



Food and Agriculture  
Organization of  
the United Nations



World Health  
Organization

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CL 2014/14-FA  
April 2014

**TO:** Codex Contact Points  
Interested International Organisations

**FROM:** Secretariat, Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission,  
Viale delle Terme di Caracalla,  
00153 Rome, Italy

**SUBJECT:** Request for information on the availability of data to re-evaluate the six priority food colours

**DEADLINE:** 15 January 2015

**COMMENTS: To:**

Secretariat  
Codex Committee on Food Additives  
China National Center for Food Safety Risk  
Assessment (CFSA),  
Building 2, No. 37 Guangqu Road,  
Chaoyang District, Beijing 100022, China,  
E-mail: [secretariat@ccfa.cc](mailto:secretariat@ccfa.cc)

**Copies to:**

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**BACKGROUND**

1. The 42<sup>nd</sup> Session in of the Committee on Food Additives (CCFA) started consideration on mechanisms for re-evaluation of substances by JECFA, including a proposed process to prioritize compounds for re-evaluation. The discussion continued in the following three sessions of CCFA which developed a tool to prioritize food additives for re-evaluation and applied it to a detailed list of the 107 food colours evaluated by JECFA since 1956.
2. The 45<sup>th</sup> CCFA considered the outcome of the prioritisation exercise and prioritised 38 of the 107 colours. However, the CCFA could not come to a conclusion regarding the necessary steps to link the prioritization exercise with the inclusion of an additive in the Priority List of Substances Proposed for Evaluation by JECFA (referred to hereafter as the "JECFA Priority List").
3. The 46<sup>th</sup> CCFA considered the pros and cons of the options presented for re-evaluation of substances and agreed that confirmation of data availability was a key criterion for allowing re-evaluation and that JECFA would allocate a limited proportion of JECFA meetings on food additives to the re-evaluation of compounds, as prioritized by CCFA. The Committee further agreed to start the process on a trial basis using the prioritization exercise done for the 45<sup>th</sup> CCFA on food colours (CX/FA 13/45/17).
4. The 46<sup>th</sup> CCFA decided to use the colours, listed as priority in Group 1 and Group 2<sup>1</sup>, as amended by the 45<sup>th</sup> CCFA<sup>2</sup>, as a working example, and to integrate them in the list of compounds to be examined by the Working Group on Priorities at its next Session.
5. The 46<sup>th</sup> CCFA further agreed that: (i) the Codex Secretariat will issue a circular letter requesting information on the availability of data to re-evaluate the six colours; and (ii) Based on responses, the Working Group on Priority of the 47<sup>th</sup> CCFA will provide JECFA with a final list of compounds prioritized for re-evaluation<sup>3</sup> as well as a possible schedule for future years.

<sup>1</sup> CX/FA 13/45/17.

<sup>2</sup> REP 13/FA para. 133.

<sup>3</sup> REP 14/FA paras 142-144.

**REQUEST FOR INFORMATION**

6. Members and interested International Organizations, as directed above, are invited to provide information on the availability of data to re-evaluate the six priority food colours, namely:

- (i) Allura red (INS 129);
- (ii) Tartrazine (INS 102);
- (iii) Brilliant blue (INS 133);
- (iv) Erythrosine (INS 127);
- (v) Fast green FCF (INS 143)
- (vi) Indigotine (INS 132).

7. Information should be submitted on the basis of the form in Annex 1 (attached).

8. Information submitted in response to this circular letter will be compiled in a working document for consideration at the 47<sup>th</sup> Session of the CCFA, to be held in China on 23 to 27 March 2015.

**Annex 1****FORM ON WHICH INFORMATION ON THE SIX COLOURS TO BE RE-EVALUATED BY JECFA SHOULD BE PROVIDED**

*In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.*

<b>Name of Substance(s) for re-evaluation (safety assessment and specifications):</b>	
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1. Information submitted by:
2. Name of substance; trade name(s); chemical name(s):
3. Names and addresses of basic producers:
4. Has the manufacturer and/or other interested parties made a commitment to provide data?
5. Identification of the manufacturer and/or other interested parties that will be providing data (Please indicate contact person):
6. Justification for use:
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)
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
- (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)
- (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.

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