: for desserts the industry provided 80 ppm as a typical use level and 110 ppm as a maximum level (EFSA, 2015).

RU: agrees with 1st CL proposal

IACM: supports proposal to adopt at 150 mg/kg. JECFA ADI of 1 mg/kg bw/day in 2019. Considering that only a fraction of products in this category contain this particular color, no concern is raised of potential average daily intake exceedance of the JECFA ADI. JECFA's summary report (2019) notes that the dietary intake of brilliant black from all reported sources does not present a safety concern

IDF: supports adoption, same level as in CXS 243.

BROWN HT	155	150		7	Colour	Adopt – proposal aligns with CXS 243-2003
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2nd Circular Proposal: Adopt with Note 362 – proposal aligns with CXS 243-2003

EWG comments on 2nd Circular:

Australia: supports the proposal, noting consistency of the new note with alignment proposal. Considers note 362 not required

EU, Guatemala, IACM, IDF: Supports proposal

RU: Does not use in this FC in RU and a number countries too. So on there need Note 161. ADI only 0-1,5 mg/kg bw!!!! Proposed ML is so higher!!! Could not support link with Standard for Fermented Milks (CXS 243-2003)

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia notes that the Alignment EWG has proposed adding note 362, with ML of 150 mg/kg as part of the alignment with CXS 243. Australia supports adoption but with addition of note 362, at ML of 150 mg/kg.

EU: no use was reported by the industry for this FC (EFSA, 2014). If needed, other colours with higher ADIs or ADI not specified should be used instead.

RU: agrees with 1st CL proposal in ML =10 mg/kg

IACM: supports proposal to adopt at 150 mg/kg. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 1.5 mg/kg bw set in 1984.

IDF: supports adoption, same level as in CXS 243						
CARAMEL II - SULFITE CARAMEL	150b	50000		4	Colour	Chair's Note: INS 150c and 150d are adopted in the FC at 2000 Adopt at 2000 with note 400 and New Note "Except for use in ice cream products with light brown colour at 3600 mg/kg"
2nd Circular Proposal: Adopt at 2000 with notes 362 and 400 and New Note "Except for use in ice cream products with light brown colour at 3600 mg/kg" Chair's Note: INS 150c and 150d are adopted in the FC at 2000						
<u>EWG comments on 2nd Circular:</u> Australia: supports the proposal, noting comments related to use and MLs from Japan. To note the ML from CXS 243 is 150 mg/kg (which relates to note 400). Considers note 362 not required EU, Guatemala, IACM, IDF: Supports proposal JAPAN: Japan supports the proposal. INS 150b is used in specific ice cream products with light brown colour (e.g. coffee-flavoured, caramel-flavoured, chestnut-flavoured, etc.) to make the food visually appealing and appetizing and to associate the colour with the flavor. Maximum use level is 3600 mg/kg. RU: Strongly opposite proposal!!!!!!!. All proposals for the use of the colour CARAMEL II- SULFITE CARAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient. 1st Circular Proposal: Adopt <u>EWG comments on 1st Circular:</u> Australia notes that the Alignment EWG has proposed adding notes 362 and 400 (for use in products conforming to the standard for Fermented Milk (CXS 243-2003) at 150 mg/kg, and leaving at step 4. Australia supports adoption, but with new notes, at ML of 50000 mg/kg. EU: for desserts the industry provided 1000 ppm as a typical use level (EFSA, 2011). The ML of 50000 is excessive. JAPAN: supports the proposal. INS 150b is used in specific ice cream products with light brown colour (e.g. coffee-flavoured, caramel-flavoured, chestnut-flavoured, etc.) to make the food visually appealing and appetizing and to associate the colour with the flavor. Maximum use level is 3600 mg/kg. RU: consider discontinuation. All proposals for the use of the colour CARAMEL II- SULFITE CARAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient. USA: Supports adoption at 50000. Authorized for use at GMP for foods in general IACM: supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.						

IDF: supports adoption, level is 150 mg/kg in CXS 243.						
CURCUMIN	100(i)	150		7	Colour	Adopt with note 402 ("For use in products conforming to the Standard for Fermented Milk (CODEX STAN 243- 2003) at 100 mg/kg")
2nd Circular Proposal: Adopt with note 362 and 402 ("For use in products conforming to the Standard for Fermented Milk (CODEX STAN 243- 2003) at 100 mg/kg")						
EWG comments on 2nd Circular:						
Australia: supports the proposal, noting essentially consistent with Alignment. As noted earlier the EWGs for GSFA and Alignment need to coordinate proposed amendments. Considers note 362 not required						
EU, Guatemala, FIA, IACM, IDF, NATCOL: Supports proposal						
RU: Could not support link with Standard for Fermented Milks (CXS 243-2003)						
1st Circular Proposal: Adopt						
EWG comments on 1st Circular:						
Australia notes that the Alignment EWG has proposed adding note 362, with a different ML of 100 mg/kg as part of the alignment with CXS 243. Australia supports adoption but with addition of note 362 and different ML of 100 mg/kg (which comes from CXS 243).						
EU: can support. The industry reported 7-20 ppm as the typical use level and 147 ppm as the maximum use level. The use level is important as the exposure to curcumin is at the ADI in the EU (EFSA, 2014).						
India: allows the use of this colour at 100 ppm in this category.						
RU: Supports 1 st CL proposal						
USA: Supports adoption at 150. Authorized for use at GMP for foods in general						
IACM: supports proposal to adopt at 150 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.						
IDF: supports adoption, level is 100 mg/kg in CXS 243.						
NATCOL: Supports adoption at 150						
LUTEIN FROM TAGETES ERECTA	161b(i)	150		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.						
EWG comments on Proposal:						
Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending discussion of inclusion in Table 3						

India: does not allow this colour in this category.						
LYCOPENE, TOMATO	160d(ii)	5000		3	Colour	Discontinue Use is already permitted in this FC under provision adopted in Table 3
1st and 2nd Circular Proposal: Discontinue. Use is already permitted in this FC under provision adopted in Table 3						
EWG comments on Proposal:						
Australia: Australia supports the proposal. This is different to how Alignment has considered the 3 lycopene colours during alignment of CXS 243 with FC 01.7. Amendment of Alignment circular is likely needed. Alignment EWG has proposed adding note 362, with a different ML of 30 mg/kg as part of the alignment with CXS 243.						
EU, INDIA, JAPAN, RU, USA, IACM, IDF, NATCOL: Supports discontinuation. Use is already permitted in this FC under provision adopted in Table 3						
JAPAN: Japan supports the proposal since INS 160d(ii) is listed in Table 3 and Food category 01.7 is not listed in the Annex to Table 3. INS 160d(ii) is actually used in foods broadly across this food category.						
PAPRIKA EXTRACT	160c(ii)	50	39	2	Colour	Adopt at 60 mg/kg with notes 39 and XS243
2nd Circular Proposal: Adopt with notes 39 and XS243						
EWG comments on 2nd Circular:						
Australia, EU, Guatemala, IACM, NATCOL: Supports proposal						
Japan: supports the proposal. INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavor.						
RU: Could not support link with Standard for Fermented Milks (CXS 243-2003)						
IDF: Supports the proposed level. IDF suggests aligning with outcome of discussion for provision for INS 160c(ii) under FC 1.1.4 (that considers removing note XS243).						
1st Circular Proposal: Adopt.						
EWG comments on 1st Circular:						
Australia: notes that the Alignment EWG has proposed adding note XS243, as part of the alignment with CXS 243, but kept at step 2. Australia can support adoption but adding note XS243, and keeping the same ML and note 39.						
EU: in the EU the industry reported 11 ppm as the typical use level and 50 ppm as the ML (EFSA 2015)						
INDIA: Paprika extract is used in India since ages as a spice extracts which also contributes coloring properties to a food.						
JAPAN: proposes the Max Level be replaced with 60 mg/kg. INS 160c(ii) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavor. Maximum use level is 60 mg/kg in fruits flavoured ice cream						

RU: Supports hold proposal						
USA: Supports adoption						
IACM: supports proposal to adopt at 50 mg/kg to impart color to ice cream, sherbet containing dairy ingredients and fruit yogurt. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.						
PONCEAU 4R (COCHINEAL RED A)	124	150	161	2008	Colour	Revise adopted provision - Remove Note 161 - proposal aligns with CXS 243-2003
2nd Circular Proposal: Remove 161 and add note 362 - proposal aligns with CXS 243-2003						
EWG comments on 2nd Circular:						
Australia: supports the proposal, noting consistent with Alignment. Considers note 362 not required						
EU: the use level is excessive. In the EU 10 ppm is considered sufficient also reflecting possible exposure concerns in the EU. The use of this colour is restricted due to its low ADI in the EU.						
Guatemala, IACM, IDF: Supports proposal						
RU: Does not agree with proposal/ ML is so higher. Could not support link with Standard for Fermented Milks (CXS 243-2003)						
1st Circular Proposal: Revise Adopted. Remove 161.						
EWG comments on 1st Circular:						
Australia: notes that the Alignment EWG has proposed adding note 362, as part of the alignment with CXS 243 with the same ML. Australia can support adoption, removal of note 161 with addition of note 362 and same ML.						
EU: the use level is excessive. In the EU 10 ppm is considered sufficient also reflecting possible exposure concerns in the EU. The use of this colour is restricted due to its low ADI in the EU.						
India: allows the use of this colour at 100 ppm in this category.						
RU: does not agree with proposal. There not safety justification. ADI 0-4 mg/kg bw						
FIA: Supports removal of Note 161						
IACM: supports proposal to revise adopted provision to remove Note 161. In its most recent safety evaluation (2011), JECFA concluded that there is no concern for a likely exceedance of the JECFA ADI of 4 mg/kg bw based on realistic lifetime intake of 0.02 mg/kg bw/day in children in Australia/New Zealand at the 90th % from all foods and beverages						
IDF: supports adoption, same level as in CXS 243						
QUINOLINE YELLOW	104	150		7	Colour	Adopt – proposal aligns with CXS 243-2003
2nd Circular Proposal: Adopt with note 362 – proposal aligns with CXS 243-2003						

EWG comments on 2nd Circular:

Australia: supports the proposal, noting consistent with Alignment. Considers note 362 not required

EU: the use level is excessive. The analytical results show 4 ppm as the mean level and 9 ppm as the maximum.

Guatemala, IACM, IDF: Supports proposal

RU: Does not agree with proposal/ ML is so higher. Could not support link with Standard for Fermented Milks (CXS 243-2003)

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding note 362, as part of the alignment with CXS 243 with the same ML. Australia can support adoption with addition of note 362 and same ML.

EU: the use level is excessive. The analytical results show 4 ppm as the mean level and 9 ppm as the maximum.

RU: does not agree with proposal. Numerical FA can't be used as GMP. ADI 0-3 mg/kg bw

IDF: supports adoption, same level as in CXS 243

SUNSET YELLOW FCF	110	300	161	2009	Colour	Remove Note 161 - proposal aligns with CXS 243-2003
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2nd Circular Proposal: Remove Note 161 and add note 362 - proposal aligns with CXS 243-2003

EWG comments on 2nd Circular:

Australia: supports the proposal, noting consistent with Alignment. Considers note 362 not required

EU: the use level is excessive. The analytical results show 3 ppm as the mean level and 4.3 ppm as the maximum.

Guatemala, FIA, IACM, IDF: Supports proposal

RU: Does not agree with proposal/ ML is so higher. Could not support link with Standard for Fermented Milks (CXS 243-2003)

1st Circular Proposal: Revise Adopted. Remove Note 161

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding note 362, as part of the alignment with CXS 243 with the same ML. Australia can support adoption, the removal of note 161 with addition of note 362 and same ML.

EU: the use level is excessive. The analytical results show 3 ppm as the mean level and 4.3 ppm as the maximum.

India: allows the use of this colour at 100 ppm in this category.

RU: does not agree with proposal. There not safety justification. ADI 0-4 mg/kg bw

USA: Supports removal of Note 161 for consistency with commodity standard. Authorized for use at GMP for foods in general

FIA: Supports removal of Note 161

IACM: supports proposal to revise adopted provision to remove Note 161. In its most recent safety evaluation (2011), JECFA concluded that there is no concern for a likely exceedance of the JECFA ADI of 4 mg/kg bw based on realistic lifetime intake of 0.12 mg/kg bw/day in children in Australia/New Zealand at the 90th % from all foods and beverages. More recent estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.8 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.2 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017). JECFA noted that the more realistic FSANZ intake was up to 3% of the ADI and concluded that there is no health concern for sunset yellow intake as a color additive.

IDF: supports adoption, same level as in CXS 243.

TARTRAZINE	102	300		7	Colour	Adopt with note 362 - proposal aligns with CXS 243-2003
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2nd Circular Proposal: Adopt with note 362 - proposal aligns with CXS 243-2003

EWG comments on 2nd Circular:

Australia: supports the proposal, noting consistent with Alignment. Considers note 362 not required

Guatemala, FIA, IACM, IDF: Supports proposal

RU: Does not agree with proposal/ ML is so higher. Could not support link with Standard for Fermented Milks (CXS 243-2003)

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding note 362, as part of the alignment with CXS 243 with the same ML. Australia can support adoption with addition of note 362 and same ML.

EU: the industry reported the maximum level of 10 ppm for this FC (EFSA, 2009).

India: allows the use of this colour at 100 ppm in this category.

RU: does not agree with proposal. There not safety justification. ADI 0-10 mg/kg bw

USA: Supports adoption. Authorized for use in foods in general

FIA: Supports the 1st CL proposal

IACM: supports proposal to adopt at 300 mg/kg. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA.

In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017).

IDF: supports adoptions. Use reported corresponds to maximum level.

ZEAXANTHIN, SYNTHETIC	161h(i)	150		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

Category No. 01.8.1 (Liquid whey and whey products, excluding whey cheeses)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: Australian comments

No Alignment work on this FC since no relevant commodity standard. Also Australian regulations do not have this specific food category, therefore Australia has provided no comments.

Additive	INS	Max Level (mg/kg)	Notes		Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	20	8		4	Colour	Discontinue

2nd Circular Proposal: Discontinue

EWG comments on 2nd Circular:

Australia, EU, RU, IDF: Supports proposal

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: discontinue. EU is not aware of the technological need. Whey is an intermediate product, therefore, there should not be any need for colours. Whey is not flavoured.

RU: does not agree with proposal. There not safety justification. Use INS 160b(i) could mislead consumers about quality of PLAIN products

IACM: supports proposal to adopt at 20 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

IDF: members do not report adding colors to whey. If detected, it may be due to carryover from the production of colored cheeses that allow this additive

ANNATTO EXTRACTS, NORBIXIN- BASED	160b(ii)	20	185		4	Colour	Discontinue
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2nd Circular Proposal: Discontinue

EWG comments on 2nd Circular:

Australia, EU, RU, IDF: Supports proposal

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: discontinue. EU is not aware of the technological need. Whey is an intermediate product, therefore, there should not be any need for colours. Whey is not flavoured.

RU: does not agree with proposal. There not safety justification. Use INS 160b(ii) could mislead consumers about quality of PLAIN products

IACM: supports proposal to adopt at 20 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI

IDF: members do not report adding colors to whey. If detected, it may be due to carryover from the production of colored cheeses that allow this additive

CARAMEL II - SULFITE CARAMEL	150b	50000			4	Colour	Discontinue
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2nd Circular Proposal: Discontinue

EWG comments on 2nd Circular:

Australia, EU, RU, IDF: Supports proposal

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

EU: discontinue. EU is not aware of the technological need. Whey is an intermediate product, therefore, there should not be any need for colours. Whey is not flavoured.

RU: consider discontinuation. All proposals for the use of the colour CAMEL II- SULFITE CAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

IACM: supports proposal to adopt at 50000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day

Category No. 01.8.2 (Dried whey and whey products, excluding whey cheeses)

Corresponding commodity standards: CODEX STAN 289-1995 (contains general reference to food additives contained in Tables 1 and 2 of the GSFA), 331-2017 (does not permit any food additives)

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: The Alignment EWG is currently (additional circulars for 2021 meeting) considering CXS 331-2017, to align provisions into the GSFA. Australia is the chair of the EWG and so provides the comments below noting this work to date reflecting the 1st circular (September 2020). As noted the commodity standard does not permit any food additives, so exclusions notes were added. No Alignment EWG work on CXS 289-1995, but appears to have been aligned earlier.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	20	8	4	Colour	Discontinue

1st and 2nd Circular Proposal: Discontinue

EWG comments on Proposal:

Australia: can support discontinuation since CXS 331-2017 does not permit any food additives and CXS 289-1995 does not have provisions for colours having already been aligned with this FC which does not permit any colours.

EU: discontinue. EU is not aware of the technological need. Whey is an intermediate product, therefore, there should not be any need for colours. Whey is not flavoured.

RU: Supports discontinuation

IDF: Supports proposal. members do not report adding colors to whey. If detected, it may be due to carryover from the production of colored cheeses that allow this additive

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	20	185	4	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
EWG comments on Proposal:						
Australia: can support discontinuation since CXS 331-2017 does not permit any food additives and CXS 289-1995 does not have provisions for colours having already been aligned with this FC which does not permit any colours.						
EU: discontinue. EU is not aware of the technological need. Whey is an intermediate product, therefore, there should not be any need for colours. Whey is not flavoured.						
RU: Supports discontinuation						
IDF: Supports proposal. members do not report adding colors to whey. If detected, it may be due to carryover from the production of colored cheeses that allow this additive						

Category No. 02.1 (Fats and oils essentially free from water)

Corresponding commodity standards: CODEX STAN 19-1981 (colours are not permitted)

GSFA: FC is in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: The Alignment EWG aligned the food additives for CXS 19-1981 as part of CX/FA 20/52/6. The comments below relate to the alignment work. Australia is comfortable addressing the provisions for these colours in the subcategories, noting that there are no colour provisions in CXS 19-1981.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
LYCOPENE, BLAKESLEA TRISPORA	160d(iii)	25		4	Colour	Discontinue
LYCOPENE, SYNTHETIC	160d(i)	25		4	Colour	Discontinue
LYCOPENE, TOMATO	160d(ii)	25		3	Colour	Discontinue

Category No. 02.1.1 (Butter oil, anhydrous milkfat, ghee)

Corresponding commodity standards: CODEX STAN 19-198 (colours are not permitted), 280-1973 (contains general reference to food additives in Tables 1 and 2 of the GSFA)

GSFA: Parent FC is in the Annex to Table 3. Colours have not previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: The Alignment EWG aligned the food additives for CXS 19-1981 as part of CX/FA 20/52/6. Standard 280-1973 appears to have been aligned earlier, so the Alignment EWG has not needed to align this standard. The comments below relate to the alignment work. Australia is comfortable discontinuing the provisions for these colours if the EWG agrees.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	100	8	4	Colour	Discontinue
1st and 2nd Circular Proposal: Discontinue						
<u>EWG comments on Proposal:</u> Australia, EU, RU, IDF: Supports discontinuation						
LYCOPENE, BLAKESLEA TRISPORA	160d(iii)	25			Colour	Do not move from FC 2.1
1st and 2nd Circular Proposal: Discontinue						
<u>EWG comments on Proposal:</u> Australia, EU, RU, IDF: Supports discontinuation						
LYCOPENE, SYNTHETIC	160d(i)	25			Colour	Do not move from FC 2.1
1st and 2nd Circular Proposal: Discontinue						
<u>EWG comments on Proposal:</u> Australia, EU, RU, IDF: Supports discontinuation						
LYCOPENE, TOMATO	160d(ii)	25			Colour	Do not move from FC 2.1
1st and 2nd Circular Proposal: Discontinue						
<u>EWG comments on Proposal:</u> Australia, EU, RU, IDF: Supports discontinuation						

Category No. 02.1.2 (Vegetable oils and fats)

Corresponding commodity standards: CODEX STAN 19-1981 (Section 3.1 states colours are not permitted in vegetable oils but then specific colours are permitted for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour – unclear if this use is allowed in vegetable oils), 33-1981, 210-1999, 325R-2017 (colours are not permitted)

GSFA: Parent FC is in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENTS on 1st CIRCULAR:

Australia: The Alignment EWG aligned the food additives for CXS 19-1981, CXS 33-1981, CXS 210-1999 (but not CXS 325R-2017, no food additives are permitted) as part of CX/FA 20/52/6. The comments below relate to the alignment work.

CANADA: In the 2018 Report of the EWG on the GSFA (CX/FA 18/50/7), it was noted:

“During discussion of provisions for the use of specific emulsifiers and acidity regulators in food categories 02.1.2 (Vegetable oils and fats) and 02.1.3 (Lard, tallow, fish oil and other animal fats), it was noted that there is a full correspondence between these food categories and the corresponding commodity standards and that emulsifiers and acidity regulators were not allowed in the corresponding commodity standards. However, several members noted that emulsifiers and acidity regulators are used in products included in food categories 02.1.2 and 02.1.3”.

As a result, the CCFA sought the advice from CCFO on the use of additives in oils and fats. Canada asks if similar advice has been asked of the CCFO for colourings, and if so, this input could be helpful in the report of this working group, to further the discussion.

In the absence of advice from the CCFO, Canada is concerned about the technological need to colours in this food category, and would recommend that colouring provisions be consistent with those set out in the commodity standards. In Canada, only carotene in vegetable fats and oils (except for in olive oil) is permitted, in an amount needed to replace the colour lost during processing. This is similar, albeit more restrictive, to the requirement set out in the Standard for edible fats and oils not covered by individual standards (CXS 19-1981):

“The following colours are permitted for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, as long as the added colour does not deceive or mislead the consumer by concealing damage or inferiority or by making the product appear to be of greater than actual value”.

In accordance with CXS 19-1981, Canada would not object to a proposal for curcumin (INS 100(i) at 5 mg/kg or annatto extracts, bixin-based (INS 160b(i) (not part of the table below)) in FC 02.1.2, with note 232 “For use in vegetable fats conforming to the Standard for Edible Fats and Oils Not Covered by Individual Standards (CODEX STAN 19-1981) only”, and optionally notes XS33, XS210 and XS325R.

Although certain carotenoids are permitted in the standard, Canada does not suggest adopting provisions for INS 160(a)(iv) at this time, pending the discussion on carotenoids.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	25	232, XS33, XS210, XS325R	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
<u>1st and 2nd Circular Proposal:</u> Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						
<u>EWG comments on Proposal:</u> Australia, EU, Guatemala, RU, USA, IACM, NATCOL: Supports holding pending carotenoid discussion						

BEET RED	162	GMP		7	Colour	Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
<p>2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS</p> <p>EWG comments on 2nd Circular: Australia, EU, RU: Supports proposal</p> <p>1st Circular Proposal: Adopt with notes XS19, XS33, XS210, XS325R</p> <p>EWG comments on 1st Circular: Australia: notes that the Alignment EWG has proposed adding notes XS19, XS33, XS210 and maintaining at step 7 at GMP. Australia can support adopting as proposed with XS325R.</p> <p>EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in the corresponding commodity standards.</p> <p>RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!</p> <p>USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general</p> <p>IACM: supports proposal to adopt at GMP with notes</p>						
CARAMEL II - SULFITE CARAMEL	150b	20000		4	Colour	Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
<p>2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS</p> <p>EWG comments on 2nd Circular: Australia, EU, RU: Supports proposal</p> <p>1st Circular Proposal: Adopt with notes XS19, XS33, XS210, XS325R</p> <p>EWG comments on 1st Circular: Australia: notes that the Alignment EWG has proposed adding notes XS19, XS33, XS210 and maintaining at step 4 at the ML of 20000 mg/kg. Australia can support adopting as proposed with XS325R.</p> <p>EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in the corresponding commodity standards.</p> <p>RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!</p> <p>USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general</p> <p>IACM: supports proposal to adopt. Although the range of use levels may vary among products to appeal to diverse consumers, the proposed maximum level is needed to meet expectations for products in this category. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake</p>						

assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day

CHLOROPHYLLS	140	GMP		7	Colour	Request clarification from CCFO on the use of INS 140 in vegetable oils to restore natural colour lost in processing or for the purpose of standardizing colour, including in virgin, cold pressed, and other oils covered by CXS 19-1981, and specifically for that purpose in vegetable oils for deep frying
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2nd Circular Proposal: Given the statements on food additives in Section 3, and on colours in Section 3.1 of CXS 19-1981, Request clarification from CCFO on the use of colours in vegetable oils to restore natural colour lost in processing or for the purpose of standardizing colour, including in virgin, cold pressed, and other oils covered by CXS 19-1981, and specifically on the use of chlorophylls (INS 140) for that purpose in vegetable oils for deep frying

EWG comments on 2nd Circular:

Australia: supports the proposal. Australia notes and repeats its earlier comments that the Alignment EWG aligned the food additives for CXS 19-1981, CXS 33-1981, CXS 210-1999 (but not CXS 325R-2017, no food additives are permitted) as part of CX/FA 20/52/6

EU, JAPAN: supports the proposal that CCFA requests clarification from CCFO.

RU: strongly opposite proposal. Vegetable oils and fats is PLAIN products!!!!!! Use of FA in this FC could mislead consumers!!!!

1st Circular Proposal: Adopt with notes XS19, XS33, XS210, XS325R

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding notes XS19, XS33, XS210 and maintaining at step 7 at GMP. Australia can support adopting as proposed with XS325R.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in the corresponding commodity standards.

JAPAN: INS 140 is used in foods broadly across this food category to restore natural colour lost in production. Maximum use level is 50 mg/kg in vegetable oil for deep-frying.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at GMP with notes

NATCOL: Supports adoption GMP for use in flavoured oils

CURCUMIN	100(i)	5		7	Colour	Chair's Note: Proposal aligns with CXS 19-1981 Adopt with Notes XS33, XS 210 and XS 325R and new note "For use in products conforming to the Standard for Edible Fats and Oils not
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						Covered by Individual Standards (CXS 19-1981) for the purposes of restoring natural colour lost in processing, or standardizing colour only”
<p>2nd Circular Proposal: Curcumin is listed in CXS 19-1981 for use as a colour at 5 mg/kg. However, given the statements on food additives in Section 3, and on colours in Section 3.1 of CXS 19-1981, Request clarification from CCFO on the use of colours in vegetable oils to restore natural colour lost in processing or for the purpose of standardizing colour, including in virgin, cold pressed, vegetable oil for deep frying, and other oils covered by CXS 19-1981, and specifically on the use of curcumin (INS 100(i)) for that purpose.</p> <p>EWG comments on 2nd Circular: Australia: supports the proposal. Australia notes and repeats its earlier comments that the Alignment EWG aligned the food additives for CXS 19-1981, CXS 33-1981, CXS 210-1999 (but not CXS 325R-2017, no food additives are permitted) as part of CX/FA 20/52/6</p> <p>EU: accepts requesting the clarification from CCFO.</p> <p>RU: strongly opposite proposal. Vegetable oils and fats is PLAI N products!!!!!! Use of FA in this FC could mislead consumers!!!!</p> <p>IACM: Supports proposal</p> <p>1st Circular Proposal: Adopt with notes XS19, XS33, XS210, XS325R</p> <p>EWG comments on 1st Circular: Australia: notes that the Alignment EWG has proposed adopting at the ML of 5 mg/kg due to alignment with two additional new notes: “Excluding virgin and cold pressed oils in products conforming to the Standard for Edible Fats and Oils not Covered by Individual Standards (CXS 19-1981) and the Standard for Named Vegetable Oils (CXS 210-1999).”, “For use in products conforming to the Standard for Edible Fats and Oils not Covered by Individual Standards (CXS 19-1981) for the purposes of restoring natural colour lost in processing or standardizing colour only”. Australia can also support XS33, XS210 and XS325R but not XS19. Australia therefore suggests staying with the Alignment EWG recommendation of the ML of 5 mg/kg, but with the 2 new notes, XS33, XS210 and XS325R.</p> <p>EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in the corresponding commodity standards.</p> <p>RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!</p> <p>USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general</p> <p>IACM: supports proposal to adopt at 5 mg/kg. The range of use levels may vary depending on the desired effect to meet consumer preferences. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.</p>						
LYCOPENE, BLAKESLEA TRISPORA	160d(iii)	25			Colour	Do not move from FC 2.1. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
<p>2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS</p> <p>EWG comments on 2nd Circular: Australia, EU, RU: Supports proposal</p>						

1st Circular Proposal: Adopt with notes XS19, XS33, XS210, XS325R

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG did not address this colour as part of the alignment work. Therefore Australia cannot provide comments related the proposed ML, but it could support adding the proposed notes XS19, XS33, XS210 and XS325R if there was EWG support for adoption.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

IACM: Supports 1st CL proposal

LYCOPENE, SYNTHETIC	160d(i)	25			Colour	Do not move from FC 2.1. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

Australia, EU, RU: Supports proposal

1st Circular Proposal: Adopt with notes XS19, XS33, XS210, XS325R

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG did not address this colour as part of the alignment work. Therefore Australia cannot provide comments related the proposed ML, but it could support adding the proposed notes XS19, XS33, XS210 and XS325R if there was EWG support for adoption.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in the corresponding commodity standards.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

IACM: Supports 1st CL proposal

LYCOPENE, TOMATO	160d(ii)	50000		3	Colour	Do not move from FC 2.1. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

Australia, EU, RU: Supports proposal

1st Circular Proposal: Adopt with notes XS19, XS33, XS210, XS325R

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding notes XS19, XS33, XS210 and maintaining at step 3 at the ML of 50000 mg/kg. Australia can support adopting as proposed with XS325R.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in the corresponding commodity standards.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general

IACM: Supports adoption at 100 mg/kg

Category No. 02.1.3 (Lard, tallow, fish oil, and other animal fats)

Corresponding commodity standards: CODEX STAN 329-2017 (colours are not permitted), 19-1981, 211-1999 (permits use of specific color additives to restore color)

GSFA: Parent FC is in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR:

AUSTRALIA: The Alignment EWG aligned the food additives for CXS 19-1981, CXS 211-1999 and CXS 329-2017 as part of CX/FA 20/52/6. The comments below relate to the alignment work.

CANADA: See comment for FC 02.1.2. Input from CCFO may be worthwhile; otherwise, with full correspondence between the food categories and colouring provisions set out in CXS 19 and 211 may be appropriate.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	25	XS211, XS239	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						
EWG comments on Proposal:						
Australia, EU, JAPAN, RU, USA, IACM, NATCOL: Supports holding pending carotenoid discussion						
BEET RED	162	GMP		7	Colour	Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS						
EWG comments on 2nd Circular:						
Australia, EU, RU: Supports proposal						

1st Circular Proposal: Adopt with Notes XS19, XS211, XS329

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding notes XS19, XS211 and XS329 and maintaining at step 7 at GMP. Australia can support adopting as proposed.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general

IACM: Supports 1st CL proposal

CARAMEL II - SULFITE CARAMEL	150b	20000		4	Colour	Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

Australia, EU, RU: Supports proposal

1st Circular Proposal: Adopt with Notes XS19, XS211, XS329

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding notes XS19, XS211 and XS329 and maintaining at step 4 at the ML of 20000 mg/kg. Australia can support adopting as proposed.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 20000 mg/kg

Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

CHLOROPHYLLS	140	GMP		7	Colour	Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

Australia, EU: Supports proposal

1st Circular Proposal: Adopt with Notes XS19, XS211, XS329

EWG Comments on 1st Circular Proposal

Australia: Adopt with Notes XS19, XS211, XS329

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general

CURCUMIN	100(i)	5		7	Colour	<p>Chair's Note: Proposal aligns with CXS</p> <p>Adopt with Notes XS329 and new notes "For use in products conforming to the Standard for Edible Fats and Oils not Covered by Individual Standards (CXS 19-1981) for the purposes of restoring natural colour lost in processing, or standardizing colour only" and "For use in products conforming to the Standard for Named Animal Fats (CXS 211-1999) for the purposes of restoring natural colour lost in processing, or standardizing colour only"</p>
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2nd Circular Proposal: Adopt with Notes XS329 and new note "For use in products conforming to the Standard for Edible Fats and Oils not Covered by Individual Standards (CXS 19-1981) and the Standard for Named Animal Fats (CXS 211-1999) for the purposes of restoring natural colour lost in processing, or standardizing colour only"

Chair's Note: Proposal aligns with CXS

EWG comments on 2nd Circular:

Australia: supports the proposal, noting it is consistent with Alignment proposal.

EU: Accepts

RU: strongly opposite proposal. Vegetable oils and fats is PLAI N products!!!!!! Use of FA in this FC could mislead consumers!!!!

IACM: Supports proposal

1st Circular Proposal: Adopt with Notes XS19, XS211, XS329

EWG comments on 1st Circular:

Australia notes that the Alignment EWG has proposed adopting at the ML of 5 mg/kg due to alignment with an additional new note: "For use in products conforming to the Standard for Edible Fats and Oils not Covered by Individual Standards (CXS 19-1981) and the Standard for Named Animal Fats (CXS 211-

1999) for the purposes of restoring natural colour lost in processing, or standardizing colour only". Australia can also support XS329 but not XS19 and XS211. Australia therefore suggests staying with the Alignment EWG recommendation of the ML of 5 mg/kg, but with the notes A2-CXS19211 and XS329.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general

IACM: supports proposal at adopt at 5 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.

INDIGOTINE (INDIGO CARMINE)	132	300	161	2009	Colour	Revoke. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Revoke. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

Australia, EU: supports the proposal

RU: strongly opposite proposal. Vegetable oils and fats is PLAI N products!!!!!! Use of FA in this FC could mislead consumers!!!!

1st Circular Proposal: Revise Adopted. Remove Note 161

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adopting with adding notes XS19, XS211 and XS329, and the ML of 300 mg/kg. Australia can support removal of note 161. Australia therefore supports adoption but with the addition of notes XS19, XS211 and XS329.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Supports removal of Note 161 with Notes XS19, XS211, XS329 for consistency with commodity standard. Authorized for use at GMP for foods in general

FIA, IACM: Supports 1st CL proposal to remove Note 161

LYCOPENE, BLAKESLEA TRISPORA	160d(iii)	25			Colour	Do not move from FC 2.1. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

<p>Australia, EU, RU: supports the proposal</p> <p>1st Circular Proposal: Adopt with Notes XS19, XS211, XS329</p> <p>EWG comments on 1st Circular: Australia: notes that the Alignment EWG did not address this colour as part of the alignment work. Therefore Australia cannot provide comments related to the proposed ML, but it could support adding the proposed notes XS19, XS211 and XS329 if there was EWG support for adoption. EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all. RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!</p> <p>IACM: Supports 1st CL proposal</p>						
LYCOPENE, SYNTHETIC	160d(i)	25			Colour	Do not move from FC 2.1. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
<p>2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS</p> <p>EWG comments on 2nd Circular: Australia, EU, RU: supports the proposal</p> <p>1st Circular Proposal: Adopt with Notes XS19, XS211, XS329</p> <p>EWG comments on 1st Circular: Australia: notes that the Alignment EWG did not address this colour as part of the alignment work. Therefore Australia cannot provide comments related to the proposed ML, but it could support adding the proposed notes XS19, XS211 and XS329 if there was EWG support for adoption. EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all. RU: strongly opposite proposal. Vegetable oils and fats is PLAIN products!!!!!! Use of FA in this FC could mislead consumers!!!!</p> <p>IACM: Supports 1st CL proposal</p>						
LYCOPENE, TOMATO	160d(ii)	5000		3	Colour	Do not move from FC 2.1. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
<p>2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS</p> <p>EWG comments on 2nd Circular: Australia, EU, RU: supports the proposal</p>						

1st Circular Proposal: Adopt with Notes XS19, XS211, XS329

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adding notes XS19, XS211 and XS329, and maintaining at step 3 at the ML of 50000 mg/kg. Australia can support adopting as proposed.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use at GMP for foods in general

IACM: Supports adoption at 100

SUNSET YELLOW FCF	110	300	161	2008	Colour	Revoke. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Revoke. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

Australia, EU: supports the proposal

RU: Supports discontinuation

1st Circular Proposal: Revise Adopted. Remove Note 161

EWG comments on 1st Circular:

Australia: notes that the Alignment EWG has proposed adopting with adding notes XS19, XS211 and XS329, and the ML of 300 mg/kg. Australia can support removal of note 161.

Australia therefore supports adoption but with the addition of notes XS19, XS211 and XS329.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Supports removal of Note 161 with Notes XS219, XS211, XS329 for consistency with commodity standard. Authorized for use at GMP for foods in general

FIA: Supports 1st CL proposal to remove Note 161

IACM: supports proposal to revise adopted provision to remove Note 161. In its most recent safety evaluation (2011), JECFA concluded that there is no concern for a likely exceedance of the JECFA ADI of 4 mg/kg bw based on realistic lifetime intake of 0.12 mg/kg bw/day in children in Australia/New Zealand at the 90th % from all foods and beverages. More recent estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.8 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.2 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017). JECFA noted that the more realistic FSANZ intake was up to 3% of the ADI and concluded that there is no health concern for sunset yellow intake as a color additive.

TARTRAZINE	102	300		4	Colour	Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS
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2nd Circular Proposal: Discontinue. One to one correlation between commodity standard and Food Category. Colours not permitted in corresponding CXS

EWG comments on 2nd Circular:

Australia, EU, RU: supports the proposal

1st Circular Proposal: Adopt with Notes XS19, XS211, XS329

EWG comments on 1st Circular:

Australia notes that the Alignment EWG has proposed adding notes XS19, XS211 and XS329, and maintaining at step 4 at the ML of 300 mg/kg. Australia can support adopting as proposed.

EU: does not support adoption. EU wonders what are the non-standardised products for which the mentioned colours are needed. EU notes that only a very limited number of colours are considered justified in CXS 211-1999 and only for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, whilst CXS 19-1981 does not permit colours at all.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Could support adoption with XS notes. Authorized for use in foods in general

IACM: supports proposal to adopt at 300 mg/kg with Notes XS19, XS211 and XS329. No concerns should be raised as the refined average daily intake is below the ADI of 10 mg/kg bw (4-73%), set by JECFA in 2016, even when using the most conservative estimates in EU children and maximum reported use levels

Category No. 02.2.1 (Butter)

Corresponding commodity standards: CODEX STAN 279-1971 (Contains general reference to food additives permitted in Tables 1 and 2 of the GSFA)

GSFA: FC is in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: Standard 279-1971 appears to have been aligned earlier, so the Alignment EWG has not needed to align this standard. Australian regulations have this specific food category, with only limited permissions for colours, which is the basis for Australia's comments.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	25	146, 291, XS279	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
<p>1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)</p>						
<p><u>EWG comments on Proposal</u> Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion</p>						
LYCOPENE, BLAKESLEA TRISPORA	160d(iii)	25		4	Colour	Discontinue
<p>2nd Circular Proposal: Discontinue.</p>						
<p><u>EWG comments on 2nd Circular:</u> Australia, EU, RU, IDF: Supports proposal</p>						
<p>1st Circular Proposal: Adopt</p>						
<p><u>EWG comments on 1st Circular:</u> Australia: does not have permission for this colour in this FC, but if there is technological justification and support then Australia could support its use as alternatives or in addition to other colours. EU: butter is a basic foodstuff, derived exclusively from milk and/or products obtained from milk. The need for food additives for butter is very limited. In the EU only carotenes are permitted to standardize colour of butter (except for butter from sheep and goats milk) as carotenes are naturally present in milk. The EU does not support addition of colours to butter which are not indigenous to milk. RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!! IACM, IDF: Supports 1st CL proposal</p>						
LYCOPENE, SYNTHETIC	160d(i)	25		4	Colour	Discontinue
<p>2nd Circular Proposal: Discontinue.</p>						
<p><u>EWG comments on 2nd Circular:</u> Australia, EU, RU, IDF: Supports proposal</p>						
<p>1st Circular Proposal: Adopt</p>						
<p><u>EWG comments on 1st Circular:</u></p>						

Australia: does not have permission for this colour in this FC, but if there is technological justification and support then Australia could support its use as alternatives or in addition to other colours.

EU: butter is a basic foodstuff, derived exclusively from milk and/or products obtained from milk. The need for food additives for butter is very limited. In the EU only carotenes are permitted to standardize colour of butter (except for butter from sheep and goats milk) as carotenes are naturally present in milk. The EU does not support addition of colours to butter which are not indigenous to milk.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

IACM: Supports 1st CL proposal

LYCOPENE, TOMATO	160d(ii)	25		3	Colour	Discontinue
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2nd Circular Proposal: Discontinue.

EWG comments on 2nd Circular:

Australia, EU, RU, IDF: Supports proposal

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia: does not have permission for this colour in this FC, but if there is technological justification and support then Australia could support its use as alternatives or in addition to other colours.

EU: butter is a basic foodstuff, derived exclusively from milk and/or products obtained from milk. The need for food additives for butter is very limited. In the EU only carotenes are permitted to standardize colour of butter (except for butter from sheep and goats milk) as carotenes are naturally present in milk. The EU does not support addition of colours to butter which are not indigenous to milk.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Supports adoption. Authorized for use at GMP for foods in general

IACM: Supports 1st CL proposal

Category No. 02.2.2 (Fat spreads, dairy fat spreads and blended spreads)

Corresponding commodity standards: CODEX STAN 253-2006 (colours are permitted in accordance with GSFA), 256-2007 (permits use of specific colours)

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: The Alignment EWG considered this FC and these commodity standards in two documents. CX/FA 20/52/6, for cancelled 2020 meeting, to be considered at 2021 meeting: CXS 256-2007. The Alignment EWG is currently (additional circulars for 2021 meeting) considering CXS 253-2006. The work to date is reflected in the 1st circular (September 2020).

Australia as chair of the Alignment EWG therefore provides comments from those documents and the alignment work undertaken.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	100	8	4	Colour	Adopt at 100 mg/kg with note 8 and new note "Except for use in products conforming to the Standard for Dairy Fat Spreads (CXS 253-2006), at 20 mg/kg" proposal aligns with corresponding commodity standards

2nd Circular Proposal: Adopt with note 8 and new note "Except for use in products conforming to the Standard for Dairy Fat Spreads (CXS 253-2006), at 20 mg/kg" proposal aligns with corresponding commodity standards

EWG comments on 2nd Circular:

Australia: supports the proposal, though the Alignment EWG has proposed an additional new note addressing CXS 256 as well, as noted in earlier Australian comments. It may be considered that this note is superfluous. The EWGs for GSFA and Alignment will need to ensure consistency of proposed provisions.

EU: technological justification for non-standardised products and for the higher ML?

Japan: supports the proposal. INS 160b(i) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavour. Maximum use level is 75 mg/kg as bixin in margarine and fat spreads.

RU: Proposed ML is so higher!!!! ADI is only 0-12 mg/kg bw. Use of FA in this FC could mislead consumers

IACM: Supports proposal. (Provided same image as seen in NATCOL comment with range from 1.9 to 74.4 ppm)

IDF: Supports proposal

NATCOL: Since the appearance depends on fat content, based on the pictures below, a Minimum of 20ppm is needed as the shade would be too pale at low fat content.



Picture at 8ppm:

Low fat High fat



Pictures at:
 52.1ppm, 59.5ppm, 67ppm, 74.4ppm
 22.3ppm, 29.8ppm, 37.2ppm, 44.6ppm
 1.9ppm, 3.7ppm, 7.4ppm, 14.9ppm

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia notes that the Alignment document CX/FA 20/52/6 recommended adoption at the same ML and note 8, but with an additional note “For use in products conforming to the Standard for Spreads and Blended Spreads (CXS 256-2007)” due to alignment with CXS 256. The 2020 Alignment document also recommended an additional note “Except for use in products conforming to the Standard for Dairy Fat Spreads (CXS 253-2006), at 20 mg/kg” (kept at step 4). Australia can support adoption as proposed with additional new notes.

EU: takes note that ANNATTO EXTRACTS, BIXIN BASED is permitted at 20ppm in CXS 253-2006 and at 100ppm in 256-2007. If no non-standardised products are identified the provision should be alignment with the respective standards. As for the ML, the EU has recently revised the provisions for annatto extracts and for the corresponding food category the ML of 10ppm (as bixin) was considered sufficient by the industry.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 100 mg/kg. Based on JECFA’s refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	35	XS253, XS256	2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion						
CARAMEL II - SULFITE CARAMEL	150b	20000		4	Colour	Adopt at 500 mg/kg with XS253 Chair's Note: proposal aligns with corresponding commodity standards
2nd Circular Proposal: Adopt at 500 with XS253 Chair's note: proposal aligns with corresponding commodity standards						
<u>EWG comments on 2nd Circular:</u> Australia: supports the proposal, as it seems to align with both CXS 253 and CXS 256. A different approach to what Alignment had proposed but seems appropriate as it is assumed the additional proposed note is viewed as superfluous. EU: Accepts RU: Use of FA in this FC could mislead consumers. Not used in this Fc in RU/ So on there need Note 161 IACM, IDF: Supports proposal 1st Circular Proposal: Adopt <u>EWG comments on 1st Circular:</u> Australia: notes that the Alignment document CX/FA 20/52/6 recommended adoption at a different ML of 500 mg/kg with the additional note "For use in products conforming to the Standard for Spreads and Blended Spreads (CXS 256-2007)" due to alignment with CXS 256. The 2020 Alignment document recommended keeping the proposed ML of 20000 mg/kg with the additional note XS253 (kept at step 4) in aligning with CXS 253. To combine the 2 alignment recommendations Australia suggests using the ML of 500 mg/kg, with the additional notes of the new note and XS253 EU: questions the technological need as this colour is not mentioned in CXS 253-2006 or 256-2007. Technological justification, including the information in what non-standardised products the use is requested, shall be provided. RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!! USA: Supports adoption at 20000. Authorized for use at GMP for foods in general IACM: supports proposal to adopt at 20000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.						
CARMINES	120	500	161, 178	2008	Colour	Revise adopted. Remove Note 161, add note XS253 Chair's Note: proposal aligns with corresponding commodity standards
2nd Circular Proposal: Revise adopted. Remove Note 161, add note XS253 Chair's Note: proposal aligns with corresponding commodity standards						

EWG comments on 2nd Circular:

Australia: supports the proposal, consistent with Alignment

EU, IACM, IDF: Supports proposal

RU: Use of FA in this FC could mislead consumers. Not used in this Fc in RU/ So on there need Note 161

1st Circular Proposal: Revise adopted. Remove Note 161

EWG comments on 1st Circular:

Australia notes that the 2020 Alignment document recommended keeping the proposed ML of 500 mg/kg with the current notes 161 and 178 as well as the additional note XS253 in aligning with CXS 253. Australia is supportive of removal of note 161. The Alignment document CX/FA 20/52/6 did not address carmines since the provision is already aligned, i.e. ML of 500 mg/kg. Australia therefore suggests adopting as provided but with the addition of note XS253.

EU: questions the technological need as this colour is not mentioned in CXS 253-2006 or 256-2007. Technological justification, including the information in what non-standardised products the use is requested, shall be provided.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Supports removal of Note 161 with Note XS256 for consistency with commodity standard. Authorized for use at GMP in foods in general

FIA, IACM: Supports proposal to remove Note 161

CURCUMIN	100(i)	10		7	Colour	Adopt with new notes “For use in products conforming to the Standard for Dairy Fat Spreads (CXS 253-2006), at 5 mg/kg” and “Except for use in mustard flavoured products at 30 mg/kg” Chair’s Note: proposal aligns with corresponding commodity standards
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2nd Circular Proposal: Adopt with new note “For use in products conforming to the Standard for Dairy Fat Spreads (CXS 253-2006), at 5 mg/kg”

Chair’s Note: proposal aligns with corresponding commodity standards

EWG comments on 2nd Circular:

Australia: supports the proposal, consistent with Alignment, though with a different approach, but consistent intent. The EWGs for GSFA and Alignment will need to ensure consistency of proposed provisions.

EU, IACM, IDF: Supports proposal

Japan: proposes adoption with new note “For use in mustard flavoured products, at 30 mg/kg.” INS 100(i) is used at 30 mg/kg in mustard flavoured fat spreads to associate the colour with the flavour

RU: Use of FA in this FC could mislead consumers. Not used in this Fc in RU/ So on there need Note 161

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia: notes that the Alignment document CX/FA 20/52/6 recommended adoption at the same ML, but with an additional note “For use in products conforming to the Standard for Spreads and Blended Spreads (CXS 256-2007)” due to alignment with CXS 256. The 2020 Alignment document also recommended an additional note “For use in products conforming to the Standard for Dairy Fat Spreads (CXS 253-2006), at 5 mg/kg” but with a different ML of 5 mg/kg due to alignment with CXS 253. Australia notes that this complicates the alignment, but suggests it requires a decision of which ML to use and then add the different one to the alternative note (i.e. stay with the ML of 10 mg/kg and add the ML of 5 mg/kg to the D253 note (highlighted below)).

EU: takes note that curcumin is permitted in CXS 253-2006 at 5 ppm and in 256-2007 at 10 ppm. If no non-standardised products are identified, the provision should be alignment with the respective standards.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Supports adoption at 10. Authorized for use at GMP for foods in general

IACM: Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.

NATCOL: Supports adoption at 10

LYCOPENE, TOMATO	160d(ii)	10000		3	Colour	Discontinue
Use is already permitted in this FC under provision adopted in Table 3						

1st and 2nd Circular Proposal: Discontinue. Use is already permitted in this FC under provision adopted in Table 3

EWG comments on Proposal:

Australia: Australia supports the proposal to discontinue but with following comments. The Alignment of CXS 253 (2nd circular, Appendix 3) proposed a new table for FC 02.2.2 linked to CXS 253 but it did not propose general provisions for colours or adding CX 253 to the entry in Table 3 since there is no provision for this colour.

However, this is not the case for the earlier alignment of CXS 256 in CX/FA 20/52/6 rev. 1, where there is provision for colours in Table 3, so provision does seem to apply in Table 3. But it is confusing. Maybe a new note is required, or would be useful, to be added to the RHS column of the entry in Table 3 to clarify differences (noting it may not be considered necessary).

EU, RU, USA, IACM, IDF, NATCOL: Supports discontinuation. Use is already permitted in this FC under provision adopted in Table 3

PAPRIKA EXTRACT	160c(ii)	40	39	2	Colour	Revise to 50 mg/kg. Refer to CCFO for guidance on the use and use level of paprika extract in products conforming to CXS 253 and 256.
Request information on whether use is limited to fat spreads or is also used in dairy fat spreads						

2nd Circular Proposal: Refer to CCFO for guidance on the use and use level of paprika extract in products conforming to CXS 253 and 256. Request information on whether use is limited to fat spreads or is also used in dairy fat spreads

EWG comments on 2nd Circular:

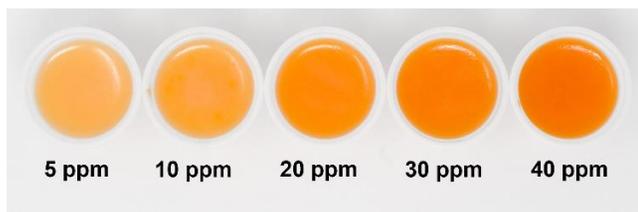
Australia, EU: Supports proposal

Japan: proposes the ML be replaced with 50 mg/kg. INS 160c(ii) is used in fat spreads broadly across this food category to make foods visually appealing and appetizing. Maximum use level is 50 mg/kg. The use is limited to fat spreads.

RU: Use of FA in this FC could mislead consumers. Not used in this Fc in RU/ So on there need Note 161

IACM: confirms need for use levels up to 40 mg/kg to restore a dairy appearance for fats and oils with less color. IACM also supports request to refer to CCFO for guidance on the use and use level of paprika extract in products confirming to CXS 253 and 256.

Paprika Extract at levels ranging from 5 - 40 ppm



NATCOL: Supports. Paprika was only included in the GSFA in 2015 and so has not been considered by the CCFO, but is oil soluble so suitable for use in these products.

Picture at 40ppm:



1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia: notes that the Alignment document CX/FA 20/52/6 recommended the same ML and keeping note 39, but with an additional note 215 due to alignment with CXS 256, but maintained at step 3. Note 215 is the same as XS256, which is the preferred note from earlier alignment/GSFA EWG discussions, where a policy was taken to use the exclusion notes, so Australia suggests XS256 should be used in preference to note 215. The 2020 Alignment document also recommended an additional note, being XS253 due to alignment with CXS 253 with the same ML and note 39, again to be maintained at step 3. In summary Australia could support adopting at the proposed ML of 40 mg/kg, with note 39 if there was EWG support but with the addition of the 2 exclusion notes XS253 and XS256.

EU: questions the technological need as this colour is not mentioned in CXS 253-2006 or 256-2007. Technological justification, including the information in what non-standardised products the use is requested, shall be provided.

JAPAN: Japan proposes the ML be replaced with 50 mg/kg. INS 160c(ii) is used in fat spreads broadly across this food category to make foods visually appealing and appetizing. Maximum use level is 50 mg/kg.

RU: strongly opposite proposal. Vegetable oils and fats is PLAI products!!!!!! Use of FA in this FC could mislead consumers!!!!

USA: Supports adoption. Authorized for use at GMP

IACM: supports proposal to adopt. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

NATCOL: Supports adoption at 40

ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

Category No. 02.3 (Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: There are no commodity standards so no alignment work related to this FC. There appears to be a comparable food category in Australian regulations so Australian comments relate to these permissions.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	10	8	4	Colour	Adopt

2nd Circular Proposal: Request information on actual use and use level

EWG comments on 2nd Circular:

Australia, EU: Supports proposal

RU: Used in RU in ML =10 mg/kg

IACM: IACM supports first circular proposal at adopt at 10 mg/kg

NATCOL: For this application encapsulated annatto (bixin) can be used. Example picture at 25ppm:



1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia: notes that in the Australian regulations there is no permission for this colour in a comparable food category to this FC.

EU: requests a clarification on types of products for which the use of this colour is requested.

RU: Supports 1st CL proposal

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 10 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

NATCOL: Supports adoption at 10

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	10	185	4	Colour	Adopt
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2nd Circular Proposal: Request information on actual use and use level

EWG comments on 2nd Circular:

Australia, EU: Supports proposal

RU: Used in RU in ML =10 mg/kg

NATCOL: Norbixn is suitable for this application.

1st Circular Proposal: Adopt

EWG comments on 1st Circular:

Australia notes that in the Australian regulations there is no permission for this colour in a comparable food category to this FC.

EU: requests a clarification on types of products for which the use of this colour is requested. The use of ANNATTO EXTRACTS, NORBIXIN-BASED has to be carefully considered due to its low ADI.

RU: Supports 1st CL proposal

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 10 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI

NATCOL: Supports adoption at 10

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	200		2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1).

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, NATCOL: Supports holding pending carotenoid discussion

CARAMEL II - SULFITE CARAMEL	150b	20000		4	Colour	Chair's Note: INS 150c is adopted in this FC at 20000 Adopt
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2nd Circular Proposal: Adopt

Chair's Note: INS 150c is adopted in this FC at 20000

EWG comments on 2nd Circular:

Australia, IACM: Supports proposal

EU: requests a clarification on types of products for which the use of this colour is requested.

RU: consider discontinuation

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia notes that the Australian regulations has permission for this colour at GMP in a comparable food category to this FC. Australia can therefore support adoption.

EU: requests a clarification on types of products for which the use of this colour is requested.

RU: consider discontinuation. All proposals for the use of the colour CAMEL II- SULFITE CAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 20000. Authorized for use at GMP for foods in general

IACM: supports proposal to adopt at 20000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

CARMINES	120	500	161, 178	2008	Colour	Revise adopted. Adopt at 150. Remove Note 161, Retain note 178
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2nd Circular Proposal: Request information on actual use and use level

EWG comments on 2nd Circular:

Australia, EU: Supports proposal

RU: 0-5 mg/kg bw

IACM: supports first circular proposal to revise adopted provision.

NATCOL: Picture at 150ppm:



1st Circular Proposal: Revise adopted. Remove Note 161

EWG comments on 1st Circular:

Australia notes that the Australian regulations has permission for this colour at GMP in a comparable food category to this FC. Australia supports removal of note 161. Australia can therefore support adoption

EU: requests a clarification on types of products for which the use of this colour is requested.

RU: does not agree with proposal. There not safety and technological justification

USA: Supports removal of Note 161. Authorized for use at GMP for foods in general

FIA, IACM: Supports proposal to remove Note 161

CURCUMIN	100(i)	500		7	Colour	Adopt at 100
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2nd Circular Proposal: Request information on actual use and use level

EWG comments on 2nd Circular:**Australia, EU:** Supports proposal**JAPAN:** INS 100(i) is used in used in foods broadly across this food category to associate the colour with the flavour. Maximum use level is 100 mg/kg in fat emulsion products for sponge cake to improve and stabilize foam.**IACM:** supports first circular proposal to adopt at 500 mg/kg**1st Circular Proposal:** Adopt.**EWG comments on 1st Circular:****Australia** notes that the Australian regulations has permission for this colour at GMP in a comparable food category to this FC. Australia can therefore support adoption.**EU:** requests a clarification on types of products for which the use of this colour is requested. The use has to be carefully considered. The exposure in the EU to this colour is at the ADI.**RU:** agrees with 1st CL proposal excluding reduced fat butter**USA:** Supports adoption at 500. Authorized for use at GMP for foods in general**IACM:** supports proposal to adopt at 500 mg/kg .The range of use levels may vary depending on the desired effect to meet consumer preferences. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003**NATCOL:** Supports adoption at 500

INDIGOTINE (INDIGO CARMINE)	132	300	161	2009	Colour	Further discussion on actual use and use level
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2nd Circular Proposal: Request information on actual use and use level**EWG comments on 2nd Circular:****Australia, EU:** Supports proposal**KR:** Not permitted to use in this category**IACM:** supports first circular proposal to revise adopted provision to remove Note 161**1st Circular Proposal:** Revise adopted. Remove Note 161**EWG comments on 1st Circular:****Australia** notes that the Australian regulations has permission for this colour at a maximum ML of 290 mg/kg (total sum of other specific colours as well) in a comparable food category to this FC. Australia supports removal of note 161. Australia can therefore support adoption.

EU: requests a clarification on types of products for which the use of this colour is requested.

RU: does not agree with proposal. There not safety and technological justification

USA: Supports removal of Note 161. Authorized for use at GMP for foods in general

FIA, IACM: Supports proposal to remove Note 161

LYCOPENE, TOMATO	160d(ii)	5000		3	Colour	Discontinue
Use is already permitted in this FC under provision adopted in Table 3						

1st and 2nd Circular Proposal: Discontinue. Use is already permitted in this FC under provision adopted in Table 3

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, NATCOL: Supports discontinuation. Use is already permitted in this FC under provision adopted in Table 3

PAPRIKA EXTRACT	160c(ii)	35	39	2	Colour	Adopt at 65 with Note 39
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2nd Circular Proposal: Adopt at 65 with Note 39. Request information on use in this FC.

EWG comments on 2nd Circular:

Australia, IACM: Supports proposal

EU: supports requesting further information

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia notes that the Australian regulations has permission for paprika oleoresins, not paprika extract, at GMP in a comparable food category to this FC. Therefore this may not be directly relevant. Australia would defer to others for any comments relating to technological justification.

EU: requests a clarification on types of products for which the use of this colour is requested.

GUATEMALA: >65 mg/kg

RU: does not agree with proposal. There not safety and technological justification

USA: Supports adoption. Authorized for use in foods at GMP

IACM: supports proposal to adopt at 35 mg/kg. Paprika extract provides a reddish orange or caramel tone depending on base and is typically used in fat-based products.

In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

ZEAXANTHIN, SYNTHETIC	161h(i)	100		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.						
EWG comments on Proposal: Australia, EU, RU, USA, IACM, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.						

Category No. 02.4 (Fat-based desserts excluding dairy-based dessert products of food category 01.7)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: There are no commodity standards so no alignment work related to this FC. There does not appear to be a comparable food category in Australian regulations so Australia has provided limited comments.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Proposal
ALLURA RED AC	129	300	161	2009	Colour	Revise Adopted to 150 mg/kg and remove Note 161
2nd Circular Proposal: Revise Adopted without Note 161 and Adopt at 150						
EWG comments on 2nd Circular: Australia: Supports proposal, noting comments EU: ML at 150ppm shall be sufficient RU: agrees with proposal only with ML=150 mg/kg IACM: Supports proposal						
1st Circular Proposal: Revise Adopted without Note 161						
EWG comments on 1st Circular: AUSTRALIA: Supports removal of Note 161 EU: lower ML than 300 should be sufficient. In the EU, the industry did not report the use in desserts However, analytical results provided by EUMS showed some limited presence of INS 129 in desserts up to 66 ppm. The ML shall not be higher than 150 ppm.						

RU: agrees with proposal only with ML=150 mg/kg

USA: Supports removal of Note 161. Authorized for use at GMP in foods in general

FIA: Supports 1st CL proposal to remove Note 161

IACM: IACM supports proposal to revise provision to remove Note 161. In JECFA's most recent safety evaluation, the highest intake of allura red from all foods was 2.9 mg/kg bw/day at the 95th % for children 3–9 years in Europe under the most conservative brand-loyal scenario; however more realistically the intake is up to 1.2 mg/kg bw/day at the 95th % in the non-brand loyal scenario, assuming that 100% products contain this color. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 2.2 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.22 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017). JECFA noted that the range of estimated dietary exposures to allura red from all foods and beverages were well below the ADI (0.4–41% of the ADI) including intake for children and including the conservative estimate by EFSA

AMARANTH	123	300		7	Colour	Discontinue
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2nd Circular Proposal: Discontinue

EWG comments on 2nd Circular:

Australia, EU, RU: Supports proposal

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: amaranth has a very low ADI. Other colours with higher ADIs or ADI not specified should be used instead.

RU: does not agree with proposal. Do not use in RU because higher toxicity

ANNATTO EXTRACTS, BIXIN BASED	160b(i)	30	8	4	Colour	Adopt at 15 with Note 8
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2nd Circular Proposal: Adopt at 15 with Note 8

EWG comments on 2nd Circular:

Australia: Supports proposal noting comments

EU, IACM: Supports proposal

RU: agrees with proposal only with ML=10 mg/kg

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: in the EU the uses of annatto extracts have been recently reviewed. The industry requested MPL of 15 ppm for bixin based annatto extracts in this FC.

RU: does not agree with proposal. There not safety justification

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 30 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

NATCOL: Supports adoption at 30 mg/ kg

ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	10	185	4	Colour	Adopt
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1st and 2nd Circular Proposal: Adopt.

EWG comments on Proposal:

Australia: Supports proposal noting comments

EU: Accepts. in the EU the uses of annatto extracts have been recently reviewed. The industry requested MPL of 7.5 ppm for norbixin based annatto extracts in this FC. The exposure to norbixin based annatto extracts is at the ADI in the EU, therefore, the ML has to be carefully considered.

JAPAN: Japan supports the proposal. INS 160b(ii) is used in foods broadly across this food category to make the food visually appealing and appetizing and to associate the colour with the flavour. Maximum use level is 0.6 mg/kg as annatto extracts

RU: agrees with proposal only with ML=10 mg/kg

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt at 10 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI

NATCOL: Supports adoption at 10 mg/kg

AZORUBINE (CARMOSINE)	122	150		7	Colour	Adopt
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1st and 2nd Circular Proposal: Adopt.

EWG comments on 2nd Circular:

Australia, EU, RU: Supports proposal

EWG comments on 1st Circular:

EU: accepts. The mean analytical value 15 ppm, the maximum 136 ppm (EFSA, 2015).

RU: Supports 1st CL proposal

IACM: supports proposal to adopt at 150 mg/kg. The JECFA ADI for azorubine is 4 mg/kg bw/day (1983).						
β -CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	150		2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)						
EWG comments on 1st Circular: Australia, EU, RU, USA, IACM, NATCOL: Supports holding pending carotenoid discussion						
BRILLIANT BLACK (BLACK PN)	151	150		7	Colour	Adopt
1st and 2nd Circular Proposal: Adopt.						
EWG comments on Proposal: Australia: Supports proposal noting comments						
EU: Accepts. for desserts the industry provided 80 ppm as a typical use level and 110 ppm as a maximum level (EFSA, 2015).						
RU: Supports 1 st CL proposal						
IACM: supports proposal to adopt at 150 mg/kg. JECFA ADI of 1 mg/kg bw/day in 2019. Considering that only a fraction of products in this category contain this particular color, no concern is raised of potential average daily intake exceedance of the JECFA ADI. JECFA's summary report (2019) notes that the dietary intake of brilliant black from all reported sources does not present a safety concern						
BROWN HT	155	150		7	Colour	Discontinue. No information specific to this FC provided.
2nd Circular Proposal: Request further information on use and use level						
EWG comments on 2nd Circular: Australia, EU: Supports proposal						
1st Circular Proposal: Adopt.						
EWG comments on 1st Circular: EU: no use was reported by the industry for this FC (EFSA, 2014). If needed, other colours with higher ADIs or ADI not specified should be used instead.						
RU: Supports 1 st CL proposal						
IACM: supports proposal to adopt at 150 mg/kg. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 1.5 mg/kg bw set in 1984.						
CAMEL II - SULFITE CAMEL	150b	20000		4	Colour	Chair's Note: INS 150c and 150d are adopted in this FC at 20000 Adopt
2nd Circular Proposal: Adopt Chair's Note: INS 150c and 150d are adopted in this FC at 20000						

EWG comments on 2nd Circular:**Australia, IACM:** Supports proposal**RU:** Does not agree with proposal/ ML is so high!**1st Circular Proposal:** Adopt.**EWG comments on 1st Circular:****EU:** for desserts the industry provided 1000 ppm as a typical use level (EFSA, 2011). The ML of 50000 is excessive.**RU:** consider discontinuation. All proposals for the use of the colour CAMEL II- SULFITE CAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It is several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.**USA:** Supports adoption at 20000. Authorized for use at GMP for foods in general**IACM:** supports proposal to adopt at 20000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

CURCUMIN	100(i)	150		7	Colour	Adopt
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1st and 2nd Circular Proposal: Adopt.**EWG comments on Proposal:****Australia:** Supports proposal noting comments**EU:** can support. The industry reported 7-20 ppm as the typical use level and 147 ppm as the maximum use level. The use level is important as the exposure to curcumin is at the ADI in the EU (EFSA, 2014).**RU:** Supports 1st CL proposal**USA:** Supports adoption at 150. Authorized for use at GMP for foods in general**IACM:** supports proposal to adopt at 150 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.**NATCOL:** Supports adoption at 150 mg/kg

LUTEIN FROM TAGETES ERECTA	161b(i)	150		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.**EWG comments on Proposal:****Australia, EU, RU, USA, IACM, NATCOL:** Supports holding pending discussion of inclusion in Table 3

PAPRIKA EXTRACT	160c(ii)	50	39	2	Colour	Adopt
1st and 2nd Circular Proposal: Adopt.						
<u>EWG comments on Proposal:</u>						
Australia: Supports proposal noting comments						
EU: Accepts. in the EU the industry reported 11 ppm as the typical use level and 50 ppm as the ML (EFSA 2015)						
RU: Supports 1 st CL proposal						
USA: Supports adoption. Authorized for use in foods in general at GMP.						
IACM: supports proposal to adopt at 50 mg/kg. Paprika extract provides a reddish orange or caramel tone depending on base and is typically used in fat-based products. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern						
NATCOL: Supports adoption at 50 mg/kg						
QUINOLINE YELLOW	104	150		7	Colour	Adopt at 9 mg/kg
2nd Circular Proposal: Adopt at 9 mg/kg						
<u>EWG comments on 2nd Circular:</u>						
Australia, EU, RU, IACM: Supports proposal						
1st Circular Proposal: Adopt.						
<u>EWG comments on 1st Circular:</u>						
EU: the use level is excessive. The analytical results show 4 ppm as the mean level and 9 ppm as the maximum.						
RU: does not agree with proposal. There not safety justification						
IACM: supports proposal to adopt. The proposed maximum level should not raise any concerns as the refined average daily intake is below the ADI (0.3 – 10%) of 3 mg/kg bw, which was reaffirmed by JECFA in 2016. In JECFA's most recent safety evaluation, the most conservative intake of quinoline yellow from all foods and beverages was 4 mg/kg bw/day at the 95th % for children in Europe using maximum reported use levels; however JECFA recognized that the FSANZ estimate of 0.01 mg/kg bw per day, for children at the 95th %, is a more realistic dietary exposure, assuming that 100% products contain this color. JECFA noted that the more realistic FSANZ intake was well below the ADI and concluded that there is no health concern for quinoline yellow intake as a color additive.						
TARTRAZINE	102	300		7	Colour	Adopt at 150 mg/kg
2nd Circular Proposal: Wide range of use levels reported by EWG members (30 – 300 mg/kg). Request further information on use level and types of product that require higher use level.						
<u>EWG comments on 2nd Circular:</u>						
Australia: Supports proposal						

EU: the industry reported the maximum level of 30 ppm for this FC (EFSA, 2009) for products falling within this FC.

KR: The maximum level of 150 mg/kg for this category

IACM: IACM suggests a use level of at least 150 mg/kg

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

EU: the industry reported the maximum level of 30 ppm for this FC (EFSA, 2009).

RU: agrees with proposal only with ML=150 mg/kg

USA: Supports adoption. Authorized for use in foods in general at GMP

IACM: supports proposal to adopt at 300 mg/kg. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017).

ZEAXANTHIN, SYNTHETIC	161h(i)	150		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

Category No. 03.0 (Edible ices, including sherbet and sorbet)

Corresponding commodity standards: None

GSFA: FC is not in the Annex to Table 3. Colours have previously been adopted in this FC

GENERAL COMMENT on 1st CIRCULAR

Australia: There are no commodity standards so no alignment work related to this FC. There appear to be a comparable food category in Australian regulations so Australian comments relate to these permissions.

Additive	INS	Max Level (mg/kg)	Notes	Step / Adopted	INS Functional Class	Final EWG Report
AMARANTH	123	300		7	Colour	Discontinue
<p>2nd Circular Proposal: Request information on actual use and use level</p> <p>EWG comments on 2nd Circular: Australia: Supports proposal seeking use and use level EU: supports requesting further information. KR: Not permitted to use in this category RU: does not agree with proposal. This FA does not use in RU because higher toxicity</p> <p>1st Circular Proposal: Adopt.</p> <p>EWG comments on 1st Circular: Australia: notes that the Australian regulations permission for this colour at 290 mg/kg in a comparable food category to this FC. Australia can therefore support adoption. EU: amaranth has a very low ADI. Other colours with higher ADIs or ADI not specified should be used instead. RU: does not agree with proposal. Do not use in RU because higher toxicity</p>						
ANNATTO EXTRACTS, BIXIN BASED	160b(i)	20	8	4	Colour	Adopt
<p>1st and 2nd Circular Proposal: Adopt.</p> <p>EWG comments on Proposal: Australia notes that the Australian regulations has permission for this colour (listed as annatto, 160b) at 25 mg/kg in a comparable food category to this FC. Australia can therefore support adoption noting comments. EU: could support the adoption if the information on the technological need is provided. in the EU the uses of annatto extracts have been recently reviewed. The industry did not request the use of ANNATTO EXTRACTS, BIXIN BASED. Technological justification shall be requested. RU: Agrees with proposal ML=20 mg/kg USA: Supports adoption. Authorized for use at GMP in foods in general</p>						

IACM: supports proposal to adopt at 20 mg/kg. Based on JECFA's refined intake assessment conducted in 2006 and an ADI of 12 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 0.2% of the ADI.

NATCOL: Support adoption at 20. Annatto Bixin is technically suitable for this application.

Picture at 16ppm in dairy based ice cream:



Picture at 10.5ppm in water ice:



ANNATTO EXTRACTS, NORBIXIN-BASED	160b(ii)	200	185	4	Colour	Adopt at 20 mg/kg with Note 185
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2nd Circular Proposal: Adopt at 20 with Note 185

EWG comments on 2nd Circular:

Australia, EU: Supports proposal

Japan: supports the proposal. INS 160b(ii) is used in specific products to make food visually appealing and appetizing and to associate the colour with the flavor. Maximum use level is 2 mg/kg in non-dairy frozen desserts.

RU: Agrees with proposal ML=20 mg/kg with Note 185

IACM: Supports proposal

NATCOL: Supports proposal. Picture at 16.5ppm in dairy based ice cream:



Picture at 7.5ppm in water ice:



1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia: notes that the Australian regulations has permission for this colour (listed as annatto, 160b) at 25 mg/kg in a comparable food category to this FC. Australia would defer to others for any comments relating to technological justification.

EU: the ML is excessive. In the EU the uses of annatto extracts have been recently reviewed. The industry requested ML of 20 ppm for norbixin based annatto extracts in this FC. The exposure to norbixin based annatto extracts is at the ADI in the EU, therefore, the ML has to be carefully considered.

JAPAN: Japan supports the proposal. INS 160b(ii) is used in specific products to make food visually appealing and appetizing and to associate the colour with the flavor. Maximum use level is 2 mg/kg in non-dairy frozen desserts.

RU: Supports 1st CL proposal

USA: Supports adoption. Authorized for use at GMP in foods in general

IACM: supports proposal to adopt. Based on JECFA’s refined intake assessment conducted in 2006 and an ADI of 0.6 mg/kg bw, there should be no safety concerns since the estimated average daily intake from all foods and beverages is only up to 4% of the ADI

NATCOL: NATCOL considers that the typical use is 20 mg/kg but also recognizes that exceptions are possible.

AZORUBINE (CARMOSINE)	122	150		7	Colour	Adopt at 50 mg/kg
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2nd Circular Proposal: Adopt at 50

EWG comments on 2nd Circular:

Australia, EU, RU, IACM: Supports proposal

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia: notes that the Australian regulations has permission for this colour at a maximum ML of 290 mg/kg (total sum of other specific colours as well) in a comparable food category to this FC. Australia can therefore support adoption.

EU: the mean analytical value 7 ppm, the maximum 50 ppm (EFSA, 2015).

IACM: supports proposal to adopt. The JECFA ADI for azorubine is 4 mg/kg bw/day (1983).

β-CAROTENE-RICH EXTRACT FROM DUNALIELLA SALINA	160(a)(iv)	200		2	Colour	Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)
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1st and 2nd Circular Proposal: Hold pending discussion of Carotenoids under Agenda Item 3(a) (see CX/FA 20/52/3 Rev.1)

EWG comments on Proposal:

Australia, EU, JAPAN, RU, USA, IACM, IDF, NATCOL: Supports holding pending carotenoid discussion

BRILLIANT BLACK (BLACK PN)	151	150		7	Colour	Adopt at 100 mg/kg
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2nd Circular Proposal: Adopt at 100

EWG comments on 2nd Circular:

Australia, EU, RU, IACM: Supports proposal

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia: notes that the Australian regulations has permission for this colour at a maximum ML of 290 mg/kg (total sum of other specific colours as well) in a comparable food category to this FC. Australia can therefore support adoption.

EU: for desserts the industry provided 10 ppm as a typical use level and 100 ppm as a maximum level (EFSA, 2015).

RU: Supports 1st CL proposal

IACM: supports proposal to adopt at 150 mg/kg. JECFA ADI of 1 mg/kg bw/day in 2019. Considering that only a fraction of products in this category contain this particular color, no concern is raised of potential average daily intake exceedance of the JECFA ADI. JECFA's summary report (2019) notes that the dietary intake of brilliant black from all reported sources does not present a safety concern.

BROWN HT	155	150		7	Colour	Discontinue. No information provided on use in this food category.
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2nd Circular Proposal: Request information on actual use and use level

EWG comments on 2nd Circular:

Australia, EU, IACM: Supports proposal

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia: notes that the Australian regulations has permission for this colour at a maximum ML of 290 mg/kg (total sum of other specific colours as well) in a comparable food category to this FC. Australia can therefore support adoption.

EU: no use was reported by the industry for this FC (EFSA, 2014). If needed, other colours with higher ADIs or ADI not specified should be used instead.

RU: Supports 1st CL proposal

IACM: supports proposal to adopt. Considering the small daily consumption of products in this food category and that only a fraction of products contain this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 1.5 mg/kg bw set in 1984.

CARAMEL II - SULFITE CARAMEL	150b	30000		4	Colour	Chair's Note: INS 150c and 150d adopted in this FC at 1000 Adopt at 8000 mg/kg
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2nd Circular Proposal: Adopt at 7620

Chair's Note: INS 150c and 150d adopted in this FC at 1000

EWG comments on 2nd Circular:

Australia: Supports proposal noting EU comments

EU: the ML could be rounded to 8000ppm

RU: Opposite proposal. All proposals for the use of the colour CARAMEL II- SULFITE CARAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

IACM: Supports proposal

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia: notes that the Australian regulations has permission for this colour at GMP in a comparable food category to this FC. Australia can therefore support adoption.

EU: the industry reported 2840-4000 ppm as a range of a typical use level and 7620 as the maximum level. The ML at 30000 is excessive.

RU: consider discontinuation. All proposals for the use of the colour CARAMEL II- SULFITE CARAMEL INS 150b should be reviewed from the position of safety and technological justification. The proposed safe levels (MLs) are not safe at all. It are several times higher than the established level of ADI 0-160 mg / kg bw. We believe that there need to take into account the fact that it is still a food additive, not a nutrient.

USA: Supports adoption at 30000. Authorized for use at GMP for foods in general

IACM: supports adoption at 30000 mg/kg. Caramel II is used at GMP or QS in several jurisdictions. As noted in JECFA's most recent intake assessment in 2000 for caramel II, this color represents <1% of total caramel color production and is produced on small scale. Use of Caramel II is limited among products of this category. The overall average daily intake from this category is a small fraction of the JECFA ADI of 160 mg/kg bw/day.

CURCUMIN	100(i)	150		7	Colour	Adopt at 100 mg/kg
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2nd Circular Proposal: Adopt at 100

EWG comments on 2nd Circular:

Australia, EU: Supports proposal

IACM: Supports 1st circular proposal to adopt at 150 mg/kg.



NATCOL: Supports.

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia: notes that the Australian regulations has permission for this colour at GMP in a comparable food category to this FC. Australia can therefore support adoption.

EU: can support. The industry reported 3-100 ppm as the typical use level and 150 ppm as the maximum use level. The use level is important as the exposure to curcumin is at the ADI in the EU (EFSA, 2014).

RU: Supports 1st CL proposal

USA: Supports adoption at 150. Authorized for use at GMP for foods in general

IACM: supports adoption at 150 mg/kg. Considering that only a fraction of products contains this particular color no concern is raised of potential average daily intake exceedance of the JECFA ADI of 3 mg/kg bw set in 2003.

NATCOL: Supports adoption at 150

LUTEIN FROM TAGETES ERECTA	161b(i)	150		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on 1st Circular:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

PAPRIKA EXTRACT	160c(ii)	55	39	2	Colour	Adopt
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1st and 2nd Circular Proposal: Adopt.

EWG comments on Proposal:

Australia: Supports proposal noting comments. Notes that the Australian regulations has permission for paprika oleoresins, not paprika extract, at GMP in a comparable food category to this FC. Therefore this maybe not be directly relevant. Australia would defer to others for any comments relating to technological justification.

EU: Accepts. in the EU the industry reported 12 ppm as the typical use level and 50 ppm as the ML (EFSA 2015).

JAPAN: INS 160c(ii) is used in products broadly across this food category to make food visually appealing and appetizing and to associate the colour with the flavor.

Maximum use level is 7 mg/kg on a total carotenoid in orange-flavoured non-dairy frozen desserts.

RU, USA: Supports 1st CL proposal

IACM: supports adoption at 55 mg/kg. In JECFA's 2014 intake assessment of paprika extract from all foods and beverages the highest intake at the 95th % of 0.2 mg/kg bw/day as carotenoids, is below the JECFA ADI of 1.5 mg/kg bw as carotenoids (up to 13% of ADI). JECFA concluded that dietary exposure to paprika extract used as a food color does not present a health concern.

NATCOL: Supports adoption at 55

QUINOLINE YELLOW	104	150		7	Colour	Discontinue
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2nd Circular Proposal: Request information on actual use and use level

EWG comments on 2nd Circular:

Australia, EU: Supports proposal requesting use and use level

RU: does not agree with proposal. There not safety justification

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia notes that the Australian regulations has permission for this colour at a maximum ML of 290 mg/kg (total sum of other specific colours as well) in a comparable food category to this FC. Australia can therefore support adoption.

EU: no use was reported by the industry for this FC (EFSA, 2015).

RU: does not agree with proposal. There not safety justification

TARTRAZINE	102	300		7	Colour	Adopt at 40 mg/kg
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2nd Circular Proposal: Adopt at 30

EWG comments on 2nd Circular:

Australia, EU: Supports proposal

Japan: proposes the maximum level be replaced with 40 mg/kg. INS 102 is used in specific products to associate the colour with the flavor. Maximum use level is 40 mg/kg in citrus-flavoured sherbet.

RU: does not agrees with proposal/ ML is so higher!!!

FIA: The proposal of maximum level at 30ppm restricts the use of tartrazine in this food category, noting that regulations in the Southeast Asia region allows the use with the following maximum limits: Vietnam, Singapore, Malaysia – GMP; Philippines – 300ppm; Indonesia – 70ppm; Thailand – 50ppm. We support the adoption of maximum level at 300ppm to facilitate the use of tartrazine in this food category.

IACM: supports use level of at least 150 mg/kg.

IDF: Reported use up to 40 mg/kg, therefore IDF would request an ML of 40 mg/kg.

1st Circular Proposal: Adopt.

EWG comments on 1st Circular:

Australia notes that the Australian regulations has permission for this colour at a maximum ML of 290 mg/kg (total sum of other specific colours as well) in a comparable food category to this FC. Australia can therefore support adoption.

EU: the industry reported the maximum level of 20 ppm for this FC (EFSA, 2009).

JAPAN: supports the proposal. INS 102 is used in specific products to associate the colour with the flavor. Maximum use level is 30 mg/kg in citrus-flavoured sherbet.

RU: agrees with proposal only with ML=150 mg/kg

USA: Supports adoption. Authorized for use in foods in general

IACM: supports adoption at 300 mg/kg. JECFA concluded that the range of estimated dietary exposures to tartrazine from all foods and beverages were well below the ADI of 10 mg/kg bw (%), set by JECFA in 2016 (4-73 % of the ADI) including intake for children and including the conservative estimate by EFSA. In JECFA's most recent safety evaluation, under the most conservative exposure scenario assuming maximum use levels in all foods and beverages, the highest intake of tartrazine from all foods was 0.4-7.3 mg/kg bw/day at the 95th % for children in Europe. More realistic intake of up to 0.08 mg/kg bw/day at the 90th % of consumers only was reported from FSANZ. Estimates in the USA (using 2-day dietary survey that overestimates exposure) confirm the range of intake is well below the ADI, with total intake from all foods and beverages up to 0.7 mg/kg bw/day at the 90th % of the high exposure scenario and assuming 100% products contain this color (Doell et al 2016), and more realistic intake up to 0.1 mg/kg bw/day at the 95th % consumption and at maximum use levels, when accounting for frequency of products in each food category with this color on the label (Bastaki et al 2017)

Zeaxanthin, Synthetic	161h(i)	150		4	Colour	Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.
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1st and 2nd Circular Proposal: Hold pending discussion of inclusion in Table 3 (see Appendix 2 of CX/FA 20/52/7). Discontinue if Table 3 provision is adopted.

EWG comments on Proposal:

Australia, EU, RU, USA, IACM, IDF, NATCOL: Supports proposal to hold pending Table 3 discussion and discontinue if adopted in Table 3.

List of Notes:

Note 3: For use in surface treatment only.

- Note 8: As bixin.
- Note 39: On a total carotenoid basis.
- Note 52: Excluding chocolate milk
- Note 146: Beta-carotene (synthetic) (INS 160a(i)) only
- Note 161: Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.
- Note 178: As carminic acid
- Note 185: As norbixin.
- Note 291: Except for use of beta-apo-8'-carotenal (INS 160e) and beta-apo-8'-carotenoic acid, methyl or ethyl ester (INS 160f) at 35 mg/kg.
- Note 362: Excluding plain products conforming to the Standard for Fermented Milks (CODEX STAN 243-2003)
- Note XS208 Excluding products conforming to the Standard for Cheese in Brine (CODEX STAN 208-1999).
- Note XS211: Excluding products conforming to the Standard for Named Animal Fat (CODEX STAN 211- 1999).
- Note XS253: Excluding products conforming to the Standard for Dairy Fat Spreads (CODEX STAN 253-2006).
- Note XS256: Excluding products conforming to the Standard for Fat Spreads and Blended Spreads (CXS 256-2007)
- Note XS263: Excluding products conforming to the Standard for Cheddar (CXS 263-1966).
- Note XS264: Excluding products conforming to the Standard for Danbo (CXS 264-1966)
- Note XS265: Excluding products conforming to the Standard for Edam (CXS 265-1966)
- Note XS266: Excluding products conforming to the Standard for Gouda (CXS 266-1966)
- Note XS267: Excluding products conforming to the Standard for Havarti (CXS 267-1966).
- Note XS268: Excluding products conforming to the Standard for Samsø (CXS 268-1966).
- Note XS269: Excluding products conforming to the Standard for Emmental (CXS 269-1967).
- Note XS270: Excluding products conforming to the Standard for Tilsiter (CXS 270-1968).
- Note XS271: Excluding products conforming to the Standard for Saint-Paulin (CXS 271-1968).
- Note XS272: Excluding products conforming to the Standard for Provolone (CXS 272-1968)
- Note XS274: Excluding products conforming to the Standard for Coulommiers (CXS 274-1969).
- Note XS276: Excluding products conforming to the Standard for Camembert (CXS 276-1973).
- Note XS277: Excluding products conforming to the Standard for Brie (CXS 277-1973).
- Note XS278: Excluding products conforming to the Standard for Extra Hard Grating Cheese (CXS 278-1978).
- Note XS279: Excluding products conforming to the Standard for Butter (CXS 279-1971).
- Note XS283: Excluding products conforming to the General Standard for Cheese (CXS 283-1978).
- Note XS329: Excluding products conforming to the Standard for Fish Oils (CXS 329-2017).