



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Forty-fifth Session

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### PROPOSED PRIORITIZED LIST OF COLOURS FOR RE-EVALUATION BY JECFA

#### Report of the Electronic Working Group on the Prioritization of Food Colours for Re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

(Prepared by Canada with the assistance of an electronic working group (eWG) whose members included Argentina, Australia, Benin, Brazil, , European Union, Ghana, Indonesia, Japan, Libya, Malaysia, New Zealand, Norway, United States of America, WHO, CCC, Cefic, Food Drink Europe, IACM, IADSA, IAI, ICGA, ICGMA, IDF, IFAC, IFT, ISDI, and NATCOL.)

1. At the 43<sup>rd</sup> session of the Codex Committee on Food Additives (CCFA) in March 2011, an eWG was established to develop Prioritization Criteria for the Re-evaluation of Food Additives by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Canada was invited to lead the eWG and presented the eWG's work at the 44<sup>th</sup> CCFA in March 2012. The eWG had worked under the following terms of reference:
  - i. To establish criteria to prioritize food additives for re-evaluation (taking into account the proposed criteria in the working document and those used by JMPR/CCPR);
  - ii. To establish a detailed list of the 107 food colours evaluated by JECFA since 1956, organized by year of evaluation;
  - iii. To compile information on these colours from members and other organizations, including from the industry producing food additives;
  - iv. To establish a prioritized list of food colours based on prioritization criteria, for action by CCFA, including for consideration for re-evaluation by JECFA.
2. The eWG completed the first two terms of reference by (1) developing a Food Additive Re-evaluation Prioritization Form for consideration by the 44<sup>th</sup> session of the CCFA to be used to recommend a prioritization ranking of food additives for re-evaluation by JECFA, and (2) obtaining a list of all the food colours that have been evaluated by JECFA. As laid out in terms of reference iii and iv, the eWG was also to compile information on the food colours as the first category of food additives to be assessed and rank them in priority for re-evaluation. However, the eWG decided not to undertake this work at that time given that developing the criteria was going to be a significant task on its own.
3. The Food Additive Re-evaluation Prioritization Form that was developed by the eWG was presented at the 44<sup>th</sup> meeting of the CCFA and endorsed with minor revisions by the Committee, as described in the Codex Alimentarius Commission's Report of the 44<sup>th</sup> CCFA (REP12/FA; Agenda Item 9b, paragraphs 164 – 172). The 44<sup>th</sup> CCFA agreed to establish another eWG, led by Canada, open to all interested members and observers and working in English only, with the following terms of reference:
  - i. To compile information from members and other organizations, including from the industry producing food additives, on the detailed list of the 107 food colours evaluated by JECFA since 1956;
  - ii. To establish a prioritized list of food colours based on prioritization tool as discussed at the present Session for action by CCFA, including for consideration for re-evaluation by JECFA.
4. The Food Additive Re-evaluation Prioritization Form developed by the first eWG, as revised by the 44<sup>th</sup> CCFA and used by the current eWG to prioritize food colours, had seven questions contained in three Sections (A, B, and C). These were preceded by a Pre-Screening Section to eliminate all colours that did not have provisions in the Codex General Standard for Food Additives (GSFA), or in a Codex food standard, or in the Codex Step process.

Section A had two questions and was concerned with the status of the food additive with JECFA, Section B had three questions and was concerned with safety information, and Section C had two questions and was concerned with intake of the food additive. Each question could obtain a score of Low, Medium or, in some cases, High.

5. The highest score assigned to any question in a Section determined the score of that Section (Low, Medium, or High). The three Sections were weighted equally and the qualitative scores of the three sections determined the final numerical score of the food additive in accordance with a prioritization schedule shown on the prioritization form. The final numerical score could range from 1 (highest priority, obtained when all three Sections were scored “High”) to 10 (lowest priority, obtained when all three Sections were scored “Low”). Additional details on scoring are described in Table 1.

6. There were over 100 colours in the list of colours previously evaluated by JECFA. After elimination based on the pre-screening criteria, 38 food colours were eligible for prioritization for re-evaluation by JECFA.

7. The process used by this eWG to prioritize food colours for re-evaluation by JECFA is summarized below:

- A list of colours that met the prescreening criterion of having a provision in the GSFA, in a Codex food standard, or in the Codex step process was circulated to the eWG. Participants were invited to assess these colours using the prioritization form and fill out a table in which they recorded, for every colour, the qualitative score for every question on the form, the qualitative score for each Section, and the final numerical score.
- The results were tabulated. For each colour, the average final numerical score was calculated and the number of Low, Medium, and High scores for each Section was recorded. If an evaluator assigned a higher score to a question than most other evaluators and if, as a result, that evaluator obtained a higher score than most evaluators for the Section in which the question was found, the evaluator was asked to provide the rationale for the higher score.
- If the requested information was received and it supported the higher score, the Section in question was assigned the higher priority score given by that evaluator.
- For any colour for which one or more Sections were rescored based on information received, the remaining Section(s) was/were also reviewed and given a final qualitative score (Low, Medium, or High). The scoring for these other Sections was often unanimous among evaluators. If the scoring wasn't unanimous, the Section was scored by 'majority rule' whether no information had been requested (because a minority of evaluators assigned a lower score than most evaluators) or whether information that had been requested (from one or more evaluators assigning a higher score than most) was not received.
- A new final numerical score was then calculated based on the revised qualitative scores of the three Sections. Twenty-eight colours received a new numerical score in this manner.
- There were ten colours for which no information was received for any Section either because none was requested or because the requested information was not provided. For four of these colours, the scoring on all Sections had been unanimous. For one colour, one evaluator gave one Section a lower score than most, and no information was requested. For five colours, one evaluator gave one Section a higher score than most, but did not respond to a request for information. These ten colours retained their original score from the first ranking.
- After the second round of scoring as described above, the colours were ranked a second and final time based on their new (or retained) numerical score. Colours with the same or similar score were ranked as a group.

8. The second and final ranking of the food colours for prioritization for re-evaluation by JECFA is shown in the first column of Table 1. Colours were prioritized in groups, based on identical or similar scores (scores are in the third column of Table 1). The groups are shown in descending order of priority, Group 1 (allura red and tartrazine) having the highest priority and Group 9 (lycopene from three sources, paprika extract, and quinolone yellow) the lowest. The fourth column of Table 1 shows the final qualitative scores assigned to each of the three Sections which determined the numerical score according to the prioritization schedule on the Food Additive Re-evaluation Prioritization Form. For colours that retained the original numerical score, the total number of Low, Medium, or High scores for Sections for which scoring was not unanimous are shown (e.g., for red 2G, Section C had 1 Low and 1 Medium). The last column of Table 1 shows whether a colour was reassessed after the first round of scoring and (re-assessed or not) the questions for which information was requested but not provided are listed.

## Comments and recommendations

9. Based on the work of this eWG and issues that arose in fulfilling the terms of reference, the following comments and six recommendations regarding the prioritization process and the Food Additive Re-evaluation Prioritization Form are offered for consideration by the 45<sup>th</sup> session of the CCFA.

- (1) The efficiency of the eWG's work would have been increased by limiting the collection of information on colours to those colours that pass the first pre-screening question on the Food Additive Re-evaluation Prioritization Form (i.e., colours for which there is a provision in the GSFA, in a Codex food standard, or in the Codex step process).

The first term of reference for this eWG was to "compile information from members and other organizations, including from the industry producing food additives, on the list of the 107 food colours evaluated by JECFA since 1956." This is very general and in fact only 38 colours were assessed after elimination through the pre-screening Section of the prioritization form. There would be no point, for the purpose of prioritization for re-evaluation, in collecting information on colours that would be eliminated from consideration for re-evaluation. Therefore, it would have been more efficient if a more targeted request for information, listing the 38 colours to be prioritized and the type of information sought for those colours, could have been sent to the eWG. As an example specific to this eWG, such a request might read as follows:

*Attached is the list of 38 colours to be evaluated by this eWG. Please provide any information you may have (or become aware of during the existence of this eWG) about any of these colours that is relevant to the work of this eWG and not available in the general scientific literature. The following type of information would be useful for the purposes of this eWG: new or old unpublished studies (specify the type of study as per Section B of the prioritization form); changes in the manufacturing process (as per Question A2); evidence that exposure to the additive is changing (as per Section C of the prioritization form). When providing information on these colours, participants are asked to ensure that, if applicable, no confidential business information is disclosed.*

**Recommendation 1: Future working groups tasked with developing a prioritized list of food additives for re-evaluation, for JECFA's consideration, should be asked to prioritize only those additives that pass the first pre-screening question on the Food Additive Re-evaluation Prioritization Form (i.e., additives for which there is a provision in the GSFA, in a Codex food standard, or in the Codex step process).**

- (2) The date of the last JECFA evaluation (question A1 on the prioritization form) is usually a straightforward matter and is available from the JECFA website (<http://apps.who.int/ipsc/database/evaluations/search.aspx>). However, as noted during the eWG's work, the most recent evaluation by JECFA may not yet be reflected at the above website.

For example, a search for "sunset yellow" at the above website indicates that this colour was evaluated in 1982 and assigned an ADI of 0 – 2.5 mg/kg bw. However, in the WHO Technical Report Series No. 966 (2011) and WHO Food Additive Series No. 65 (2012), JECFA reported that it withdrew the ADI of 0 – 2.5 and replaced it with an ADI of 0 – 4.0 mg/kg bw at its seventy-fourth meeting in 2011. In TRS 966 and FAS 65, JECFA states that it was requested to evaluate sunset yellow by the 42<sup>nd</sup> CCFA and that it took note of three unpublished long-term feeding studies in rodents provided by the USA and a recently completed review by the European Food Safety Authority (EFSA). In the same TRS and FAS Reports, JECFA also reported having evaluated ponceau 4R and quinoline yellow at the seventy-fourth meeting, whereas according to the above website the latest evaluations were in 1983 and 1984, respectively. In its 2011 evaluations, JECFA retained the ADI for ponceau 4R but withdrew the ADI of 0 – 10 mg/kg bw for quinolone yellow and established a temporary ADI of 0 – 5 mg/kg bw for this colour pending studies to be submitted by the end of 2013.

Based on the above information, one evaluator in the eWG assigned a score of Low to question A1 for the three colours, but suggested that quinoline yellow should have a high priority as it was already in the process of re-evaluation by JECFA. This evaluator noted that the current prioritization form has no mechanism to deal with colours that are in the process of being re-evaluated by JECFA. All the other evaluators for the three colours assigned a score of Medium (>15 years) for the date of the last JECFA evaluation, presumably because of the date given on the JECFA website.

Given that the latest JECFA evaluations of sunset yellow, ponceau 4R, and quinoline yellow in the WHO Food Additive Series were published in 2012, that JECFA took into account recent questions concerning these colours (e.g., the Southampton studies) in addition to previously unavailable information, that two ADIs were revised (one revised ADI being established as temporary) and one left unchanged based on the evaluations, and that JECFA is awaiting studies for one colour (quinoline

yellow) such that it is currently under review, the approach taken by the evaluator assigning a Low score was reasonable. Consequently, in assigning the final prioritization ranking for these three colours in Table 1, this participant's scores for all three Sections of the prioritization form were used, as changing the date of the last JECFA evaluation in Section A to 2011 also changed the answers to the questions in Sections B and C about new safety studies and new intake information since the last JECFA evaluation.

**Recommendation 2:** Question A1 of the prioritization form should be revised to consider the World Health Organization Technical Report Series (TRS) or Food Additive Series (FAS) reports, in addition to the JECFA website, as sources for the date of the latest JECFA evaluation of an additive. The following text is for consideration by the CCFA: *“When did JECFA last evaluate this additive? To obtain the date, refer to the JECFA website and a World Health Organization Technical Report Series (TRS) or Food Additive Series (FAS) report. If there is a discrepancy between the JECFA website and a report, choose the date given in the report.”*

**Recommendation 3:** A second pre-screening question should be added to the prioritization form to screen out additives that are currently under review by JECFA or for which JECFA has requested information by a specified date. The following text is for consideration by CCFA: *“Is this additive currently under review by JECFA, or has JECFA requested more information about this additive by a specified date?”*

A “Yes” reply to this question would eliminate the colour from the prioritization process. Due to the addition of a second pre-screening question, the “score” of the “Yes” response to the first pre-screening question would be changed from “Proceed to Section A” to “Proceed to [Pre-screening] Question 2”.

- (3) There could be some variability in additives obtained from natural sources that results from the source material used and is not variation that results from the manufacturing process. Such variability is not clearly addressed by question A2 in the prioritization form.

Question A2 asks whether, since the last JECFA evaluation, there have been any significant changes to the manufacturing process, or whether there is variability in the manufacturing process, that could affect the identity or purity of the additive, including the type and levels of impurities in the additive. In answering this question, one eWG participant assigned a score of Medium for the natural food colours annatto extract, paprika extract, and paprika oleoresin, indicating that there have been changes or there is variability but these are not expected to affect the identity or purity of the substance. Other evaluators had assigned a Low score (“No”) for these colours.

This participant reasoned that natural colours contain more than one active pigment and that consequently (1) the ratio of pigment constituents would vary with climate or region of production and (2) the chemical structures of the constituents and the ratio of constituents could vary with the process of extraction and deodorization.

If this type of variability is considered in answering question A2, no colour obtained from a natural source could be assigned a score of Low for this question. Even if all manufacturers used the same extraction process, there could theoretically be differences in the sources harvested from different regions.

Concerns about the identity, purity or safety of an additive because of variation in the source from which the additive is obtained could be addressed through the specifications for the additive. JECFA has established purity tests for the colours that it has evaluated, including natural colours. For example, for paprika extract, it has established a procedure for extracting and measuring the amount of capsaicinoids and of capsanthin/capsorubin. For the latter group, the peaks that can be identified and quantified will elute in a given order, as follows: neoxanthin, capsorubin, violaxanthin, capsanthin, antheraxanthin, mutatoxanthin, cucurbitaxanthin A (capsolutein), zeaxanthin, cryptocapsin,  $\beta$ -cryptoxanthin,  $\beta$ -carotene.

A score of Medium or High for question A2 should be assigned only if a new manufacturing process is developed or if concerns have been expressed about the variation in manufacturing processes that could potentially lead to a significant variability in the nature and levels of constituents of toxicological concern. In a 2011 opinion, for example, the European Food Safety Authority (EFSA) expressed such a concern for the caramel colours.

**Recommendation 4:** Question A2 should be revised to specifically exclude variation in a food additive that is a result of variation in the source material and is not related to the manufacturing process if the variation is addressed through JECFA's specifications for the additive. The following text is for consideration by the CCFA: "Since the last JECFA evaluation have there been any significant changes to the manufacturing process, or is there variability in the manufacturing process, that could affect the identity or purity of the additive, including the type and level of impurities in the food additive? This does not include variability in additives obtained from a natural source that results from variation in the natural source and for which any identification, purity or safety concerns could be addressed through JECFA's specifications for the additive."

- (4) A revised Food Additive Re-evaluation Prioritization Form, with the changes suggested in Recommendations 2, 3, and 4, is shown in Appendix 1.

**Recommendation 5:** The CCFA consider the revised Food Additive Re-evaluation Prioritization Form, as shown in Appendix 1, for future use in developing prioritized lists of food additives for re-evaluation for JECFA's consideration.

**Recommendation 6:** The CCFA consider the ranking of the food colours as shown in Table 1 for recommending to JECFA the prioritization of colours for re-evaluation. In doing so, the Committee may wish to consider that if the colours had been ranked using the revised prioritization form in Appendix 1, quinoline yellow would have been eliminated from prioritization because JECFA is awaiting studies of this colour to be submitted by the end of 2013.

- (5) Finally, the following comments not directly related to the terms of reference for this eWG but pertaining to the classification of certain food colours are for consideration by the CCFA.

There is inconsistency in the classification of the colours called "Carotenoids" between the GSFA and JECFA. The GSFA groups the following four chemicals under the name Carotenoids: (1) carotenal, beta-apo-8'-; (2) carotenoic acid, ethyl ester, beta-apo-8'- (3) beta-carotenes, synthetic; (4) beta-carotenes, *Blakeslea trispora*. These chemicals were never given a group acceptable daily intake (ADI) by JECFA, which defines a different group of chemicals as "Carotenoids, mixed". However, JECFA assigned each of the above four chemicals, individually, an ADI of 0 – 5 mg/kg bw.

One of the eWG participants brought to the eWG's attention that new studies were available for some of the carotenoids and reported that EFSA had evaluated beta-apo-8'-carotenal (the first chemical in the above list) in 2012 and assigned to this colour an ADI of 0 – 0.05 mg/kg bw. The EFSA's ADI is one hundred times lower than that established by JECFA in 1974. The EFSA also evaluated carotenes from four different sources as one group: plant carotenes, algal carotenes, synthetic beta-carotene, and beta-carotene obtained by fermentation of the fungus *Blakeslea trispora* (the latter two colours being the same as the third and fourth above from the GSFA).

This participant proposed that the following four compounds be re-evaluated together: beta-carotenes synthetic, beta-carotenes *Blakeslea trispora*, carotenes vegetable, and algal carotenes.

Carotenoids are available from several natural sources and can be synthesized chemically. They could potentially be available from additional natural sources in the future. A range of compounds are obtained when carotenoids are extracted from natural sources and it is possible that different extraction methods could produce different ratios of chemicals in the finished colours even if the colours are from the same source.

Harmonization of the classification of "carotenoids" in terms of chemical structure and origin between the GSFA and JECFA would be helpful for anyone prioritizing food colours for re-evaluation in the future. In that regard, it may be useful to consult with industry on current manufacturing practices and uses for these colours.

Table 1: Final scores assigned to 38 food colours that were prioritized for re-evaluation by JECFA. Colours that received the same or a similar score are prioritized as a group. Scores could range from 1 (highest priority) to 10 (lowest priority). The qualitative scores for the three Sections (A, B, C) of the prioritization form from which the numerical score was derived are also shown. The Comments column indicates whether a colour was re-evaluated after an initial round of scoring and where requested information was not received from an evaluator who assigned a higher score to a Section than the one shown. More detailed information on the scoring process is provided in the Note at the end of this table.

Final Priority Ranking	Name of Colour	Final Prioritization Score	Final Scores (L, M, or H) for Sections A, B, and C, respectively*	Reassessed after first round of scoring? (Yes/No) Comments (including unanswered questions from first round)
<b>Group 1</b>	Allura red	<b>2</b>	M, H, H	(Yes)
	Tartrazine	<b>2</b>	M, H, H	(Yes)
<b>Group 2</b>	Brilliant blue	<b>4</b>	M, H, M	(Yes)
	Caramel colour class III	<b>4</b>	M, H, M	(Yes) Two of five evaluators gave Section C a Medium score (three gave Low). One provided information for Medium for question C1. Information from another for Medium for C2 was requested but not provided; however the score for Section C was changed to Medium based on question C1.
	Caramel colour class IV	<b>4</b>	M, H, M	(Yes) Two of five evaluators gave Section C a Medium score (three gave Low). One provided information for Medium for question C1. Information from another for Medium for C2 was requested but not provided; however the score for Section C was changed to Medium based on question C1.
	Erythrosine	<b>4</b>	M, H, M	(Yes)
	Fast green	<b>4</b>	M, H, M	(Yes)
	Indigotine	<b>4</b>	M, H, M	(Yes)
<b>Group 3</b>	Red 2G	<b>4.5</b>	M, H, (1L, 1M)	(No) One of two evaluators gave Section C a Medium (for question C1). Information was requested but not received. The original score was not changed.
	Brilliant black	<b>4.75</b>	M, H, (3L, 1M)	(No) One of four evaluators gave Section C a Medium (for question C2). Information was requested but not received. The original score was not changed.
<b>Group 4</b>	Caramel colour class I	<b>5</b>	M, H, L	(Yes) Four of six evaluators gave Section C a Low, but it received one each of Medium (for question C2) and High (for C1). Information was requested but not received.
	Caramel colour class II	<b>5</b>	M, H, L	(Yes)
	Carotenes (vegetable)	<b>5</b>	M, H, L	(Yes) One of six evaluators gave Section C a Medium (for question C2). Information was requested but not received.
	Carotenoids	<b>5</b>	M, H, L	(Yes)
	Grape skin extract	<b>5</b>	M, H, L	(Yes)
	Riboflavin	<b>5</b>	M, H, L	(Yes)
<b>Group 5</b>	Brown HT	<b>5.8</b>	M, (4H, 1L), L	(No)
	Paprika oleoresin	<b>6</b>	L, H, L	(Yes)
	Lutein from <i>Tagetes erecta</i>	<b>7</b>	M, M, M	(Yes)

Final Priority Ranking	Name of Colour	Final Prioritization Score	Final Scores (L, M, or H) for Sections A, B, and C, respectively*	Reassessed after first round of scoring? (Yes/No) Comments (including unanswered questions from first round)
<b>Group 6</b>	Beet red	8	M, M, L	(Yes)
	Canthaxanthin	8	M, M, L	(Yes) Two evaluators gave Section B a Low, one each gave it a Medium (for B1 and B2) and High (B1). Based on the information of one evaluator, the scores for B1 and B2 were changed to Medium. No information was provided by the evaluator who gave B1 a High; therefore Section B was scored as Medium.
	Chlorophylls, copper complexes	8	M, M, L	(Yes)
	Iron oxide red	8	M, (3L, 1H), L	(No) Information for the single High score for Section B (for question B1) was requested but not received. The original score was not changed.
	Iron oxide yellow	8	M, M, L	(Yes) One of three evaluators gave Section B a High (for question B1). Information was requested but not received.
	Titanium dioxide	8	M, M, L	(Yes)
<b>Group 7</b>	Iron oxide black	8.25	(1L, 3M), (3L, 1H), L	(No) Information for the single High score for Section B (for question B1) was requested but not received. The original score was not changed.
	Chlorophylls	8.83	M, L, (5L, 1M)	(No) Information for the single Medium score for Section C (for question C2) was requested but not received. The original score was not changed.
<b>Group 8</b>	Annatto extracts	9	L, M, L	(Yes) One of six evaluators gave Section C a Medium (for question C2). Information was requested but not received.
	Calcium hydrogen carbonate (Calcium carbonate in GSFA)	9	M, L, L	(No)
	Carmines	9	L, M, L	(Yes) One of six evaluators gave Section C a Medium (for question C2). Information was requested but not received.
	Chlorophyllins, copper complexes, sodium and potassium salts	9	M, L, L	(Yes) One of four evaluators gave Section B a High (for question B1). Information was requested but not received.
	Ponceau 4R	9	L, M, L	(Yes) This is the score given by one evaluator who took into account that JECFA re-evaluated ponceau 4R in 2011 (see discussion in Report).
	Sunset yellow	9	L, M, L	(Yes) This is the score given by one evaluator who took into account that JECFA re-evaluated sunset yellow in 2011 (see discussion in Report).
<b>Group 9</b>	Lycopene (synthetic)	10	L, L, L	(No)
	Lycopene extract from tomato	10	L, L, L	(No)
	Lycopene from <i>Blakeslea trispora</i>	10	L, L, L	(No)
	Paprika extract	10	L, L, L	(Yes) One of four evaluators gave Section B a Medium (for question B1). Information was requested but not received.
	Quinoline yellow	10	L, L, L	(Yes) One evaluator took into account that JECFA re-evaluated sunset yellow in 2011 (see discussion in Report); this score was used. JECFA is waiting submission of studies by the end of 2013. The current prioritization form does not have a mechanism for a case like this. The eWG recommends including a pre-screening question in the form for additives that are already in the process of being assessed by JECFA or for which JECFA is waiting for information by a specific date.

\* L = Low, M = Medium, H = High. For the colours that were not rescored in the second round, the number of H, M, L assigned to a given Section is shown in parentheses if all evaluators did not assign the same qualitative score to that Section.

**Note:** During a first round of scoring, all colours were assessed by individual evaluators using the Food Additive Re-evaluation Prioritization Form presented at the 44<sup>th</sup> meeting of the CCFA and endorsed with minor revisions by the Committee at that meeting. For each colour, the qualitative (Low, Medium, or High) scores given by individual evaluators to each of the two or three questions in each of the three Sections (A, B, and C) of the prioritization form and the resulting qualitative scores for each Section (determined by the highest score for any question in that Section) were tabulated, as was the numerical prioritization score obtained by each evaluator for that colour. The numerical prioritization score for a colour was derived from the qualitative score (Low, Medium, or High) assigned to each of the three Sections according to the prioritization schedule on the prioritization form. The numerical score could range from 1 for the highest priority (obtained when all three Sections were scored High) to 10 for the lowest priority (obtained when all three Sections were scored Low). The numerical prioritization score assigned to each colour in the first round of evaluations was the average of the numerical scores obtained by all the evaluators for that colour. When an evaluator's score for a question resulted in a higher priority ranking for the Section in which the question was found relative to that of most other evaluators, the evaluator was asked to provide reasons for assigning the higher score to that question. Based on the information the evaluator provided in response, the score for that question (and consequently for the Section in which it was found) could be changed. If the information requested was not provided, no changes were made as a result of that evaluator's higher score. When the score for a Section was changed based on an evaluator's input, the scores for the other Sections were then also reassessed to determine the most accurate qualitative score for those Sections — in the absence of other information this was usually determined by 'majority rule'. The final numerical scores shown in this table were derived from the qualitative scores assigned to the three Sections after input from the evaluators to the first scoring round.



**Appendix 1:**

Food Additive Re-evaluation Prioritization Form with proposed revisions shown in ***bold italics***. The changes include the addition of a second pre-screening question (as a result of which minor changes were made to the first pre-screening question), and changes to questions A1 and A2. (See Final Report, Recommendations 2, 3, and 4 for explanation).

Food Additive Re-evaluation Prioritization Form		Priority:
<b>Identification of Food Additive</b> (INS number, name of food additive, technological purpose)		____ - ____ - ____

**Pre-screening Section for Re-evaluation of a Food Additive**

**1) Are there currently one or more provisions for this additive in the Codex General Standard for Food Additives, in a Codex food standard, or in the Codex step process?**

No	= Does not require re-evaluation
Yes	= Proceed to <b>Question 2</b>

**2) Is this additive currently under review by JECFA, or has JECFA requested more information about this additive by a specified date?**

No	= Proceed to <b>Section A</b>
Yes	= Does not require re-evaluation

A. Status of the Food Additive with JECFA Score: Low, Medium, or High	Score
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**1) When *did* JECFA last evaluate this additive? To obtain the date, refer to the JECFA website and a World Health Organization Technical Report Series (TRS) or Food Additive Series (FAS) report. If there is a discrepancy between the JECFA website and a report, choose the date given in the report.**

≤15 years ago	= Low
> 15 years ago	= Medium

**2) Since the last JECFA evaluation have there been any significant changes to the manufacturing process, or is there variability in the manufacturing process, that could affect the identity or purity of the additive, including the type and level of impurities in the food additive? *This does not include variability in additives obtained from a natural source that results from variation in the natural source and for which any identification, purity or safety concerns could be addressed through JECFA's specifications for the additive.***

No	= Low
Yes, but the change(s) or variability is (are) not expected to affect the identity or purity of the food additive	= Medium
Yes, the change(s) or variability may affect the identity or purity of the food additive	= High

Total score for Status of the Food Additive with JECFA: Assign a score of Low, Medium, or High based on the highest score of Question 1 or 2	
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<b>B. Safety Information for the Food Additive</b> <b>Score: Low, Medium, or High</b>	<b>Score</b>
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1) Since the last JECFA evaluation, have any new toxicological studies or reviews, conducted in accordance with scientifically accepted principles, become available?	
No	= Low
Yes, there are new acute, ADME, subchronic, or genotoxicity studies	= Medium
Yes, there are new chronic, reproductive, developmental, or special studies (e.g. neurotoxicity study) or there is an overall review of available data (including new studies)	= High

2) Have any concerns about the food additive been raised by non-standard toxicological studies (e.g., clinical trials, epidemiological studies, studies on behavioural effects, biological properties, low-dose mechanistic studies)?	
No	= Low
Yes, one or more studies suggested the potential for minor health effects, or the relevance of observed effects in human health is unclear	= Medium
Yes, one or more studies suggested the potential for serious health effects	= High

3) Have there been any case reports, adverse reaction reports, or similar reports suggesting adverse health effects in humans?	
No	= Low
Yes	= Medium

<b>Total Score for Safety Information for the Food Additive: Assign a score of Low, Medium, or High based on the highest score of Question 1, 2, or 3</b>	
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<b>C. Intake of the Food Additive</b> <b>Score: Low, Medium, or High</b>	<b>Score</b>
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1) Since the last JECFA evaluation, have intake data, dietary modelling data, or other such data become available, which suggest that intake of the food additive could exceed the JECFA ADI?	
No	= Low
Yes, the available data based on conservative estimates suggest that intake may exceed the JECFA ADI	= Medium
Yes, the available data based on actual use levels suggest that intake may exceed the JECFA ADI	= High

2) Since the last JECFA evaluation, have disappearance data or similar data become available that suggest increased use of the food additive in the food supply?	
No	= Low
Yes, the available data suggest that use of the food additive has increased or may be increasing	= Medium

<b>Total Score for Intake of the Food Additive: Assign a score of Low, Medium, or High based on the highest score of Question 1 or 2</b>	
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**Total Score for Prioritization:**

The total score for prioritization is decided by the score of each of the three sections (A: Status of the Food Additive with JECFA, B: Safety Information for the Food Additive, C: Intake of the Food Additive).

The prioritization schedule below shows the ten possible outcomes ranked in order of precedence. Since all three sections are weighted equally, a score of, for example, "High, Medium, Medium" could mean any of the following:

A = High, B = Medium, C = Medium;

A = Medium, B = High, C = Medium;

A = Medium, B = Medium, C = High.

**Prioritization Schedule:**

- (1) High-High-High (2) High-High-Medium (3) High-High-Low
- (4) High-Medium-Medium (5) High-Medium-Low (6) High-Low-Low
- (7) Medium-Medium-Medium (8) Medium-Medium-Low (9) Medium-Low-Low
- (10) Low-Low-Low

**Note:** In addition to this categorization process, there are other streams by which a substance may be added to the priority list for re-evaluation. This would include substances whose re-evaluation has specifically been requested through the working group on priorities and agreed to by CCFA. Such a request for re-evaluation could also elevate the position of a substance already on the priority list.