CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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DISCUSSION PAPER ON MECHANISMS FOR RE-EVALUATION OF SUBSTANCES BY JECFA

(prepared by the JECFA secretariat)

Introduction

1. The need to develop a more systematic approach on the re-evaluation of food additives, for which the JECFA assessment has been performed a long time ago has been discussed by JECFA as well as by CCFA repeatedly.

2. Over the last decades, risk assessment methods and principles have been further developed, and also additional data may have become available for many additives previously evaluated. Hence it seems appropriate to re-evaluates several of the food additives.

3. The 41st session of the Codex Committee on Food Additives (CCFA) noted the importance of a systematic review programme on food additives previously assessed, when changes in knowledge and scientific advancements become available, thereby contributing to the assurance of the safety.

4. The Committee requested the JECFA Secretariat to prepare a discussion paper, in which more information should be provided, for further discussion on this issue at the 43rd session of CCFA.1

Background

5. JECFA was established in 1956. Since then, JECFA evaluated more than 2400 chemicals (around 600 food additives excluding flavouring agents). According to an analysis performed by the secretariat (see Table 1 for details),

- More than 420 food additives (66%) were evaluated before 1990
- About 180 evaluations of food additives (30%) are older than 30 years

6. Of the 512 current specifications monographs:

- 2000-2010 29%
- 1990-1999 27%
- 1980-1989 24%
- Before 1980 20%

7. It has to be acknowledged that, in addition to this above information, all specifications monographs with limits for metals and arsenic, which constitute a large majority of the specifications monograph, have been updated during the last 10 years. These updated specifications monographs have been adopted as Codex specifications.

8. JECFA continually stressed the importance of a periodic review on substances previously assessed, and asked to develop the mechanism to reflect the changing knowledge and scientific advancement to

[1] ALINORM 09/32/12, paras 141-142

provide the best possible assurance of consumer safety related to food additives (see Reports of JECFA meetings: 3rd, 7th, 8th, 9th, 21st; also EHC 70)

9. Reviews of past decisions on safety of food additives, contaminants and residues of pesticides and veterinary drugs may be necessary as a result of one or more of the following developments (adapted from FAO/WHO, 1970):

- A new manufacturing process;
- A new specification;
- New data on the biological properties of the compound;
- New data concerning the nature or the biological properties, or both, of the impurities present;
- Advances in scientific knowledge germane to the nature or mode of action;
- Changes in consumption patterns, levels of use or dietary exposure estimates;
- Improved standards of safety evaluation.

10. A considerable amount of re-evaluation of substances is already carried based on specific requests, but not in systematic way. A process to select and prioritize compounds for re-evaluation should be developed.

11. Establishing a priority order for the re-evaluation of compounds requires input from a number of sources. Within the risk analysis paradigm, the system for periodic review, including the determination of priorities for re-evaluation, is part of risk management and, for JECFA, this is the responsibility of FAO, WHO and CAC, through its committees.

12. The following situations are triggers for prioritizing substances for re-evaluation:

- Substances for which new data raise suspicion of significant hazard;
- Substances for which there is evidence to question the validity of the data submitted for the previous evaluation;
- Substances previously allocated a temporary ADI, where the requested additional data are available;
- Substances whose re-evaluation has been requested by FAO or WHO; and
- Substances whose re-evaluation has been requested by CAC.

13. The use of an international forum to devise and implement a system for the periodic review of chemicals used in or on food could also be of great economic and practical value to Member States. It would ensure a uniform approach, duplication of effort would be minimized, and emphasis on such a programme would give added reassurance to consumers throughout the world that the food supply continues to be safe. Such a programme could be developed in cooperation with CAC and CCFA.

Other body's activity

JMPR

Purpose

14. The Codex Committee on Pesticide Residues (CCPR) has a Periodic Review Programme in place that provides an opportunity for data submission for scheduled compounds based on a timetable that is made for several years ahead and reviewed annually. ADIs and MRLs will be revoked if no data or inadequate data are provided.

Criteria

15. CCPR applies criteria for periodic re-evaluation such as the level of public health concern, available data, the elapsed time since the last toxicological review (> 15 years) or issues in trade.

System

16. The first periodic reviews were carried out by JMPR in 1992 following wide discussion of the principles at CCPR in 1991 and 1992. JMPR will evaluate available studies according to modern scientific

standards and will not rely on data submissions to FAO and WHO from previous years. Up to now JMPR has a continuous re-evaluation system for pesticides.

17. Some countries/regions may have started re-evaluation programs. As an example the program for a systematic re-evaluation recently started within the EU is described below.

Europe (EFSA and Nordic Group)

Purpose

18. The European Commission has asked the European Food Safety Authority (EFSA) to undertake a re-evaluation of all currently permitted food additives. This review has started with food colours and will then progress to other groups of food additives.

19. In 2000, a report entitled "Food additives in Europe 2000" [2] has been submitted by the Nordic Council of Ministers to the Directorate-General Health and Consumer Protection, European Commission. More than 300 of food additives sorted by E number were considered in this report.

20. The strategy is to establish health based priorities for re-evaluation.

Criteria

21. In determining the extent of re-evaluation necessary, the weight given to various types of information needs to be considered.

- Reported adverse effects in humans.
- Reported new toxicological studies.
- Estimated or actual exposure data, if indicating that the intake exceeds the ADI.
- Evidence of reproducibility of effects and results from well-designed and controlled studies.
- The quality of the data, being expected to conform to GLP.
- Case by case.

System

22. A four stages process constitutes the EFSA re-evaluation system.

- Stage 1. An information gathering stage. The information included:
    - Brief summary and evaluation of existing EU and JECFA evaluations.
    - Consideration of the evaluation of the additive in the Nordic report and its comments on the substance.
    - A literature search to identify relevant published literature.
- Stage 2. Decision stage undertaken by expert panel (AFC Additives Working Group). Based on the current guidelines for the assessment of food additives (SCF, 2001) and used to identify whether there are a. Data gaps, b. Uncertainties in the existing data, c. Any new evidence of potentially harmful effects.
- Stage 3. Data request: provision of data by industry and other interested parties, for each additive identified as needing further re-evaluation.
- Stage 4. Evaluation stage. Once the required data have been submitted, six months from supply of these data is scheduled for EFSA's re-evaluation.

Proposed framework for a JECFA re-evaluation system for food additives

23. Establishment of detailed list of food additives evaluated by JECFA, organized by year of evaluation and grouped by reported main technical function.

[2] Nordic Council of Ministers, Food additives in Europe 2000- Status of safety assessments of food additives presently permitted in the EU

24. Gathering information from member countries, literatures and other organizations on food additives previously evaluated by JECFA.

25. Establishing a prioritized list of food additives (except flavours) for re-evaluations, based on the following proposed criteria:

- New information on changes in manufacturing process or specification;
- New data on biological properties of the compound;
- Advances in scientific knowledge germane to the nature or mode of action;
- Changes in consumption patterns, levels of use or dietary exposure estimates;
- Overall indication that previous evaluation may be changed
- Time since last evaluation
- Concern raised by Member State or Organization.

26. Propose re-evaluation schedule for the next 5-10 years.

Further step

27. Member Countries and Organizations are invited to consider this discussion paper regarding a periodic re-evaluation system for food additives.

28. It is proposed that an electronic work group should be established to agree on criteria for a periodic re-evaluation system, and based on these criteria establish a prioritized list of food-additives for re-evaluation by JECFA, based on information and more recent evaluations available at national and regional authorities.

Table 1 the status of food additives evaluated by JECFA since 1956 through 2008

Years of evaluation / Technological class	*Older than 30 years number(percent of total)*	*20-30 years number(percent of total)*	*10-20 years number(percent of total)*	*Less than 10 years number(percent of total)*	*Total*
Colour	52 (49%)	36 (34%)	7 (7%)	12 (11%)	107
Emulsifier	29 (28%)	42 (41%)	21 (20%)	11 (11%)	103
Texturizer, thickener, stabilizer, glazing agent, etc.	17 (19%)	43 (49%)	12 (14%)	16 (18%)	88
Preservative	21 (40%)	3 (6%)	20 (38%)	9 (17%)	53
Antioxidant	21 (41%)	10 (20%)	18 (35%)	2 (4%)	51
Sequestrant	14 (36%)	20 (51%)	4 (10%)	1 (3%)	39
Sweetener	1 (4%)	11 (39%)	9 (32%)	7 (25%)	28
Carrier	1 (5%)	10 (45%)	3 (14%)	8 (36%)	22
Flavouring enhancer	2 (9%)	12 (55%)	4 (18%)	4 (18%)	22
Acidity regulator	6 (32%)	8 (42%)	4 (21%)	1 (5%)	19
Colour retention agent	2 (11%)	6 (32%)	7 (37%)	4 (21%)	19
Flour treatment and beaching	11 (73%)	1 (7%)	1 (7%)	2 (13%)	15
Humectants	1 (7%)	6 (43%)	3 (21%)	4 (29%)	14
Firming agent	7 (54%)	2 (15%)	3 (23%)	1 (8%)	13
Other functions	3 (6%)	29 (62%)	2 (4%)	13 (28%)	47
OVERALL	**188 (29%)**	**239 (37%)**	**118 (18%)**	**95 (15%)**	**640**

Information is extracted from the WHO JECFA summary database of evaluation summaries: http://apps.who.int/ipsc/database/evaluations/search.aspx