DISCUSSION PAPER ON SECONDARY FOOD ADDITIVES

Prepared by an electronic Working Group (EWG) led by the European Union whose members included Argentina, Australia, Belgium, Benin, Brazil, China, France, Greece, India, Indonesia, Iran, Japan, Luxembourg, Malaysia, Netherlands, New Zealand, Nigeria, Norway, Russia, South Africa, Republic of Korea, United Kingdom, United States of America, Joint FAO/WHO Expert Committee on Food Additives (JECFA), Calorie Control Council (CCC), European Chemical Industry Council (CEFIC), Collagen Casing Trade Association (CCTA), European Specialty Food Industries (ELC), International Association of Color Manufacturers (ICMA), International Alliance of Dietary/Food Supplement Associations (IADSA), Institute of Food Technologists (IFT), International Frozen Food Association (IFFA), International Chewing Gum Association (ICGA), International Council of Beverage Associations (ICBA), International Food Additives Council (IFAC), International Council of Grocery Manufacturers Associations (ICGMA), International Organization of the Flavor Industry (IOFI), International Special Dietary Foods Industries (ISDI) and Specialised Nutrition Europe (SNE)

Background

1. At the 45th Session of the Committee on Food Additives (hereafter the Committee) the delegation of the European Union expressed its reservation on the references to food additives used in food additives (secondary food additives) in specifications arising from the 76th Session of JECFA. The delegation was of the opinion that the Committee, in its capacity as 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 delegation of the European Union agreed to prepare a discussion paper on the use of secondary additives for the next session of the Committee (REP13/FA, paras. 121-122).

2. The discussion paper (CX/FA 14/46/18) was presented at the 46th Session of the Committee. The paper outlined that secondary additives were normally incorporated in preparations of food additives, enzymes, flavourings and nutrients and noted that there was neither single consolidated source of information on secondary additives nor any harmonised principles and rules on how to deal with them. In the discussion the delegations recognised the importance of the topic and that principles and criteria could be developed to help clarify how secondary additives can be managed best. However, there were differing views on how to proceed and other aspects (e.g. limited CCFA resources; no reported safety concerns) were mentioned as well.

3. As a way forward the Committee supported the proposal of the Chairperson and agreed to establish an EWG, led by the European Union and working in English only, to further develop the discussion paper and, in particular, to develop a definition for secondary additives and analyse the issue of secondary additives including potential inconsistencies in their current handling by the CCFA. The EWG can make recommendations, if appropriate, to the 47th session of the CCFA on possible ways to address the use of secondary additives (REP14/FA, paras. 126-128).

Discussion by the EWG

4. Two rounds of consultation were undertaken within the EWG.

5. In the first round a definition of secondary food additives was proposed by the Chair and the members of the EWG were requested to comment on the proposal. In addition, the Chair presented an analysis of the issue of secondary additives including reasoning why the use of secondary additives should be addressed reflecting the current principles/criteria applicable to food additives. The members of the EWG were requested to send their comments and/or to offer alternative ways forward.
6. In the second round the EWG members were requested to comment on the proposals for changes to the definition received in reply to the first circular. As regards possible ways forward the proposals received in reply to the first circular were summarised and formulated into four options. The members of the EWG were requested whether the options proposed cover all appropriate ways how to address the use of secondary additives.

7. The following parts of the discussion paper summarise the outcomes of the two rounds of consultation and present the recommendations to the Committee.

**General considerations on secondary food additives**

8. Food additives, enzymes, flavourings and nutrients are often marketed as preparations/formulations in which substances such as food additives and/or other food ingredients are incorporated during or immediately after the manufacture to ensure their stability (e.g. antioxidants in carotenoid colours; preservatives in enzymes) or later on to ensure their effective use (e.g. making a fat soluble additive water soluble/miscible; diluting to facilitate effective mixing with food; standardising an additive).

9. Those food additives, which have a technological function only in the preparations and not in the foods in which the primary additive or the enzyme, flavouring or nutrient has a function, can be considered secondary additives. The primary additive has no function in the additive preparation, but only in the food in which the preparation is used.

10. When a food additive in a food additive, food enzyme, food flavouring, or nutrient is added to a food and still has a technological function in that food, it shall be considered a food additive of that food and not a secondary food additive, and must then comply with the conditions of use for that food as provided for in the GSFA in the appropriate food category.

11. In case an additive is present in a final food due to carry over from its use/function in an ingredient other than a preparation of food additives, enzymes, flavourings or nutrients then this additive is not a secondary additive.

12. Secondary additives should also be distinguished from processing aids, which: (i) do not have any technological function either in preparations or in any other foods; and (ii) which may be present only as a non-intentional but unavoidable residue. In food additives, processing aids may be present as a result of the manufacturing process (e.g. sulphur dioxide in anthocyanin colours) and maximum levels for residues are, where appropriate, included as a criterion in the specification monographs.

1- Definition of secondary food additives

13. Based on the above considerations and taking into account the definitions of a “Food Additive” and a “Processing Aid” as laid down in the Codex Procedural Manual1 the following definition of secondary food additives was proposed in the first circular:

“**Secondary food additive** is a food additive used in preparations of food additives, enzymes, flavourings or nutrients exerting a technological function in those preparations and not having a technological function in the final food. Secondary food additives are incorporated in the preparations in particular to facilitate their storage, standardisation, dispersion, dilution or dissolution. The term does not include processing aids which do not have any technological function in the preparations.”

14. The majority of members of the EWG supported the definition as proposed. However, some members expressed their doubts on whether such definition was needed. In addition, certain changes to the definition were suggested (e.g. changing the scope of the definition) and certain remarks requesting further clarification were raised (e.g. to clarify differences and relationship between carriers and secondary additives). The comments received on the definition proposed in the first circular were formulated into 8 proposals tabled for discussion in the second circular. Taking into account the comments received in reply to the second circular the definition was revised and the Recommendation 1 was formulated (see below).

Recommendation 1

15. The Committee is invited to endorse the definition of secondary additive presented below and to consider its inclusion in the Codex Procedural Manual (Definitions for the purposes of the Codex Alimentarius, 22nd Ed. (2014)) and/or Section 2 (Definitions) of the Preamble to the GSFA.

“**Secondary food additive** means any food additive that: (i) is used in preparations of food additives, enzymes, flavourings or nutrients (including substances with physiological effect) that are formulated particularly for commercial use; (ii) exerts a technological function in those preparations; and (iii) does

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not have a technological function in the food in which those preparations have a function. Secondary food additives are incorporated in the preparations to fulfil a technological function in that preparation (e.g. to facilitate their storage, standardisation, dispersion, dilution or dissolution). The term does not include processing aids which do not have any technological function in the preparations or in the food in which the preparations have a function."

2- Analyses of the issue of secondary additives

16. There is no single consolidated source of information on secondary additives in the existing Codex texts, but such information is scattered in different documents. Also no harmonised principles and rules to deal with secondary additives have been developed by Codex.

2.1 – Secondary additives in the GSFA

17. The GSFA sets forth the conditions under which food additives may be used in foods. Section 1.1 of the Preamble to the GSFA clarifies 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". Section 1.2 of the Preamble stipulates that "the GSFA should be the single authoritative reference point for food additives". While the Preamble does not provide specific guidance on how to account for secondary additives within the GSFA, Section 4.1\(^2\) indicates that a (secondary) additive may be present in a food as a result of carry-over from its use in a (primary) food additive provided such use is acceptable according to the GSFA (see Section 4.1a) and that the amount of the (secondary) additive in the (primary) additive shall not exceed the maximum use level specified in the GSFA (see Section 4.1b).

18. Section 5 of the Preamble clarifies that the food category system is a tool for assigning food additive uses in the GSFA and that the food category system applies to all foodstuffs. Despite the fact that according to the Codex definition of food the preparations of additives, enzymes, flavourings and nutrients are foods and that food additive provisions are principally assigned to the food categories in which the additives are functionally effective, there is currently no food category within the GSFA that corresponds specifically to preparations to address the use of additives which are functionally effective in the preparations only. In the absence of specific guidance a few notes indicating a possible use of secondary additives have been included in the GSFA within the current food category structure - e.g. Note 12: Carryover from flavouring substances (1 provision), Note 65: Carryover from nutrient preparations (no provision), Note 131: As a result of use as a flavour carrier (3 provisions). It remains unclear whether other food additive provisions for secondary additives without any note indicated such use have been introduced in the GSFA.

2.2 – Information on secondary additives from other sources

19. Information on secondary additives is also contained in documents other than the GSFA such as the Guidelines for the Use of Flavourings (CAC/GL 66-2008), the General Specifications and Considerations for Enzyme Preparations used in Food Processing\(^*\) or the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979). In certain cases, JECFA has included information on secondary additives in specifications for additives or enzymes (see CX/FA 14/46/18, paras. 9-11).

20. The absence of clarity as to whether and how secondary food additives should be addressed in the GSFA has created misunderstandings and complicated discussions on the food additive provisions proposed for inclusion in the GSFA. Whilst general information on secondary additives in specification monographs might be beneficial for the producers and users of the preparations, it is the responsibility of the Committee in its role of risk manager to consider the application of the principles for the use of food additives and endorsing food additive provisions to secondary additives.

\(^2\) 4.1 Conditions Applying to Carry-Over of Food Additives from ingredients and raw materials into foods

Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that:

a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this 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 this Standard;

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 this standard.

\(^3\) http://www.fao.org/ag/agn/jecfa-additives/docs/enzymes_en.htm
3- Possible ways to address the use of secondary food additives

21. While there might be different options on how to address the use of secondary additives the majority of the EWG members supported the view presented in the first circular that the use of secondary additives should be addressed within the GSFA. Addressing the issue within the GSFA would be the most pragmatic and consistent approach which would fully reflect the current principles/criteria applicable to food additives.

22. The reasoning for such approach is detailed in the bullet points below:

- Preamble to the GSFA indicates that secondary additives are in its scope (are not excluded);
- Inclusion of secondary additive provisions in the GSFA on a consistent basis will create clarity, legitimacy and certainty for their use which will be recognised at the international level in the Codex standard;
- Principles and criteria of inclusion of food additive provisions in the GSFA are transparent and well elaborated, therefore, it seems appropriate to also use the same approach for secondary additives (no additional burden comparing to the current practices);
- The GSFA has the aspiration to be the single authoritative reference point for food additives, therefore, it seems logical that the standard deals also with secondary additives.

23. In reply to the first circular proposals how to address the use of secondary food additives were submitted by the EWG members. The proposals were summarised and formulated into 4 options which were included in the second circular together with their analysis and an example demonstrating a possible impact of the options proposed.

24. The options were:

(i) Establishment of a new category in the GSFA food category system to address the use of secondary additives – i.e. “Preparations of food additives, enzymes, flavourings and nutrients”;
(ii) Addressing the use of secondary additives by use of notes within the current GSFA food category system;
(iii) Addressing the use of secondary additives through inclusion of appropriate limits in specifications for food additives, and for preparations of enzymes, flavourings and nutrients; and
(iv) Introducing changes to the Preamble to the GSFA to legitimatise the use of secondary additives.

25. The majority of the EWG members supported the establishment of a new category in the GSFA. Some support was also expressed to address the use of secondary additives by means of notes. Those two options are proposed for further consideration (Recommendation 2).

26. Addressing the use of secondary additives via specifications was not supported. It was questioned whether such option would be feasible, that it would require too many resources and that the interaction between JECFA and CCFA would need to be clarified.

27. Option 4, was only supported by Codex Observers, and no support was expressed by Codex Members on this option alone. However, in the comments it was indicated that certain changes to the Preamble to the GSFA might be needed when enacting the other options. Therefore, the Recommendation 3 was formulated for consideration of the Committee. The comments referred in particular to Section 4 of the Preamble to the GSFA.

28. In reply to the second circular a new option to consider developing a separate Guideline for the Use of Secondary Food Additives which would explain the use of secondary additives in various preparations and its relationship to the relevant provisions in the GSFA was proposed. That proposal is reflected in the Recommendation 4.

29. It should be noted that some EWG members were not favourable to further work on secondary additives, or whilst admitting that clarification is desirable for the sake of clarity and consistency alone, they proposed to progress step by step in addressing the issue in the GSFA. It was raised that while assessing the way forward the impact on the other Codex texts which refer to secondary additives should be considered.
Recommendation 2

30. The Committee is invited to consider if the use of secondary additives should be addressed within the GSFA. If this is supported the CCFA is invited to consider the two options proposed to address the use of secondary additives in the GSFA:

Option 1

Establishment of a new category in the GSFA food category system to address the use of secondary additives – i.e. “Preparations of food additives, enzymes, flavourings and nutrients”

Option 2

Addressing the use of secondary additives by use of notes within the current GSFA food category system

Recommendation 3

31. If recommendation 2 is supported, the Committee is invited to consider if changes to the Preamble to the GSFA would be needed.

Recommendation 4

32. The Committee is invited to consider whether developing a separate “Guideline for the Use of Secondary Food Additives” would be useful to explain the use of secondary additives in various preparations and its relationship to the relevant provisions in the GSFA.