

# Electronic Working Group on Options for the Use of the Prioritization Exercise of Compounds for Re-Evaluation by JECFA

First Circulated Draft for Comments

## Background

The 43<sup>rd</sup> session of the Codex Committee on Food Additives (CCFA) established an electronic working group (eWG) whose mandate was to establish criteria to prioritize food additives for re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This eWG was also tasked with establishing a detailed list of the 107 colours evaluated by JECFA since 1956; compiling information on these colours from members and other organizations; and establishing a prioritized list of food colours based on the prioritization criteria, for action by CCFA, including for consideration for re-evaluation by JECFA.

The eWG presented its work to the 44<sup>th</sup> Session of the CCFA in the document *Discussion Paper on Mechanisms for Re-evaluation of Substances by JECFA (CX/FA 12/44/17)*. The eWG had developed a tool that contained proposed criteria to prioritize food additives for re-evaluation. The 44<sup>th</sup> Session of the Committee revised the prioritization tool and established another eWG to (i) 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; and (ii) establish a prioritized list of food colours, based on the prioritization tool as revised at that session, for action by CCFA, including for consideration for re-evaluation by JECFA. This second eWG found that 38 food colours passed the prioritization tool's pre-screening question. The eWG prioritized the 38 colours using the tool, as revised by the 44<sup>th</sup> Session of the CCFA, and presented the outcome of this prioritization exercise at the 45<sup>th</sup> session of the CCFA in *Proposed Prioritised List of Colours for Re-evaluation by JECFA (CX/FA 13/45/17; Annex 1)*. However, the 45<sup>th</sup> Session of the Committee could not come to a conclusion regarding the necessary steps to link the prioritization exercise with the inclusion of a compound in the JECFA Priority List.

## Mandate

The 45<sup>th</sup> session of the CCFA agreed to establish a third eWG, led by Canada, open to all members and observers and working in English only, to prepare a discussion paper that would consider different options for the use of the outcomes of the prioritization exercise and other feasible steps to identify compounds for re-evaluation by JECFA, for consideration at the next session of the CCFA. Two options are proposed in this draft discussion document to address this mandate.

**Proposed options for linking the outcome of the re-evaluation prioritization process with the inclusion of a compound on the JECFA priority list.**

Before examining the options for linking the re-evaluation prioritization process to the JECFA priority list, it should be recognized that regardless of the final option selected, no changes are proposed that would affect the current mechanism allowing members to make urgent requests to include food additives on the JECFA priority list during the in-session working group on the priority list of compounds that is established by the CCFA at each of the Committee's sessions.

**Option 1:** Expand the *Priority List of Substances Proposed for Evaluation by JECFA* to include the list of food additives prioritized for re-evaluation and, in general, request that JECFA consider the additives in order of their priority ranking.

Option 1 necessitates that the CCFA establish eWGs to prioritize the other functional classes of food additives for re-evaluation, similar to the approach used with food colours by the 44<sup>th</sup> session of the Committee. The member leading the eWG would then present the prioritized list of additives to the in-session working group on the priority list of compounds that is established by the CCFA at each of the Committee's sessions. In general, the recommendation to the plenary session of the CCFA would be that the CCFA request JECFA to consider re-evaluating the additives based on their priority ranking according to the prioritization exercise until all additives on the list have been re-evaluated or otherwise considered.

The in-session working group could also recommend to the plenary that high priority be assigned to the re-evaluation of one or more of the additives. Assignment of high priority would be relative to the other requests for safety assessment and/or establishment of specifications of substances that are normally considered by the in-session working group. It would ultimately be up to JECFA to determine how many additives from the list could be re-evaluated at each of its meetings. JECFA might also wish to group various substances together, even though they may not be of the same priority for re-evaluation, in order to more efficiently conduct the re-evaluation.

The in-session working group would also identify the party that will be responsible for providing the data to JECFA and a date by which the data will be supplied. This is the same procedure that is currently used by the in-session working group for requests for safety assessments and/or establishment of specifications.

The recommendations of the in-session working group to the plenary would be made in consultation with JECFA since JECFA participates in the working group.

The CCFA may wish to consider whether to establish in advance a list of the functional classes of food additives to be prioritized for re-evaluation and the respective eWG leads for the prioritization of each group, or whether to decide on the next group to prioritize for re-evaluation as the need arises. The

Committee will also need to decide whether to continue the same re-evaluation approach once all additives within the Codex system that are eligible for re-evaluation have been considered by JECFA.

**Advantage(s) of Option 1:**

Option 1 allows for the eventual re-evaluation, at least once, of all food additives within the Codex system that are eligible for re-evaluation. It is not overly burdensome on JECFA's resources as JECFA would be able to re-evaluate the additives on the list according to its own work prioritization process until all the additives on the list have been considered.

**Disadvantage(s) of Option 1:**

Option 1 does not create a timeframe to complete the re-evaluation of food additives at least once and it does not create a schedule or cycle for ongoing re-evaluation of additives.

**Option 2:** Discontinue work to establish a formal re-evaluation process for all food additives and instead, formally recognize the current process for submitting proposals for additions and changes to the priority list of food additives proposed for evaluation by JECFA as a means for requesting re-evaluation of food additives on a case-by-case basis.

In the current process for submitting proposals for additions and changes to the priority list of food additives proposed for evaluation by JECFA, there is nothing preventing a member from proposing that a particular substance be added to the priority list to request that JECFA re-evaluate the additive. A member may wish to do this, for example, if new scientific information becomes available that, in the member's view, raises a safety concern about the additive.

To do so, the member would need to submit the request to CCFA using the *Form on Which Information on the Compound to Be Evaluated by JECFA Is Provided*, taking into consideration the criteria for the inclusion of substances in the Priority List.<sup>1</sup> Such requests would be submitted in reply to the Circular Letter requesting information and comments on the priority list of substances proposed for evaluation by JECFA that is distributed by the Codex Secretariat prior to each session of the CCFA. The CCFA would then consider the request during the in-session working group on the priority list of compounds proposed for evaluation by JECFA and by the plenary session of the Committee. The Committee can then decide whether to forward the request to JECFA (and whether to assign a particular priority to the request) for JECFA to consider in its own work prioritization.

The member would be responsible for identifying the relevant new scientific safety information on the *Form on Which Information on the Compound to Be Evaluated by JECFA Is Provided* and then for providing a date by which the Member could provide this information to JECFA for consideration.

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<sup>1</sup> The request for re-evaluation can be identified in the "Question(s) to be answered by JECFA" section at the top of the "Form On Which Information On The Compound To Be Evaluated By JECFA Is Provided".

**Advantage(s) of Option 2:**

Requests for JECFA to re-evaluate food additives would be submitted to JECFA on an as-needed basis in response to new safety information that has become available. This would satisfy the need for up-to-date safety assessments of food additives of immediate concern, while not overburdening JECFA's resources with potentially unnecessary re-evaluations.

**Disadvantage(s) of Option 2:**

Without a formal prioritization program for re-evaluating food additives, some additives may continue to go unevaluated for an indeterminate length of time, since no new scientific information may have become available that raises a safety concern. However, a re-evaluation of the additive could potentially reveal that the safety information upon which its permitted use(s) is (are) based may be inadequate by today's standards.

The Committee may need to determine whether or not an alternative process should be created to allow additives that have not been re-evaluated for a certain amount of time to be prioritized for re-evaluation.

**Action required by CCFA as a result of re-evaluation**

The CCFA will need to determine appropriate action for a food additive based on the outcome of JECFA's re-evaluation of the additive or other advice with respect to the additive. However, the Committee already can already make a recommendation to the Codex Alimentarius Commission to add, modify or remove food additive provisions of the General Standard for Food Additives (GSFA) based on JECFA's advice, so no new procedure is needed to act on the outcome of a re-evaluation by JECFA.

**Date for Comments**

Canada requests comments on these options by November 8th, 2013. Comments can be e-mailed directly to Mr. Steve Theriault ([steve.theriault@hc-sc.gc.ca](mailto:steve.theriault@hc-sc.gc.ca)), with a c.c. to Mr. Matthew Bauder ([matthew.bauder@hc-sc.gc.ca](mailto:matthew.bauder@hc-sc.gc.ca)) and to the Codex contact point Canada ([codex\\_canada@hc-sc.gc.ca](mailto:codex_canada@hc-sc.gc.ca)).

**List of food colours prioritized for re-evaluation by JECFA (excerpt from CX/FA 13/45/17)**

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.

<b>Final Priority Ranking</b>	<b>Name of Colour</b>	<b>Final Prioritization Score</b>	<b>Final Scores (L, M, H) for sections A, B, and C, respectively</b>	<b>Reassessed after first round of scoring? (Yes/No) Comments (including unanswered questions from first round)</b>
Group 1	Allura Red	2	M, H, H	(Yes)
	Tartrazine	2	M, H, H	(Yes)
Group 2	Brilliant blue	4	M, H, M	(Yes)
	Caramel colour class III	4	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	4	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.
	Erythosine	4	M, H, M	(Yes)
	Fast green	4	M, H, M	(Yes)
	Indigotine	4	M, H, M	(Yes)
Group 3	Red 2G	4.5	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.

Final Priority Ranking	Name of Colour	Final Prioritization Score	Final Scores (L, M, H) for sections A, B, and C, respectively	Reassessed after first round of scoring? (Yes/No) Comments (including unanswered questions from first round)
	Brilliant black	4.75	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.
Group 4	Caramel colour class I	5	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	5	M, H, L	(Yes)
	Carotenes (vegetable)	5	M, H, L	(Yes) One of six evaluators gave Section C a Medium (for question C2). Information was requested but not received.
	Carotenoids	5	M, H, L	(Yes)
	Grape skin extract	5	M, H, L	(Yes)
	Riboflavin	5	M, H, L	(Yes)
Group 5	Brown HT	5.8	M, (4H, 1L), L	(No)
	Paprika oleoresin	6	L, H, L	(Yes)
	Lutein from <i>Tagetes erecta</i>	7	M, M, M	(Yes)
Group 6	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)
Group 7	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.

Final Priority Ranking	Name of Colour	Final Prioritization Score	Final Scores (L, M, H) for sections A, B, and C, respectively	Reassessed after first round of scoring? (Yes/No) Comments (including unanswered questions from first round)
	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.
Group 8	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).
Group 9	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