



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Sixth Session

Hong Kong, China, 17-21 March 2014

DISCUSSION PAPER ON OPTIONS FOR THE USE OF OUTCOMES OF THE PRIORITIZATION EXERCISE AND OTHER FEASIBLE STEPS TO IDENTIFY COMPOUNDS FOR RE-EVALUATION BY JECFA

Outcome of the work of the electronic working group established by the 45<sup>th</sup> CCFA

*"The first JECFA meeting, in looking ahead, envisaged, in addition to the continuing evaluation of food additives, that there would be a re-evaluation process associated with the programme on food additive safety assessment."*<sup>1</sup>

**Background**

1. 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.

2. 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*.<sup>2</sup> 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 an additive in the Priority List of Substances Proposed for Evaluation by JECFA (referred to hereafter as the "JECFA Priority List").

**Mandate**

3. 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.

**Outcome of the eWG's work**

4. The eWG considered a draft discussion document in which two options were proposed for linking the outcome of the re-evaluation prioritization process with the inclusion of a compound on the JECFA priority list. The first option was to expand the existing JECFA Priority List to include the list of food additives

<sup>1</sup> Section 2.2 of *Principles for the Safety Assessment of Food Additives and Contaminants in Food*, Environmental Health Criteria 70, International Programme on Chemical Safety, 1987, referencing the first report from JECFA.

<sup>2</sup> CX/FA 13/45/17, Table 1

prioritized for re-evaluation and, in general, request that JECFA consider the additives in order of their priority ranking. The second option was to 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 JECFA Priority List as a means for requesting re-evaluation of food additives on a case-by-case basis.

5. Thirteen eWG participants commented on the two options.<sup>3</sup> It was clear from comments received that there is still debate about whether a systematic re-evaluation process for all additives in the Codex system is necessary. Overall, the eWG was of the view that there are conditions under which re-evaluation of food additives is warranted, but opinion was divided about whether a process should be in place to re-evaluate all eligible food additives or whether additives should only be re-evaluated on a case-by-case basis when, for example, new safety data about the additive become available.

6. A number of additives in the Codex system were evaluated many years ago, and their safety assessments and/or the data upon which those assessments were based may not meet today's standards. A systematic process for re-evaluating all eligible additives, such as that proposed in Option 1, would provide assurance that all food additives in the GSFA have been evaluated based on current safety assessment standards, whether or not new data about the additive have become available. However, a key issue is the resource constraints faced by JECFA in terms of its capacity to conduct re-evaluations in addition to its existing workload. It is questionable whether or not it is a good use of JECFA's resources to conduct re-evaluations of additives if new safety data about the additives are not available or safety concerns have not been raised. The work required of CCFA in prioritizing food additives for re-evaluation, which in the case of food colours proved to be intensive, also needs to be considered. Option 2, which proposes to formalize a process for re-evaluation on a case-by-case basis, meets the concern about resource constraints while addressing potential food safety concerns that are raised about an additive.

7. This document presents Options 1 and 2, much as they were presented in proposed form to the eWG, for the Committee's consideration, and also proposes a third option (Option 3) that was not reviewed by the eWG. Option 3 is a modification of Option 1 that may reconcile, at least to some extent, the major concerns identified by the eWG. Option 3 would see that all food additives that are enabled for use in the Codex system have undergone a safety assessment under today's assessment standards, and would do so without unduly impacting the resources of CCFA and JECFA.

8. The fourth and obvious option of *status quo* is put forward, as well. However, regardless of the option that is agreed upon by the CCFA, there is nothing that would preclude an urgent request for re-evaluation being made to JECFA, either directly or through CCFA, using current procedures (see Option 4 for details).

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

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

9. Option 1 necessitates that the CCFA prioritize the functional classes of food additives for re-evaluation, and then establish one or more eWGs to prioritize the additives in each functional class. The latter prioritization exercise would be similar to the approach used with food colours by the eWG established by the 44<sup>th</sup> session of the Committee. The Food Additive Re-evaluation Prioritization Form would be used for this work.<sup>4</sup>

10. The member leading the eWG for a given prioritization exercise would then present the prioritized list of additives from the functional class under consideration 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 requests of 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.

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<sup>3</sup> Comments were received from Australia, the European Union, the Federation of European Specialty Food Ingredients Industries (ELC), FoodDrinkEurope, the International Aluminum Institute (IAI), the International Association of Colour Manufacturers (IACM), the International Council of Beverages Association (ICBA), the International Food Additives Council (IFAC), Iran, the Natural Food Colours Association (NATCOL), the Netherlands, Russia, and the United States of America.

<sup>4</sup> CX/FA 13/45/17, Appendix 1

11. 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 JECFA Priority 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, to conduct the re-evaluations more efficiently. To avoid conflict between re-evaluation priorities between different functional classes, CCFA should only submit requests for re-evaluation of additives on one functional class at a time, until JECFA completes the re-evaluations of the additives from that list (unless an urgent request arises).

12. 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.

13. 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.

14. Once the CCFA has decided on the requests for re-evaluation to be made to JECFA, the Committee would need to establish an eWG to prioritize the additives for re-evaluation in the next functional class to be considered. 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. For example, the Committee may wish to consider establishing a regular cycle for re-evaluation.

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

15. 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.

16. Re-evaluation of all additives, at least once, would provide assurance that food additive provisions in the GSFA are acceptable based on current food safety assessment standards. JECFA would be able to re-evaluate the additives according to its own work prioritization process until all the additives to be re-evaluated have been considered.

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

17. Although JECFA could determine its own priority schedule for re-evaluating additives, a systematic re-evaluation of all food additives that are eligible for re-evaluation would, nevertheless, be a strain on resources for JECFA and the CCFA. The CCFA would have to prioritize the various functional classes of food additives for re-evaluation, and then prioritize the additives within each functional class for re-evaluation. The latter exercise, in the case of food colours, proved to be resource-intensive for the eWG that was established by the 44<sup>th</sup> session of the CCFA. JECFA would then need to re-evaluate the prioritized additives, and there is concern that this would compete with the evaluations of new food additives and processing aids and thereby negatively impact international trade in foods.

18. Also, Option 1 as it is currently framed 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-evaluations of additives (although, as suggested above, the Committee may wish to consider establishing a regular cycle for re-evaluation). It could be some time before JECFA is able to re-evaluate all the additives in a single functional class, and there are a number of functional classes of additives, so the Committee can expect it will take years to complete the first re-evaluation of all eligible food additives.

**Option 2:** Discontinue work to establish a formal re-evaluation process for all food additives, and formally recognize the *status quo* process for submitting requests for additions and changes to the JECFA Priority List as the recommended means for requesting re-evaluation of food additives on a case-by-case basis.

19. Under option 2, members would submit to CCFA proposals for re-evaluation in the same manner they would propose any other addition or change to the JECFA Priority List. A member might 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 JECFA Priority List.<sup>5</sup> Such requests would be submitted in reply to the Circular Letter requesting information and comments on the JECFA Priority List 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 JECFA Priority List 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.

20. 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.

21. Since requests for re-evaluation would be made on a case-by-case basis, there would be no need for CCFA to establish eWGs to prioritize all eligible additives within a given functional class using the Food Additive Re-evaluation Prioritization Form.

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

22. The only requirement for CCFA to implement Option 2 is that the Committee agree to formally recognize the process for submitting proposals for additions and changes to the JECFA Priority List as a means for requesting re-evaluation of food additives on a case-by-case basis. The advantage it offers over the *status quo*, is that if the CCFA formalizes the process for requesting a re-evaluation, there might be a broader awareness that one can make such a request through the Committee, and the Committee might then have a measure of control over the demand on JECFA's resources since the CCFA would determine which additives are appropriate, at the international level, for re-evaluation.

23. Requests from the CCFA to JECFA to re-evaluate food additives would be submitted to JECFA on an as-needed basis (for example, 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**

24. Without a formal prioritization program for re-evaluating all food additives that are eligible for re-evaluation, some additives may continue to go without a current safety assessment for an indeterminate length of time, since no new scientific safety research may be done with respect to the additive, and a re-evaluation of the additive could potentially reveal that the safety information upon which its GSFA provision(s) is (are) based may be inadequate by today's standards.

25. There is, however, little difference between Option 2 and the current process for adding substances to the JECFA Priority List that could be used for re-evaluation (i.e., *status quo*), and there is concern that this option would not add any added value to the current practice of submitting proposals for re-evaluation and that it would undermine the work done by previous eWGs concerning the prioritization of food additives.

**Option 3:** Prioritize the eligible additives in a given functional class that were evaluated before a particular year (i.e., a year before which evaluations may not necessarily meet current safety assessment standards, referred to hereafter as the "cut-off" year), and request that JECFA consider re-evaluating the prioritized additives. Consideration for re-evaluation may mean, for example, that JECFA re-evaluate an additive, deem a re-evaluation to be unnecessary, or identify data deficiencies that prevent re-evaluation and issue a call for data.

26. Once JECFA has considered the requests for re-evaluation, a continuous cycle for re-evaluation (or the consideration of re-evaluation) of all food additives once a particular time period has elapsed since their previous evaluation could be established.

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<sup>5</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 3**

This option specifically addresses the issue that the provisions for some additives within the Codex system are based on old safety assessments that may not meet current assessment standards, without initially burdening JECFA with the re-evaluation of all eligible additives within each functional class, as would occur with Option 1. It would also provide assurance that food additive provisions in the GSFA are based on current safety assessment standards since it would implement a cycle for re-evaluating all additives.

### **Disadvantage(s) of Option 3**

27. It could be argued that Option 3, like Option 1, still entails a suboptimal use of JECFA's resources because the re-evaluations would be conducted primarily on the basis of time since their last evaluation, and not necessarily because a safety concern has been raised.

### **Option 4: Status quo.**

28. The Committee can already use the current mechanism for adding substances to the JECFA priority list to make requests for re-evaluation on a case-by-case basis. Also, requests for re-evaluation can be submitted directly to the JECFA Secretariat without going through CCFA, and the JECFA Secretariat can, itself, include re-evaluation of a food additive on the agenda of a JECFA meeting even if an outside request for re-evaluation has not been received.<sup>6</sup>

### **Advantage(s) of Option 4**

29. The *status quo* already allows for the re-evaluation of additives on a case-by-case basis, so maintaining it does not place any additional burden on CCFA or JECFA, unless there is an increase in the number of such requests for re-evaluation.

### **Disadvantage(s) of Option 4**

30. As with Option 2, without a formal prioritization program for re-evaluating all food additives that are eligible for re-evaluation, some additives may continue to go without a current safety assessment for an indeterminate length of time. This is because no new scientific information may become available that raises a safety concern, yet a re-evaluation of the additive could potentially reveal that the safety assessment upon which its provision(s) for use is (are) based may be inadequate by today's standards.

### **Comments and recommendations**

31. A key concern with a systematic re-evaluation program is the resource constraints faced by JECFA in terms of its capacity to conduct re-evaluations in addition to its existing workload. The work required of CCFA in prioritizing food additives for re-evaluation needs also to be considered.

### **Recommendation 1**

32. The CCFA should request of the JECFA Secretariat to comment on JECFA's capacity to add the re-evaluation of food additives to its existing workload, and on how JECFA's ability to evaluate additives and flavourings and establish their specifications would be impacted by a systematic re-evaluation process. Also, both CCFA and the JECFA Secretariat should consider how requests for re-evaluation, submitted directly to the JECFA Secretariat without routing them through CCFA, could have an impact on JECFA's work.

### **Recommendation 2**

33. Consider Options 1, 2, 3 and 4, propose modifications to these options or propose alternatives, and decide upon which option to proceed with.

### **Recommendation 3**

34. If the CCFA proceeds with Option 1 or a modification thereof, the Committee should establish a list of the functional classes of food additives to be re-evaluated, in priority sequence, and set a schedule for eWGs to prioritize each functional class.

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<sup>6</sup> *Food additives and food contaminants - FAO procedural guidelines for the Joint FAO/WHO Expert Committee on Food Additives*. Rome: FAO Joint Secretariat to JECFA, 2003. [http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/2003-02-24\\_Food\\_Add\\_Cont\\_Guidelines.pdf](http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/2003-02-24_Food_Add_Cont_Guidelines.pdf)

**Recommendation 4**

35. If the CCFA proceeds with Option 3 or a modification thereof, request the JECFA Secretariat's advice regarding which year would be an appropriate cut-off year for determining which additives need to be prioritized for re-evaluation. For example, is there a cut-off year before which safety evaluations would not, in general, be considered to meet current safety assessment standards? To help create a re-evaluation cycle, the CCFA should also ask the JECFA Secretariat's advice regarding an appropriate time period that can elapse before a re-evaluation should be done, in the absence of a safety concern being raised.

**Recommendation 5**

36. Pursuant to recommendation 4, if Option 3 is selected, the elapsed time from the last evaluation by JECFA is the primary consideration in the eligibility of an additive for re-evaluation. The eligible additives in any functional class would then be prioritized in a similar fashion as was done for food colours using the Food Additive Re-evaluation Prioritization Form, but without considering the time elapsed since the previous evaluation. Consequently, the Committee should consider deleting question 1 in Section A ("Status of the Food Additive with JECFA") of the Food-additive Re-evaluation Prioritization form, concerning the date that the last JECFA evaluation was performed.

**Recommendation 6**

37. The Committee should consider, in consultation with the JECFA Secretariat, whether to add some or all the prioritized food colours, which were considered by the 45<sup>th</sup> session of the CCFA (see Annex I), to the JECFA Priority List.

**Recommendation 7**

38. If Option 1, 2 or 3 is agreed upon by the CCFA, establish an eWG tasked with preparing a discussion paper to propose the operational procedure(s) for the option (Option 4, *status quo*, does not need a new procedure).

**Annex 1****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.
	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)

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)
	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.
	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



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)
				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.