



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

## CODEX COMMITTEE ON FOOD ADDITIVES

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## DISCUSSION PAPER ON USE OF ADDITIVES IN ADDITIVES (SECONDARY ADDITIVES)

Prepared by the European Union

1. At the 45<sup>th</sup> Session of the Codex Committee on Food Additives (hereafter the Committee) the delegation of the European Union expressed concerns on the issue of food additives used in food additives in relation with the specifications arising from the 76th Session of JECFA. The Delegation was of the opinion that the Committee, in its capacity of risk manager, should first consider how the use of food additives in food additives should be addressed and whether criteria for their use should be developed. The Committee supported the recommendation of the JECFA Secretariat to develop guidance on how to address the use of additives in additives and to prepare a discussion paper for the next session of the Committee.<sup>1</sup>

**Introduction**

2. The General Standard for Food Additives (GSFA) sets forth the conditions under which food additives may be used in foods. The food category system is used as a tool for assigning food additive uses in the Standard. However, food additives are often marketed as preparations/formulations in which substances such as food additives (called "secondary additives"<sup>2</sup> for the purpose of this document) and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dispersing, dilution or dissolution. The same applies to preparations of enzymes, flavourings and nutrients. In all these cases secondary additives are used to have a technological function in preparations and not in the final food. The preparations of food additives, food flavourings, food enzymes or nutrients are not mentioned in the food category system of the GSFA.

3. There is in some cases a technological reason for the use of secondary additives (e.g. polyols used as carriers in preparations, emulsifiers used in glazing agent preparations, preservatives used in colour preparations etc.).

4. Secondary additives have to be distinguished from processing aids which do not have any technological function in preparations, which may be present only as non-intentional but unavoidable residue and may form an integral constituent (impurity) of a food additive for which limits could be established in the specifications.

5. The aim of the discussion paper is to consider how to address the use of secondary additives and whether principles/criteria for their use should be developed by the Committee. As secondary additives are used not only in preparations of additives but also in preparations of enzymes, flavourings and nutrients also the latter uses are considered in this paper.

**Issues Identified**1- Secondary additives in the GSFA

6. The GSFA does not contain principles/criteria how to deal with secondary additives. Certain reference to secondary additives is included in Section 4 "Carry-over of Food Additives in Foods"<sup>3</sup>. Although secondary additives used in enzymes, flavourings or nutrients are not explicitly mentioned in this section, it could be assumed that they would be covered by the term "ingredients".

<sup>1</sup> REP13/FA, paras. 121-122.

<sup>2</sup> The term "secondary additives" refers to food additives used in the preparations of additives, enzymes, flavourings or nutrients not having a technological function in the final food.

<sup>3</sup> This section stipulates that an additive may be present in a food as a result of carry-over from a raw material or ingredients provided that (a) the additive is acceptable for use in the raw materials or other ingredients (including food

7. According to the applicable principles, the Committee identifies and recommends appropriate food categories and use levels for inclusion in Tables 1 and 2 of the GSFA. Food additives with “Not Specified” Acceptable Daily Intake are included in Table 3 of the GSFA. If the technological function of an additive relates only to food additives, flavourings, enzymes or nutrients then this use falls out of the scope of the current GSFA food category system and no further guidance how to deal with these uses is provided.

8. Despite the missing principles/criteria for secondary additives in the GSFA several provisions for these additives have already been included therein. For example, some GSFA notes indicate a possible use of secondary additives (e.g. *Note 12 Carryover from flavouring substances*, *Note 65 Carryover from nutrient preparations*, *Note 131 As a result of use as a flavour carrier* etc.).

## 2- Information on secondary additives from other sources than the GSFA

9. The *Guidelines for the Use of Flavourings* (CAC/GL 66-2008) contain the general principles for the use of non-flavouring ingredients including secondary additives. According to the Guidelines non-flavouring food ingredients should be (a) *limited to the lowest level required to ensure the safety and quality of the flavourings, and to facilitate their storage and ease of use; (b) reduced to the lowest level reasonably possible when not intended to accomplish a technological function in the food itself; and, (c) used in accordance with the provisions of the Codex General Standard for Food Additives (GSFA; CODEX STAN 192) whenever they are intended to provide a technological function in the finished food.*

10. Information on secondary additives used in enzyme preparations is contained in the General Specifications and Considerations for Enzyme Preparations used in Food Processing<sup>4</sup>. In the definition of enzyme preparations it is clarified that *they may contain one or more active components as well as carriers, solvents, preservatives, antioxidants and other substances consistent with good manufacturing practice.* Furthermore, it is outlined that *the carriers, diluents, excipients, supports and other additives and ingredients (including processing aids) used in the production, distribution and application of enzyme preparations must be substances that are acceptable for the relevant food uses of the enzyme preparations concerned, or substances which are insoluble in food and removed from the food material after processing.*

11. In certain cases, JECFA includes information on secondary additives in specifications for additives or enzymes (e.g. using sentences like “*Antioxidants permitted for use in food may be added for stabilizing purposes.*” or “*The final product is formulated using food-grade stabilizing and preserving agents and is standardized to the desired activity.*”).

## **Discussion**

12. The Section 1.1 of the GSFA Preamble states that *only the food additives listed in the GSFA are recognized as suitable for use in foods in conformance with the provisions of the Standard.* It has to be noted that also secondary additives could be carried-over to foods from their use in additives, enzymes, flavourings or nutrients.

13. According to the section 1.2 of the GSFA Preamble, the GSFA should be the single authoritative reference point for food additives. The section 4 indicates that principles/criteria for the use of secondary additives should be in the Standard and that the use of secondary additives should adhere to them (e.g. “*the additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the Standard*”). The GSFA does not provide any specific principles/criteria for the use of secondary additives, however, it does not exclude secondary additives from the current principles either. The absence of such principles/criteria might be perceived as a gap in the GSFA. On the other hand principles/criteria, if developed, will provide the necessary certainty and clarity as regards the use of secondary additives.

14. The inclusion of a food additive provision in the GSFA is considered if there is a function in a food falling under the GSFA food category system. However, missing rules on how to deal with secondary additives in the GSFA have created misunderstandings and complicated discussions on the food additive provisions proposed for inclusion in the Standard. In the absence of clear guidance several provisions on secondary additives have been included in the GSFA creating inconsistencies.

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additives) according to the Standard, (b) the amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the Standard and (c) the food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of the standard.

<sup>4</sup> [http://www.fao.org/ag/agn/jecfa-additives/docs/enzymes\\_en.htm](http://www.fao.org/ag/agn/jecfa-additives/docs/enzymes_en.htm)

15. Information on secondary additives is contained in other documents than the GSFA such as the *Guidelines for the Use of Flavourings*, the General Specifications and Considerations for Enzyme Preparations used in Food Processing and JECFA specifications for certain food additives and enzymes.

16. In relation to JECFA specifications of food additives, further clarification should be provided as regards the part "definition". It could be questioned whether it is appropriate that the definition of certain food additives includes reference/s to secondary additive/s. It should be clarified by the risk assessor whether the safety evaluation is related to the substance itself or to its preparation (e.g. if secondary additives would be needed to assure the safety of the additive assessed) and also whether a possible exposure to secondary additives was considered in the risk assessment.

17. The responsibility for establishing the criteria to be used as well as to endorse food additive provisions is in the remit of the Committee in its role of risk manager in accordance to the rules and principles outlined in the Procedural Manual and the GSFA Preamble. Whilst the general references to secondary additives in specifications developed by JECFA might provide the user with useful information it is up to the Committee to establish principles/criteria for the use of secondary additives.

18. In addition to procedural aspects (role of risk assessors versus risk managers) it is unclear how exposure assessment to food additives could be carried out when general references to secondary additives (e.g. "*antioxidants permitted for use in food may be added for stabilizing purposes*") are included in the specifications.

19. The exposure assessment is defined as *the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant*<sup>5</sup>. Currently, general references to secondary additives in specifications do not provide any information which would be useful for the exposure assessment. In many cases there would not be an exposure concern (e.g. for food additives with the Acceptable Daily Intake (ADI) "Not Specified") and therefore in such cases the development of general principles for the use of secondary additives might be considered as sufficient. However, certain additives have been assigned very low numerical ADIs and the contribution to the intake from their use as secondary additives might not be negligible. Also if the exceedance of an ADI is indicated for a certain food additive a possible restriction of its use as a secondary additive should be considered as well. In this respect, it is essential to determine the conditions for use of secondary additives and apply an uniform approach.

### **Should principles/criteria for the use of secondary additives be developed?**

20. The development of harmonised principles/criteria on secondary additives is necessary not only to provide certainty and clarity for their use but also from a safety point of view (use of certain secondary additives with low numerical ADI values to ensure that the overall intake does not exceed their ADIs). Therefore, it seems appropriate to address the use of secondary additives by developing harmonised principles/criteria applicable to the use of all secondary additives (not only to additives in additives) in the GSFA. It would be appropriate to take into account the information available (e.g. from the *Guidelines for the use of flavourings* or the *General Specifications and Considerations for Enzyme Preparations used in Food Processing*).

### **Recommendations**

21. Reflecting upon the arguments outlined in the discussion paper the Committee is invited to consider the following recommendations:

#### **Recommendation 1**

22. The Committee is invited to consider whether principles/criteria for the use of secondary additives should be developed:

##### **Option 1**

Principles and criteria for the use of secondary additives should be developed to improve the current situation which is unclear.

##### **Option 2**

There are not sufficient grounds to develop principles and criteria for the use of secondary additives.

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<sup>5</sup> Procedural Manual – 21<sup>st</sup> edition, page 115.

**Recommendations below are only to be considered if Option 1 of the Recommendation 1 is supported**

**Recommendation 2**

23. The Committee is invited to consider whether principles/criteria to be developed should be applicable to all secondary additives or limited to food additives in food additives:

**Option 1**

Principles and criteria should be applicable to all uses of secondary additives (i.e. the use of additives in food additive preparations/formulations, additives in preparations of food enzymes, additives in flavourings and additives in nutrients).

**Option 2**

Principles and criteria should be limited to the uses of secondary additives in food additives.

This option may lead to inconsistencies on the use of secondary additives since several documents currently refer to the use of secondary additives (e.g. *Guidelines for the Use of Flavourings* and *General Specifications and Considerations for Enzyme Preparations used in Food Processing*).

24. If the Committee supports the development of principles/criteria at a later stage it should be considered how they should be enacted. Furthermore, the GSFA should be scrutinised to identify the secondary additive provisions already included in the Standard and consider how to deal with these provisions in accordance with the established principles/criteria.