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RE. ICGMA eWG Comments on Prioritization Criteria for the Reevaluation of Food Additives by JECFA

The International Council of Grocery Manufacturers Associations (ICGMA) is a nongovernmental organization that represents foods and consumer packaged goods manufacturers globally. ICGMA promotes the harmonization of food standards and policies based on science and is a strong supporter of Codex Alimentarius. ICGMA also works to facilitate international trade of food products by eliminating or preventing artificial barriers to trade and believes that global harmonization of food additive standards is important to achieve that goal.

ICGMA thanks the Canadian delegation for its work on a proposed approach by which the Codex Committee on Food Additives (CCFA) may be able to prioritize existing substances for re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). ICGMA welcomes the opportunity to critically evaluate this first draft of the prioritization approach.

As noted in the June 17, 2011 circulation, the terms of reference for this eWG are as follows:

i) to establish criteria to prioritize food additives for re-evaluation;
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.

ICGMA wishes to underscore the importance of the very first term of reference, “establish criteria to prioritize food additives for re-evaluation.” We believe that terms of reference (iii) and (iv) cannot be satisfactorily addressed without an initial thorough consideration of what would constitute appropriate prioritization criteria. As such, ICGMA believes that a focus on collecting specific information (e.g., safety data, information on manufacture and use) on colours at this point, or any other particular additive class, is premature and distracts from the critical preliminary work of establishing appropriate general prioritization criteria. Additionally, there seems to be confusion: (a) between risk management, risk assessment, and prioritization principles in the draft document, and (b) about the appropriate bodies that would be responsible for each task.
ICGMA Recommendation

ICGMA recommends a more simplified and streamlined approach to an effective prioritization mechanism that will allow CCFA to set JECFA priorities, limited only by available JECFA resources. ICGMA’s proposed prioritization mechanism would allow JECFA to focus re-evaluation on those substances that may have a significant impact (i.e., negative or positive) on consumer health, and that are more widely used and/or highly consumed by certain sub-populations. In summary, we recommend that prioritization may be warranted if and when valid and reliable information becomes available indicating (1) an increase or decrease in human health concern, and (2) a significant change in exposure/use pattern since the most recent JECFA review. We discuss this in more detail below.

Suggested Criteria. ICGMA suggests the following prioritization criteria for a JECFA re-evaluation of existing substances based on safety:

- Where an expert scientific risk assessment body has derived a health based guidance value (HBGV) (e.g., Acceptable Daily Intake (ADI), Tolerable Weekly Intake (TWI)) for a particular additive significantly lower or higher than the established JECFA HBGV for that additive, and
- Where consumption data (e.g., reliable monitoring data, intake estimates) from 2 or more countries indicate the potential for a significant increase in exposure since the previous JECFA assessment.

Some of the concepts in the eWG draft document that should be considered within the above framework include:

- Is there currently widespread use of the additive?
- New information on existing substance is forthcoming. Tentative ADI is ranked higher than no ADI which is ranked higher than numerical ADI which is ranked higher than ADI “Not Specified”.
- An independent expert scientific panel deems that the new information is: (i) relevant to human health, (ii) based on an adequate study design and study protocols that follow internationally recognized guidelines, and (iii) is of sufficient quality to be reliable.
- Change in specification (e.g., new limit for heavy metals, change in manufacturing process, etc.) should only be considered when that change suggests a potential safety concern (e.g., possible presence of new impurities or a change in levels of existing minor constituents not considered in the previous JECFA review)
- Existing dietary intake estimates or changes in anticipated food consumption patterns \(^1\) may result in exceeding the JECFA established ADI.

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\(^1\) Existing dietary intake estimates OR change in anticipated food consumption patterns should be based on a number of different geographic regions as defined by the GEMS/Food Consumption Cluster Diets. (Risk Analysis Principles for CCCF – 20th ed. Codex Procedural Manual p.120, p. 132)
ICGMA General Comments
After reviewing the first draft of Canada’s “list of prioritization criteria”\(^2\), ICGMA has many concerns with the proposed approach as noted below:

- The granularity of the suggested approach, specifically, the assignment of quantitative values to specified criteria, is misleading. The numerical values assigned to specified criteria and the calculation of a numerical overall score depend on arbitrary assumptions. There is an implication that the approach is truly quantitative, when it is not. There should be general CCFA agreement on any values or relative weights assigned to different prioritization criteria.
- Inappropriate grouping of criteria as surrogates for safety and exposure.
- The inappropriate weighting scheme for surrogates of safety and exposure criteria. This likely skews the outcome.
- The criteria themselves do not seem to adequately address safety/exposure concerns, and in some cases are not criteria at all. (please see Appendix – Notes B(iii) and C(i).)
- Outcome of the prioritization exercise may rely too heavily on a single government’s concern (without sufficient supporting data from other governments).
- Exposure information from a single national authority should not be the sole criterion by which an additive is prioritized for evaluation by JECFA, unless there is reason to expect the diets of other countries and/or regions would also be affected.\(^1\)
- There is no opportunity for a JECFA re-evaluation of those substances for which recent toxicological evaluation demonstrates a lowered safety concern, thereby increasing the HBGV thus allowing for increased international trade of foods containing those substances.

ICGMA commends the Canadian delegation for its leadership in this effort and thanks you for taking these comments into consideration.

Sincerely,

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\(^2\) FA Prioritization Criteria, eWG draft1, 17Jun2011.doc
Appendix – ICGMA Specific Comments

A. Status of Food Additive with JECFA:
   i. Point A1 places too much emphasis on the date of last evaluation. It is more important to determine whether new data since the last evaluation justifies the need for re-evaluation. More importantly, the first threshold question ought to be whether the substance actually has widespread use.
   ii. Point A2 suggests that more weight would be given to a substance with an allocated ADI, over a substance without.
   iii. Point A2 regarding ADIs that were not allocated due to lack of information (or tentative ADIs) ought to be linked up with Point B1 where an outstanding request for more information has been (or is expected to be) received.
   iv. Point A2 also suggests that an ADI of “Not Specified” is of equal concern as a numerical ADI. This is contrary to the concept of generally safe for use when certain substances are assigned ADIs of “Not Specified”.
   v. Point A3 incorrectly suggests that a change to the food additive specification warrants a re-review. Point A3 ought to be linked with Point A4 referring to a change in the manufacturing process AND Point B7 in which levels of impurities may vary due to a change in the manufacturing process.

B. Safety Information for the Food Additive:
   i. Point B1 as stated above ought to be linked with Point A2, regarding outstanding requests for information to help refine the existing ADI.
   ii. Points B2, B3, B4, and B5 ought to be combined as they relate to NEW information that has come available since the last JECFA evaluation indicating potential concern. NEW information ought to be considered ONLY IF it is relevant to human health, the study design is adequate to address the concern raised, AND the data is of sufficient quality that it is reliable. A causal link between the food additive ingested AND adverse impact noted is very rarely established in epidemiological studies. An independent expert scientific panel review of all the available information would need to occur to help identify which data are relevant for further consideration. This independent expert scientific panel would be a “risk assessment” body, not a “risk management” body. A change in ADI (by a national expert scientific panel) may warrant prioritization and further review by JECFA.
   iii. Point B6 relates to a change in national standards for a food additive provision, which may not necessarily reflect a safety concern but result from a risk management decision. This criterion ought to be deleted. Limiting use or imposing warning labels is the responsibility of the “risk management” body (not the “risk assessment” body). The risk management body has different objectives and operates under different set of rules.3,4 Other considerations such as economic

3 The European Commission (EC) is currently evaluating which of the authorized additives are still currently in use, proposing to revise/delete existing authorized provisions according to use (not safety).

4 The European Commission now requires a warning label for each of the 6 Southampton Colors specifying that these colors “may have an adverse effect on activity and attention in children”, in spite of the European Food Safety Authority (EFSA) Opinion that (i) for 3 of the 6 colors a lower ADI is not warranted, and (ii) for Sunset Yellow, a lower ADI was not the result of any neurobehavioral concerns. (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178694648892.htm) The warning label is out of an abundance of precaution, not due to any real safety concern. All of the color additives used in the Southampton Study and listed in Annex V of Regulation 1333/2008 have received positive safety assessments from the main safety bodies globally. The proposed
consequences (e.g., due to the nature and particular constraints of the production or processing methods, transport and storage) may also influence risk management decisions.

iv. As mentioned previously, Point B7 ought to be linked up with Points A3 and A4.

C. Exposure to the Food Additive

i. Points C1 and C2 ought to be combined as the question of provisions should not be considered twice, whether in the GSFA or in the Step process. However, existing provisions do not indicate that those additives are ALWAYS used for those food categories but indicate that they MAY be used. A more appropriate surrogate for exposure may be to consider which food categories are major contributors of exposure to a given additive for a specified subpopulation/high eater, which have HIGH maximum use levels, and whether there is reason for concern based on these conservative estimates. Thus, Points C1 and C2 ought to be lumped together with Point C3, in which the question of current dietary intake exceeding JECFA ADI is raised. However, current dietary intake estimates should factor in multiple national surveys, as Codex serves as an international standard. The toxicological concern as stated in Point C3 is reflected in the ADI and does not have to be restated when considering whether dietary intake exceeds the established ADI.

ii. Point C4 pertains to a “change” in anticipated use patterns, and whether the dietary intake of a particular additive would likely increase/decrease as a result of this change. Any change in use pattern would be reflected in national food consumption surveys. However, this criterion by itself should not justify the need to re-evaluate an existing substance, as Codex represents an international standard. A number of different geographic regions as defined by the GEMS/Food Consumption Cluster Diets ought to be an important factor when considering “change” in use pattern within different countries.\(^1\)

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\(^1\) Labeling requirements for foods containing certain colours ignores even the European Food Safety Authority (EFSA) opinion on the Southampton study, which concluded that it contained several weaknesses and that there was no reason to change the official position that these additives are safe for use. Opinions on the study from other food safety assessment bodies support the EFSA position (e.g., UK Committee on Toxicity, German Federal Institute of Risk Assessment, Food Standards Australia and New Zealand (FSANZ)).