JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD ADDITIVES
Forty-Seventh Session
Xi’an, China, 23-27 March 2015

INFORMATION ON THE AVAILABILITY OF DATA FOR THE RE-EVALUATION OF SIX PRIORITY
COLOURS
(Replies to CL 2014/14-FA)
Replies of Costa Rica, Japan and IACM

COSTA RICA
Costa Rica welcomes the request for information on the availability of data to re-evaluate the six priority food
colours, however at the moment we don’t have comments.

JAPAN

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation (safety assessment and specifications):</th>
<th>Allura Red AC (INS129)</th>
</tr>
</thead>
</table>

1. Information submitted by:
Japan

2. Name of substance; trade name(s); chemical name(s):
   - Trade name: NA
   - Chemical name: Disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfonatophenyl)diazenyl]naphthalene-2-
sulfonate

3. Names and addresses of basic producers:
   - Name: Mr. Kouichi Nakashima
   - Address: 1-1-11, Sanwa-cho, Toyonaka, Osaka 561-8588, Japan
   - San-Ei Gen F.F.I., Inc.

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
Yes

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please
indicate contact person):
   - Contact person: Mr. Shim-mo Hayashi, DVM, PhD
   - Department: Global Regulatory Affairs
   - TEL: +81-6-6333-0597
   - e-mail address: shinmo-hayashi@saneigenffi.co.jp

6. Justification for use:
   - colours

7. Food products and food categories within the GSFA in which the substance is used as a food
additive or as an ingredient, including use level(s):

8. Is the substance currently used in food that is legally traded in more than one country? (please
identify the countries); or, has the substance been approved for use in food in one or more country?
(please identify the country(ies))
9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Allura Red AC has not been recently evaluated in Japan.

10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Toxicological data

(i) Metabolic and pharmacokinetic studies

None

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies

Comet assay: Yu F. Sasaki et al., Mutation Research 519(2002) 103-119, The comet assay with 8 mouse organs: results with 39 currently used food additives

Reproductive toxicity study in mouse: Toyohito Tanaka, Toxicology 92(1994) 169-177, Reproductive and neurobehavioral effects of Allura Red AC administered to mice in the diet

DNA damage in colon : C. Shimada et al., J. Toxicol. Sci. 35(2010), 547-554, Differential colon DNA damage induced by azo food additives between rats and mice


(iii) Epidemiological and/or clinical studies and special considerations

None

(iv) Other data

None

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used

None

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Estimation of dietary intakes in Japan in 2012 is available.
11. Date on which data could be submitted to JECFA.
Available

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation (safety assessment and specifications):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tartrazine (INS102)</td>
</tr>
</tbody>
</table>

1. Information submitted by:
Japan

2. Name of substance; trade name(s); chemical name(s):
   Trade name: NA
   Chemical name: Disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfonatophenyl)diazenyl]naphthalene-2-sulfonate

3. Names and addresses of basic producers:
   Name: Mr. Kouichi Nakashima
   Address: 1-1-11, Sanwa-cho, Toyonaka, Osaka 561-8588, Japan
   San-Ei Gen F.F.I., Inc.

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
Yes

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):
   Contact person: Mr. Shim-mo Hayashi, DVM, PhD
   Department: Global Regulatory Affairs
   TEL: +81-6-6333-0597
   e-mail address: shinmo-hayashi@saneigenffi.co.jp

6. Justification for use:
colours

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)
Tartrazine has not been recently evaluated in Japan.

10. List of data available (please check, if available)
   The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

   Toxicological data
   (i) Metabolic and pharmacokinetic studies
   None
   (ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
   Comet assay: Yu F. Sasaki et al., Mutation Research 519(2002) 103-119, The comet assay with 8 mouse organs: results with 39 currently used food additives
   Reproductive toxicity study in mouse: T. Tanaka Food and Chemical Toxicology 44(2006)179-187, Reproductive and neurobehavioral toxicity study tartrazine administered to mice in the diet
Three-generation toxicity: T. Tanaka, et al., Food Chemical Toxicol. 26(2008), 156-163, Effects of tartrazine on exploratory behavior in a three-generation toxicity study in mice


General toxicity in rat: H. M. F. Adb, et al., Toxicology and Industrial Health 29(2012), 224-232, Toxic effects of some synthetic food colorants and/or flavor additives on male rats


Cytogenicity: P. Mpountoukas, et al., Food Chemical Toxicol. 48(2010), 2934-2944, Cytogenetic evaluation and DNA interaction studies of the food colorants amaranth, erythrosine and tartrazine

Renal, hepatic toxicity: K. A. Amin, et al., Food Chemical Toxicol. 48(2010), 2994-2999, Effect of food azo dye tartrazine and carmoisine on biochemical parameters related to renal, haptic function and oxidative stress biomarkers in young male rats


Genotoxicity in mouse: M. Poul, et al., Food Chemical Toxicol. 47(2009), 443-448, Lack of genotoxic effect of food dyes amaranth, sunset yellow and tartrazine and their metabolites in the gut micronucleus assay in mice

Toxicity to Gastric mucosa in rat: ILD. Moutihno, et al., Braz. J. Biol. 67(2007), 41-145, Prolonged use of the food dye tartrazine (FD&C yellow 5) and its effects on the gastric mucosa of Wistar rats

(iii) Epidemiological and/or clinical studies and special considerations

None

(iv) Other data

None

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used

None

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Estimation of dietary intakes in Japan in 2012 is available.

11. Date on which data could be submitted to JECFA.

Available

Name of Substance(s) for re-evaluation (safety assessment and specifications):

Brilliant blue FCF (INS133)

1. Information submitted by:

Japan

2. Name of substance; trade name(s); chemical name(s):

Trade name: NA
Chemical name: Trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-[(4-sulfonatophenyl)diazenyl]-1H-pyrazole-3-carboxyate

3. Names and addresses of basic producers:
Name: Mr. Kouichi Nakashima
Address: 1-1-11, Sanwa-cho, Toyonaka, Osaka 561-8588, Japan
San-Ei Gen F.F.I., Inc.

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
Yes

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):
Contact person: Mr. Shim-mo Hayashi, DVM, PhD
Department: Global Regulatory Affairs
TEL: +81-6-6333-0597
e-mail address: shinmo-hayashi@saneigenffi.co.jp

6. Justification for use:
colours

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))
Brilliant blue FCF has not been recently evaluated in Japan.

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

10. List of data available (please check, if available)
The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Toxicological data
(i) Metabolic and pharmacokinetic studies
None
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
Comet assay: Yu F. Sasaki et al., Mutation Research 519(2002) 103-119, The comet assay with 8 mouse organs: results with 39 currently used food additives
Reproductive and Neurobehavioural effect in mouse: T. Tanaka, et al., Birth Defects Research 95(2012), 295-409, Preproductive and Neurobehavioural Effects of Brilliant Blue FCF in Mice
General toxicity in rat: H. M. F. Abd, et al., Toxicology and Industrial Health 29(2012), 224-232, Toxic effects of some synthetic food colorants and/or flavor additives on male rats

(iii) Epidemiological and/or clinical studies and special considerations
None
(iv) Other data
None

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used
None

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Estimation of dietary intakes in Japan in 2012 is available.

11. Date on which data could be submitted to JECFA.
Available

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation (safety assessment and specifications):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythrosine (INS127)</td>
</tr>
</tbody>
</table>

1. Information submitted by:

Japan

2. Name of substance; trade name(s); chemical name(s):

Trade name: NA

Chemical name: Trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-[(4-sulfonatophenyl)diazenyl]-1H-pyrazole-3-carboxyate

3. Names and addresses of basic producers:

Name: Mr. Kouichi Nakashima
Address: 1-1-11, Sanwa-cho, Toyonaka, Osaka 561-8588, Japan
San-Ei Gen F.F.I., Inc.

4. Has the manufacturer and/or other interested parties made a commitment to provide data?

Yes

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):

Contact person: Mr. Shim-mo Hayashi, DVM, PhD
Department: Global Regulatory Affairs
TEL: +81-6-6333-0597
e-mail address: shinmo-hayashi@saneigenffi.co.jp

6. Justification for use:

colours

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):
8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Erythrosine has not been recently evaluated in Japan.

10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Toxicological data

(i) Metabolic and pharmacokinetic studies

None

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies

Comet assay: Yu F. Sasaki et al., Mutation Research 519(2002) 103-119, The comet assay with 8 mouse organs: results with 39 currently used food additives

Reproductive toxicity study in mouse: T. Tanaka, Food Chemical Toxicol. 39(2001), 447-454, Reproductive and neurobehavioral toxicity study of erythrosine administered to mice in the diet

Learning & behaviour in children: D. K. Doguc et al., Toxicology and Industrial Health 29(2012), 616-623, Effects of maternally exposed colouring food additives on cognitive performance in rats

Genotoxicity & Mutagenicity on HepG2 cells: F. M. D. Chequer, et al., Food Chemical Toxicol. 50(2012), 3447-3451, Genotoxic and mutagenic effects of erythrosine B, a xanthene food dye, on HepG2 cells

Cytogenicity: P. Mpountoukas, et al., Food Chemical Toxicol. 48(2010), 2934-2944, Cytogenetic evaluation and DNA interaction studies of the food colorants amaranth, erythrosine and tartrazine

(iii) Epidemiological and/or clinical studies and special considerations

None

(iv) Other data

None

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used

None

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Estimation of dietary intakes in Japan in 2012 is available.

11. Date on which data could be submitted to JECFA.

Available
Name of Substance(s) for re-evaluation (safety assessment and specifications):

<table>
<thead>
<tr>
<th>Substance</th>
<th>Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast green FCF (INS143)</td>
<td></td>
</tr>
</tbody>
</table>

1. Information submitted by:
Japan

2. Name of substance; trade name(s); chemical name(s):

Trade name: NA
Chemical name: Trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-[(4-sulfonatophenyl)diazenyl]-1H-pyrazole-3-carboxylate

3. Names and addresses of basic producers:

Name: Mr. Kouichi Nakashima
Address: 1-1-11, Sanwa-cho, Toyonaka, Osaka 561-8588, Japan
San-Ei Gen F.F.I., Inc.

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
Yes

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):

Contact person: Mr. Shim-mo Hayashi, DVM, PhD
Department: Global Regulatory Affairs
TEL: +81-6-6333-0597
e-mail address: shinmo-hayashi@saneigenffi.co.jp

6. Justification for use:

colours

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Fast green FCF has not been recently evaluated in Japan.

10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Toxicological data

(i) Metabolic and pharmacokinetic studies
None

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
None

(iii) Epidemiological and/or clinical studies and special considerations
None

(iv) Other data
None
Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used

None

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Estimation of dietary intakes in Japan in 2012 is available.

11. Date on which data could be submitted to JECFA.

Available

Name of Substance(s) for re-evaluation (safety assessment and specifications):

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation</th>
<th>Indigotine (INS132)</th>
</tr>
</thead>
</table>

1. Information submitted by:

Japan

2. Name of substance; trade name(s); chemical name(s):

Trade name: NA

Chemical name: Trisodium 5-hydroxy-1-(4-sulfonatophenyl)-4-[(4-sulfonatophenyl)diazenyl]-1H-pyrazole-3-carboxyate

3. Names and addresses of basic producers:

Name: Mr. Kouichi Nakashima
Address: 1-1-11, Sanwa-cho, Toyonaka, Osaka 561-8588, Japan
San-Ei Gen F.F.I., Inc.

4. Has the manufacturer and/or other interested parties made a commitment to provide data?

Yes

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):

Contact person: Mr. Shim-mo Hayashi, DVM, PhD
Department: Global Regulatory Affairs
TEL: +81-6-6333-0597
e-mail address: shinmo-hayashi@saneigenffi.co.jp

6. Justification for use:

colours

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Indigotine has not been recently evaluated in Japan.

10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided,
where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

**Toxicological data**

(i) Metabolic and pharmacokinetic studies
None

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


DNA damage in breast epithelial cells: Y. A. Masannat, et al., J. Surgical Research 154(2009), 234-238, DNA Damaging Effects of the Dyes Used in Sentinel Node Biopsy: Possible Implications for Clinical Practice

(iii) Epidemiological and/or clinical studies and special considerations
None

(iv) Other data
None

**Technological data**

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

**Intake assessment data**

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used
None

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Estimation of dietary intakes in Japan in 2012 is available.

11. Date on which data could be submitted to JECFA.
Available

**INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS (IACM)**

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation</th>
<th>Allura Red AC (INS129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(safety assessment and specifications):</td>
<td></td>
</tr>
</tbody>
</table>

1. Information submitted by:
International Association of Color Manufacturers (IACM)

2. Name of substance; trade name(s); chemical name(s):
Allura Red; Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4sulfophenyl) azo]-2-naphthalenesulfonic acid

3. Names and addresses of basic producers:
N/A

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
IACM is committed to supporting JECFA safety evaluations, and will submit a dossier for this material upon request.
5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):
International Association of Color Manufacturers
Sarah Codrea, Executive Director

6. Justification for use:
Allura Red is an essential color additive that is used to replace natural color that is lost during food processing, and to provide an expected color for consumers for many different foodstuffs.

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

a. The GSFA list of food categories is found here:
http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=110


<table>
<thead>
<tr>
<th>Food categories</th>
<th>MPL (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-alcoholic flavoured drinks</td>
<td></td>
</tr>
<tr>
<td>Bitter soda, bitter vino</td>
<td>100</td>
</tr>
<tr>
<td>Liquid food supplements/dietary integrators</td>
<td></td>
</tr>
<tr>
<td>Spirituous beverages</td>
<td></td>
</tr>
<tr>
<td>Aromatized wines, aromatized wine-based drinks and aromatized wine product cocktails</td>
<td>200</td>
</tr>
<tr>
<td>Fruit wines, cider and perry</td>
<td></td>
</tr>
<tr>
<td>Luncheon meat</td>
<td></td>
</tr>
<tr>
<td>Breakfast sausages with a minimum cereal content of 6 %</td>
<td>25</td>
</tr>
<tr>
<td>Complete formulae for weight control intended to replace total daily food intake or an individual meal</td>
<td>50</td>
</tr>
<tr>
<td>Complete formulae and nutritional supplements for use under medical supervision</td>
<td></td>
</tr>
<tr>
<td>Soups</td>
<td></td>
</tr>
<tr>
<td>Flavoured processed cheese</td>
<td></td>
</tr>
<tr>
<td>Fish paste and crustaceans paste</td>
<td>100</td>
</tr>
<tr>
<td>Smoked fish</td>
<td></td>
</tr>
<tr>
<td>Savoury snack products and savoury coated nuts</td>
<td></td>
</tr>
<tr>
<td>Meat and fish analogues based on vegetable proteins</td>
<td></td>
</tr>
<tr>
<td>Edible ices</td>
<td>150</td>
</tr>
<tr>
<td>Desserts including flavoured milk products</td>
<td></td>
</tr>
<tr>
<td>Fine bakery wares</td>
<td></td>
</tr>
<tr>
<td>Candied fruit and vegetables, Mostarda di frutta</td>
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</tr>
<tr>
<td>Preserves of red fruits</td>
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</tr>
<tr>
<td>Extruded or expanded savoury snack products</td>
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</tr>
<tr>
<td>Pre-cooked crustaceans</td>
<td>250</td>
</tr>
<tr>
<td>Confectionery</td>
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</tr>
<tr>
<td>Mustard</td>
<td>300</td>
</tr>
<tr>
<td>Fish roe</td>
<td></td>
</tr>
<tr>
<td>Solid food supplements/dietary integrators</td>
<td></td>
</tr>
<tr>
<td>Decorations and coatings</td>
<td></td>
</tr>
<tr>
<td>Sauces, seasonings, pickles, relishes, chutney and piccalilli</td>
<td>500</td>
</tr>
<tr>
<td>Salmon substitutes</td>
<td></td>
</tr>
<tr>
<td>Surimi</td>
<td></td>
</tr>
<tr>
<td>Edible cheese rind and edible casings</td>
<td>QS</td>
</tr>
</tbody>
</table>

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

Yes, the color is approved for use in many countries, including but not limited to:
Australia/New Zealand, Barbados, Bermuda, Brazil, Canada, Chile, China, Dominican Republic, Ecuador, European Union, Fiji, China (Hong Kong SAR), Israel, Japan, Republic of Korea, Malaysia, Mexico, Peru, Philippines, Singapore, South Africa, Uganda, USA and Vietnam. In addition in countries of the Eurasian Customs Union (Belarus, Kazakhstan and Russia) and of Central American Customs Union.
9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Yes, the safety of Allura red as a food coloring substance was most recently reviewed by EFSA in 2013. The Scientific Opinion can be found here:


10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

**Published safety evaluations of Allura Red by EFSA:**


**Toxicological data**

**Studies published after last JECFA evaluation of 1980:**

(i) Metabolic and pharmacokinetic studies

No additional data were found

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


NTP (National Toxicology Program), 2000. Allura red. Available at NTP website: http://ntp.niehs.nih.gov/index.cfm?objectid=E87EF85F-BDB5-82F8-FDED9AB34EFB2FAD


(iii) Epidemiological and/or clinical studies and special considerations

No additional data were found

(iv) Other data


**Studies reviewed in the last JECFA evaluation of 1980:**

(i) Metabolic and pharmacokinetic studies


(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


Sondergaard D, Hansen E and Wurtzen HA, 1977. A short-term study in the pig of the effects on the liver and on the blood of eight azo dyes. Toxicology 8, 381-386 (as referred to by JECFA, 1980).


(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data

**Technological data**

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

EFSA reviewed the specifications previously reported in JECFA 1980. No changes have been required to the specifications published in JECFA 1980.

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

**Intake assessment data**

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used


(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

An exposure assessment was conducted by EFSA and published in the 2009 Scientific Opinion. Additional exposure assessment was conducted by Connolly et al (2010).


11. Date on which data could be submitted to JECFA.

As Allura Red is a group 1 priority substance, data could be submitted by the deadline for the 2016 JECFA meeting, on approximately December 1, 2015.

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation (safety assessment and specifications):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tartrazine (INS102)</td>
</tr>
</tbody>
</table>

1. Information submitted by: 
International Association of Color Manufacturers (IACM)

2. Name of substance; trade name(s); chemical name(s):
Tartrazine (INS 102); 5-oxo-1-(p-sulfophenyl)-4-[(p-sulfophenyl)azo]-2-pyrazoline-3-carboxylic acid, trisodium salt

3. Names and addresses of basic producers: 
N/A

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
IACM is committed to supporting JECFA safety evaluations, and will submit a dossier for this material upon request.

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):
International Association of Color Manufacturers
Sarah Codrea, Executive Director

6. Justification for use:
Tartrazine is an essential color additive that is used to replace natural color that is lost during food processing, and to provide an expected color for consumers for many different foodstuffs.

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

a. The GSFA list of food categories is not currently available (this color is at Step 7 in the Step process).


<table>
<thead>
<tr>
<th>Food categories</th>
<th>MPL (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-alcoholic flavoured drinks</td>
<td></td>
</tr>
<tr>
<td>Americano</td>
<td></td>
</tr>
<tr>
<td>Bitter soda, bitter vino</td>
<td></td>
</tr>
<tr>
<td>Liquid food supplements/dietary integrators</td>
<td></td>
</tr>
<tr>
<td>Spirituous beverages</td>
<td></td>
</tr>
<tr>
<td>Aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails</td>
<td>200</td>
</tr>
<tr>
<td>Spirituous beverages</td>
<td></td>
</tr>
<tr>
<td>Fruit wines, cider and perry</td>
<td></td>
</tr>
<tr>
<td>Complete formulae for weight control intended to replace total daily food intake or an individual meal</td>
<td>50</td>
</tr>
<tr>
<td>Complete formulae and nutritional supplements for use under medical supervision</td>
<td></td>
</tr>
<tr>
<td>Soups</td>
<td></td>
</tr>
<tr>
<td>Flavoured processed cheese</td>
<td></td>
</tr>
<tr>
<td>Fish paste and crustaceans paste</td>
<td></td>
</tr>
<tr>
<td>Smoked fish</td>
<td></td>
</tr>
<tr>
<td>Savoury snack products and savoury coated nuts</td>
<td>100</td>
</tr>
<tr>
<td>Meat and fish analogues based on vegetable proteins</td>
<td></td>
</tr>
<tr>
<td>Processed mushy and garden peas (canned)</td>
<td></td>
</tr>
<tr>
<td>Edible ices</td>
<td></td>
</tr>
<tr>
<td>Desserts including flavoured milk products</td>
<td>150</td>
</tr>
<tr>
<td>Fine bakery wares</td>
<td></td>
</tr>
<tr>
<td>Candied fruit and vegetables, Mostarda di frutta</td>
<td></td>
</tr>
<tr>
<td>Preserves of red fruits</td>
<td></td>
</tr>
<tr>
<td>Extruded or expanded savoury snack products</td>
<td></td>
</tr>
<tr>
<td>Pre-cooked crustaceans</td>
<td>250</td>
</tr>
<tr>
<td>Confectionery</td>
<td></td>
</tr>
<tr>
<td>Mustard</td>
<td>300</td>
</tr>
<tr>
<td>Fish roe</td>
<td></td>
</tr>
<tr>
<td>Solid food supplements/dietary integrators</td>
<td></td>
</tr>
<tr>
<td>Decorations and coatings</td>
<td></td>
</tr>
<tr>
<td>Sauces, seasonings, pickles, relishes, chutney and piccalilli</td>
<td>500</td>
</tr>
<tr>
<td>Salmon substitutes</td>
<td></td>
</tr>
<tr>
<td>Surimi</td>
<td></td>
</tr>
<tr>
<td>Edible cheese rind and edible casings</td>
<td>QS</td>
</tr>
</tbody>
</table>

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

Yes, the color is approved for use in many countries, including but not limited to:
Australia/New Zealand, Barbados, Bermuda, Brazil, Canada, Chile, China, Dominican Republic, Ecuador, European Union, Fiji, China (Hong Kong SAR), India, Israel, Japan, Republic of Korea, Malaysia, Mexico,
Peru, Philippines, Singapore, South Africa, Uganda, USA and Vietnam. In addition in countries of the Eurasian Customs Union (Belarus, Kazakhstan and Russia) and of Central American Customs Union.

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Yes, the safety of Tartrazine as a food coloring substance was most recently reviewed by EFSA in 2009 and 2010. The Scientific Opinions can be found here:


10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Published safety evaluations of Tartrazine by EFSA:


Toxicological data

Studies published after last JECFA evaluation of 1966 (or not reviewed):

(i) Metabolic and pharmacokinetic studies


(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


Chung KT. The significance of azo-reduction in the mutagenesis and carcinogenesis of azo dyes. Mutat Res. 1983 Apr;114(3):269-81. Review.


(iii) Epidemiological and/or clinical studies and special considerations


Thuvander A, 1995. [Hypersensitivity to azo coloring agents. Tartrazine in food may cause rash and asthma]. Lakartidningen. 92, 296-298 (as referred to by TemaNord, 2002).


(iv) Other data


Studies reviewed in the last JECFA evaluation of 1966:

(i) Metabolic and pharmacokinetic studies


(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

EFSA (2009) reviewed the specifications previously reported in JECFA 2006. Certain differences were noted between the specifications according JECFA 2006 and those according to Directive 2008/128/EC (EFSA 2009).


(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used


(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

An exposure assessment was conducted by EFSA and published in the 2009 Scientific Opinion. Additional exposure assessment was conducted by Connolly et al (2010).


11. Date on which data could be submitted to JECFA.

Since Tartrazine is a Priority Group 1 substance, IACM can commit to submitting data by the deadline for the 2016 JECFA meeting, on approximately December 1, 2015.

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation (safety assessment and specifications):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brilliant Blue (INS 133)</td>
</tr>
</tbody>
</table>

1. Information submitted by:

International Association of Color Manufacturers (IACM)

2. Name of substance; trade name(s); chemical name(s):

Brilliant Blue FCF; N-Ethyl-N-(4-[4-ethyl[(3-sulphophenyl)methyl]-amino]phenyl) (2-sulphophenyl)methylene]-2,5-cyclohexadien-1-yldiene)-3-sulphobenzenemethanaminium hydroxide inner salt, disodium salt.

3. Names and addresses of basic producers:

N/A

4. Has the manufacturer and/or other interested parties made a commitment to provide data?

IACM is committed to supporting JECFA safety evaluations, and will submit a dossier for this material upon request.

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):

International Association of Color Manufacturers

Sarah Codrea, Executive Director

6. Justification for use:

Brilliant Blue is an essential color additive that is used to replace natural color that is lost during food processing, and to provide an expected color for consumers for many different foodstuffs.

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

a. The GSFA list of food categories is found here:

http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=111


<table>
<thead>
<tr>
<th>Food categories</th>
<th>MPL (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit wines, cider and perry</td>
<td>200</td>
</tr>
<tr>
<td>Non-alcoholic flavoured drinks</td>
<td>100</td>
</tr>
<tr>
<td>Liquid food supplements/dietary integrators</td>
<td>100</td>
</tr>
<tr>
<td>Spirituous beverages</td>
<td>200</td>
</tr>
<tr>
<td>Aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails</td>
<td>200</td>
</tr>
<tr>
<td>Complete formulae and nutritional supplements for use under medical supervision</td>
<td>50</td>
</tr>
<tr>
<td>Complete formulae for weight control intended to replace total daily food intake or an individual meal</td>
<td>50</td>
</tr>
<tr>
<td>Soups</td>
<td></td>
</tr>
<tr>
<td>Flavoured processed cheese</td>
<td></td>
</tr>
<tr>
<td>Fish paste and crustaceans paste</td>
<td></td>
</tr>
<tr>
<td>Smoked fish</td>
<td>100</td>
</tr>
<tr>
<td>Savoury snack products and savoury coated nuts</td>
<td></td>
</tr>
<tr>
<td>Meat and fish analogues based on vegetable proteins</td>
<td></td>
</tr>
<tr>
<td>Desserts including flavoured milk products</td>
<td>150</td>
</tr>
<tr>
<td>Edible ices</td>
<td>150</td>
</tr>
<tr>
<td>Fine bakery wares</td>
<td>200</td>
</tr>
</tbody>
</table>
Food categories | MPL (ppm)
---|---
Candied fruit and vegetables, Mostarda di frutta | 200
Preserves of red fruits | 200
Extruded or expanded savoury snack products | 200
Pre-cooked crustaceans | 250
Confectionery | 300
Mustard | 300
Fish roe | 300
Solid food supplements/dietary integrators | 300
Sauces, seasonings, pickles, relishes, chutney and piccalilli | 500
Salmon substitutes | 500
Surimi | 500
Decorations and coatings | 500
Edible cheese rind and edible casings Quantum satis | QS
Edible casings | QS

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

Yes, the color is approved for use in many countries, including but not limited to:

Australia/New Zealand, Barbados, Bermuda, Brazil, Canada, Chile, China, Dominican Republic, Ecuador, European Union, Fiji, China (Hong Kong SAR), India, Israel, Japan, Republic of Korea, Malaysia, Mexico, Peru, Philippines, Singapore, South Africa, Uganda, USA and Vietnam. In addition in countries of the Eurasian Customs Union (Belarus, Kazakhstan and Russia) and of Central American Customs Union.

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Yes, the safety of Brilliant Blue as a food coloring substance was most recently reviewed by EFSA in 2010. The Scientific Opinion can be found here:


10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Toxicological data

Studies published after last JECFA evaluation of 1970 (or not reviewed):

(i) Metabolic and pharmacokinetic studies


(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


BIBRA (British Industrial Biological Research Association), 1982. A review of the toxicology of nine food colours. BIBRA Information Services Ltd. Surrey, UK.


Borzelleca JF, Depukat K and Hallagan JB, 1990. Lifetime toxicity/carcinogenicity studies of FD & C Blue No. 1 (Brilliant blue FCF) in rats and mice. Food and Chemical Toxicology. 28, 221-234.


El-Wahab HM, Moram GS. Toxic effects of some synthetic food colorants and/or flavor additives on male rats. Toxicol Ind Health. 2013


(iii) Epidemiological and/or clinical studies and special considerations


(iv) Other data


Studies reviewed in the last JECFA evaluation of 1970:

(i) Metabolic and pharmacokinetic studies

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


Klinke, 1955. Referred to by JECFA but not included in reference list (as referred to by JECFA, 1970).


A(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

EFSA (2010) reviewed the specifications previously reported in JECFA 2006. The purity of the material and content of non-coloring matter were noted as requiring additional data to characterize the material for constituents not accounted for in the specifications according JECFA 2006 and those according to the Commission Directive 2008/128/EC (EFSA 2010).


(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used


(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

An exposure assessment was conducted by EFSA and published in the 2014 Scientific Opinion.


11. Date on which data could be submitted to JECFA.

As Brilliant Blue is a Group 2 priority substance, IACM can commit to preparation of data to be submitted by the deadline for the 2017 JECFA meeting, on approximately December 1, 2016.

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation</th>
<th>Erythrosine (INS127)</th>
</tr>
</thead>
</table>

1. Information submitted by: International Association of Color Manufacturers (IACM)

2. Name of substance; trade name(s); chemical name(s):
Erythrosine; 2',4',5',7'-Tetraiodo-3',6'-dihydroxy-spiro[3H-isobenzofuran-1,9'-xanthen]-3-one disodium salt

3. Names and addresses of basic producers:
N/A

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
IACM is committed to supporting JECFA safety evaluations, and will submit a dossier for this material upon request.

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):
International Association of Color Manufacturers
Sarah Codrea, Executive Director

6. Justification for use:
Erythrosine is an essential color additive that is used to replace natural color that is lost during food processing, and to provide an expected color for consumers for many different foodstuffs.

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

a. The GSFA list of food categories is found here:
http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=87


<table>
<thead>
<tr>
<th>Food categories</th>
<th>MPL (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cocktail cherries and candied cherries</td>
<td>200</td>
</tr>
<tr>
<td>Bigarreaux cherries in syrup and in cocktail</td>
<td>150</td>
</tr>
</tbody>
</table>

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))
Yes, the color is approved for use in many countries, including but not limited to:
Australia/New Zealand, Barbados, Bermuda, Brazil, Canada, Chile, China, Dominican Republic, Ecuador, European Union, Fiji, China (Hong Kong SAR), India, Israel, Japan, Republic of Korea, Malaysia, Mexico,
Peru, Philippines, Singapore, South Africa, Uganda, USA and Vietnam. In addition in countries of the Eurasian Customs Union (Belarus, Kazakhstan and Russia) and of Central American Customs Union.

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Yes, the safety of Erythrosine as a food coloring substance was most recently reviewed by EFSA in 2011. The Scientific Opinion can be found here:


10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Published safety evaluations of Erythrosine by EFSA:


Toxicological data

Studies published after last JECFA evaluation of 1990 (or not reviewed):

(i) Metabolic and pharmacokinetic studies

No additional studies were reported since last JECFA evaluation

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


Hagiwara M, Watanabe E, Barrett EW and Tsutsui T, 2006. Assessment of genotoxicity of 14 chemical agents used in dental practice: Ability to induce chromosome aberrations in Syrian hamster embryo cells. Mutation Research 603, 111-120.


(iii) Epidemiological and/or clinical studies and special considerations

No additional studies have been reported

(iv) Other data

**Technological data**

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

EFSA (2011) reviewed the specifications previously reported in JECFA 2006. No changes have been required to the specifications published in JECFA 2006.

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

**Intake assessment data**

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used


(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

Exposure of adults to erythrosine was estimated by EFSA and published in the 2011 Scientific Opinion. Additional exposure assessment was conducted by Gilsenan and Gibney (2004) and GlaxoSmithKline (submitted to EFSA).


GSK (GlaxoSmithKline Consumer Healthcare), 2008. Submission to the Scientific Committee on consumer products, Erythrosine (CI45430).

**11. Date on which data could be submitted to JECFA.**

As Erythrosine is a Group 2 priority substance, IACM can commit to preparation of data to be submitted by the deadline for the 2017 JECFA meeting, on approximately December 1, 2016.

<table>
<thead>
<tr>
<th>Name of Substance(s) for re-evaluation (safety assessment and specifications):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast green FCF (INS143)</td>
</tr>
</tbody>
</table>

1. Information submitted by:

International Association of Color Manufacturers (IACM)
2. Name of substance; trade name(s); chemical name(s):
Fast Green FCF; N-ethyl-N-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl][4-hydroxy-2-sulfophenyl]methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzene -methanaminium hydroxide

3. Names and addresses of basic producers:
N/A

4. Has the manufacturer and/or other interested parties made a commitment to provide data?
IACM is committed to supporting JECFA safety evaluations, and will submit a dossier for this material upon request.

5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):
International Association of Color Manufacturers
Sarah Codrea, Executive Director

6. Justification for use:
Fast Green is an essential color additive that is used to replace natural color that is lost during food processing, and to provide an expected color for consumers for many different foodstuffs.

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):
a. The GSFA list of food categories is found here:
http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=106

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))
Yes, the color is approved for use in many countries, including but not limited to:
Australia/New Zealand, Barbados, Bermuda, Brazil, Canada, Chile, China, Dominican Republic, Ecuador, European Union, Fiji, China (Hong Kong SAR), India, Israel, Japan, Republic of Korea, Malaysia, Mexico, Peru, Philippines, Singapore, South Africa, Uganda, USA and Vietnam. In addition in countries of the Eurasian Customs Union (Belarus, Kazakhstan and Russia) and of Central American Customs Union.

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)
Fast Green is not used as a food coloring substance in Europe and has not been reviewed by EFSA.

10. List of data available (please check, if available)
The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Toxicological data

Studies published after last JECFA evaluation of 1986 (or not reviewed):
(i) Metabolic and pharmacokinetic studies
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data


**Technological data**

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

The specifications of Fast Green FCF were last reviewed by the JECFA in 2008 (TRS 952; WHO 2009). The USA specifications for Fast Green FCF (FD&C Green No 3) are listed in the USA Code of Federal Regulations (CFR): 21CFR Part 74.203.

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

**Intake assessment data**

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used

Use of Fast Green complies with current guidelines in the USA as published in the USA Code of Federal Regulations (21CFR Part 74.203).

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.


**11.Date on which data could be submitted to JECFA.**

As Fast Green is a Group 2 priority substance, IACM can commit to preparation of data to be submitted by the deadline for the 2017 JECFA meeting, on approximately December 1, 2016.

### Name of Substance(s) for re-evaluation (safety assessment and specifications):

| Indigotine (INS132) |

1. **Information submitted by:**

   International Association of Color Manufacturers (IACM)

2. **Name of substance; trade name(s); chemical name(s):**

   Indigotine; Indigo Carmine; Disodium (2E)-3-oxo-2-(3-oxo-5-sulphonato-2,3-dihydro-1H-indol-2-ylidene)-2,3-dihydro-1H-indole-5-sulphonate

3. **Names and addresses of basic producers:**

   N/A

4. **Has the manufacturer and/or other interested parties made a commitment to provide data?**

   IACM is committed to supporting JECFA safety evaluations, and will submit a dossier for this material upon request.

5. **Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):**

   International Association of Color Manufacturers

   Sarah Codrea, Executive Director
6. Justification for use:
Indigotine is an essential color additive that is used to replace natural color that is lost during food processing, and to provide an expected color for consumers for many different foodstuffs.

7. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):

a. The GSFA list of food categories is found here:
http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=96


<table>
<thead>
<tr>
<th>FCS(a) Category number</th>
<th>Food category</th>
<th>Restrictions/exceptions</th>
<th>MPL (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.4</td>
<td>Flavoured fermented milk products including heat-treated products</td>
<td></td>
<td>150</td>
</tr>
<tr>
<td>01.6.3</td>
<td>Other creams</td>
<td>only flavoured creams</td>
<td>150</td>
</tr>
<tr>
<td>01.7.1</td>
<td>Unripened cheese excluding products falling in category 16</td>
<td>only flavoured unripened cheese</td>
<td>150</td>
</tr>
<tr>
<td>01.7.3</td>
<td>Edible cheese rind</td>
<td></td>
<td>QS</td>
</tr>
<tr>
<td>01.7.6</td>
<td>Cheese products (excluding products falling in category 16)</td>
<td>only flavoured unripened products</td>
<td>100</td>
</tr>
<tr>
<td>03</td>
<td>Edible ices</td>
<td></td>
<td>150</td>
</tr>
<tr>
<td>04.2.4.1</td>
<td>Fruit and vegetable preparations excluding compote</td>
<td>only mostarda di frutta</td>
<td>200</td>
</tr>
<tr>
<td>05.2</td>
<td>Other confectionery including breath freshening microsweets</td>
<td>except candied fruit and vegetables</td>
<td>300</td>
</tr>
<tr>
<td>05.2</td>
<td>Other confectionery including breath freshening microsweets</td>
<td>only candied fruit and vegetables</td>
<td>200</td>
</tr>
<tr>
<td>05.3</td>
<td>Chewing gum</td>
<td></td>
<td>300</td>
</tr>
<tr>
<td>05.4</td>
<td>Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4</td>
<td>only decorations, coatings and sauces, except fillings</td>
<td>500</td>
</tr>
<tr>
<td>05.4</td>
<td>Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4</td>
<td>only fillings</td>
<td>300</td>
</tr>
<tr>
<td>06.6</td>
<td>Batters</td>
<td>only batters for coating</td>
<td>500</td>
</tr>
<tr>
<td>07.2</td>
<td>Fine bakery wares</td>
<td></td>
<td>200</td>
</tr>
<tr>
<td>08.2.3</td>
<td>Casings and coatings and decorations for meat</td>
<td>only decorations and coatings except edible external coating of pasturmas</td>
<td>500</td>
</tr>
<tr>
<td>08.2.3</td>
<td>Casings and coatings and decorations for meat</td>
<td>only edible casings</td>
<td>QS</td>
</tr>
<tr>
<td>09.2</td>
<td>Processed fish and fishery products including molluscs and crustaceans</td>
<td>only surimi and similar products and salmon substitutes</td>
<td>500</td>
</tr>
<tr>
<td>09.3</td>
<td>Fish roe</td>
<td>except Sturgeons’ eggs (Caviar)</td>
<td>300</td>
</tr>
<tr>
<td>12.2.2</td>
<td>Seasonings and condiments</td>
<td>Only seasonings, for example curry powder, tandoori</td>
<td>500</td>
</tr>
<tr>
<td>12.4</td>
<td>Mustard</td>
<td></td>
<td>300</td>
</tr>
<tr>
<td>12.5</td>
<td>Soups and broths</td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>12.6</td>
<td>Sauces</td>
<td>including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces</td>
<td>500</td>
</tr>
<tr>
<td>12.9</td>
<td>Protein products, excluding products covered in category 01.8</td>
<td>only meat and fish analogues based on vegetable proteins</td>
<td>100</td>
</tr>
<tr>
<td>13.2</td>
<td>Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)</td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>FCS(a) Category number</td>
<td>Food category</td>
<td>Restrictions/exceptions</td>
<td>MPL (ppm)</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>13.3</td>
<td>Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)</td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>14.1.4</td>
<td>Flavoured drinks</td>
<td>excluding chocolate milk and malt products</td>
<td>100</td>
</tr>
<tr>
<td>14.2.3</td>
<td>Cider and perry</td>
<td>excluding cidre bouché</td>
<td>200</td>
</tr>
<tr>
<td>14.2.4</td>
<td>Fruit wine and made wine</td>
<td>excluding wino owocowe markowe</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>Spirit drinks as defined in Regulation (EC) No 110/2008</td>
<td>except: spirit drinks as defined in Article 5(1) and sales denominations listed in Annex II, paragraphs 1-14 of Regulation (EC) No 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, Geist (with the name of the fruit or the raw material used), London Gin, Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà</td>
<td>200</td>
</tr>
<tr>
<td>14.2.7.1</td>
<td>Aromatised wines</td>
<td>except americano, bitter vino</td>
<td>200</td>
</tr>
<tr>
<td>14.2.7.2</td>
<td>Aromatised wine-based drinks</td>
<td>except bitter soda, sangria, claria, zurra</td>
<td>200</td>
</tr>
<tr>
<td>14.2.7.3</td>
<td>Aromatised wine-product cocktails</td>
<td></td>
<td>200</td>
</tr>
<tr>
<td>14.2.8</td>
<td>Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol</td>
<td>only alcoholic drinks with less than 15% of alcohol and nalewka na winie owocowym, aromatyzowana nalewka na winie owocowym, nalewka na winie z soku winogronowego, aromatyzowana nalewka na winie z soku winogronowego, napój winny owocowy lub miodowy, aromatyzowany napój winny owocowy lub miodowy, wino owocowe niskoalkoholowe and aromatyzowane wino owocowe niskoalkoholowe</td>
<td>200</td>
</tr>
<tr>
<td>15.1</td>
<td>Potato-, cereal-, flour- or starch-based snacks</td>
<td>excluding extruded or expanded savoury snack products</td>
<td>100</td>
</tr>
<tr>
<td>15.1</td>
<td>Potato-, cereal-, flour- or starch-based snacks</td>
<td>only extruded or expanded savoury snack products</td>
<td>200</td>
</tr>
<tr>
<td>15.2</td>
<td>Processed nuts</td>
<td>only savoury-coated nuts</td>
<td>100</td>
</tr>
<tr>
<td>16</td>
<td>Desserts excluding products covered in categories 01, 03 and 04</td>
<td></td>
<td>150</td>
</tr>
<tr>
<td>17.1</td>
<td>Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms</td>
<td></td>
<td>300</td>
</tr>
<tr>
<td>17.2</td>
<td>Food supplements supplied in a liquid form</td>
<td></td>
<td>100</td>
</tr>
<tr>
<td>17.3</td>
<td>Food supplements supplied in a syrup-type or chewable form</td>
<td>only solid food supplements</td>
<td>300</td>
</tr>
<tr>
<td>17.3</td>
<td>Food supplements supplied in a syrup-type or chewable form</td>
<td>only liquid food supplements</td>
<td>100</td>
</tr>
</tbody>
</table>

8. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))

Yes, the color is approved for use in many countries, including but not limited to:
Australia/New Zealand, Barbados, Bermuda, Brazil, Canada, Chile, China, Dominican Republic, Ecuador, European Union, Fiji, China (Hong Kong SAR), India, Israel, Japan, Republic of Korea, Malaysia, Mexico, Peru, Philippines, Singapore, South Africa, Uganda, USA and Vietnam. In addition in countries of the Eurasian Customs Union (Belarus, Kazakhstan and Russia) and of Central American Customs Union.

9. Was the substance recently evaluated at national or regional level by a risk assessment body? (please identify the country and the source of the report)

Yes, the safety of Indigotine as a food coloring substance was most recently reviewed by EFSA in 2014. The Scientific Opinion can be found here:


10. List of data available (please check, if available)

The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference to relevant published studies should also be provided, where applicable. In addition to original data, the submission of existing regulatory dossiers from national/regional regulatory agencies as well as summaries in the form of monographs is helpful and is therefore strongly recommended.

Published safety evaluations of Indigotine by EFSA:


Toxicological data

Studies published after last JECFA evaluation of 1975 (or not reviewed):

(i) Metabolic and pharmacokinetic studies


(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


Borzelleca JF, Goldenthal EI and Wazeter FX, 1986. Multigeneration study of FD&C Blue No. 2 in rats. Food and Chemical Toxicology, 24, 159-163.


(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data


Studies reviewed in the last JECFA evaluation of 1975:

(i) Metabolic and pharmacokinetic studies


(ii) Toxicological studies
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies


Prüfung der in Westdeutschland zugelassenen und ursprünglich vorgeschlagenen Lebensmittelfarbstoffe ant mutagene Wirkung an Escherichia coli. Z. Lebensmitt.- Untersuch. 112, 157-174 (as referred to by JECFA, 1975).

(iii) Epidemiological and/or clinical studies and special considerations

(iv) Other data

Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

EFSA (2014) reviewed the specifications previously reported in JECFA 2010. The purity and content of non-coloring matter were noted as requiring additional data to characterize the material for constituents not accounted for in the specifications according JECFA 2010 and those according to the Commission Regulation (EU) No 231/2012 (EFSA 2014).


(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

Intake assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used

Use of Indigotine complies with current guidelines in the USA and Europe, as published in the USA Code of Federal Regulations (21CFR Part 74.102) and in Annex II of Regulation (EC) No 1333/2008, respectively.

(ii) Estimation of dietary intakes based on food consumption data for foods in which the substance may be used.

An exposure assessment was conducted by EFSA and published in the 2014 Scientific Opinion.


11. Date on which data could be submitted to JECFA.

As Indigotine is a Group 2 priority substance, IACM can commit to preparation of data to be submitted by the deadline for the 2017 JECFA meeting, on approximately December 1, 2016.