

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME****CODEX COMMITTEE ON FOOD ADDITIVES****Forty-Eighth Session****Xi'an, China, 14-18 March 2016****DISCUSSION PAPER ON SECONDARY FOOD ADDITIVES**

Prepared by an electronic Working Group (EWG) led by the European Union

whose members included Argentina, Australia, Belgium, Brazil, Canada, China, Czech Republic, India, Indonesia, Iran, Ireland, Japan, Kenya, Malaysia, New Zealand, Republic of Korea, Russian Federation, Singapore, Spain, Switzerland, United Kingdom, United States of America, Association of Manufacturers and Formulators of Enzyme Products (AMFEP), Calorie Control Council (CCC), European Specialty Food Ingredients Industries (ELC), FoodDrinkEurope (FDE), International Association of Color Manufacturers (ICMA), International Chewing Gum Association (ICGA), International Alliance of Dietary/Food Supplement Associations (IADSA), 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 (CCFA45) 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 meeting 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 delegation of the European Union agreed to prepare a discussion paper for the 46th Session of the Committee ([REP13/FA](#), paras. 121-122).
2. The discussion paper ([CX/FA 14/46/18](#)) 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.
3. At CCF46 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 relevant aspects were mentioned as well. Therefore, the Committee agreed to establish an EWG to develop a definition for secondary additives and analyse the issue of secondary additives and if appropriate, to make recommendations on possible ways forward ([REP14/FA](#), paras. 126-128).
4. The discussion paper ([CX/FA 15/47/19](#)) for CCFA47 invited the Committee to endorse the definition developed by the EWG and to consider the recommendations on possible ways forward as formulated in Recommendation 2 (i.e. addressing the use of secondary additives within the GSFA (i) by establishment of a new category or (ii) by use of notes), Recommendation 3 (if recommendation 2 is supported to consider if changes to the Preamble to the GSFA are needed) and Recommendation 4 (development of a guideline on secondary food additives).
5. CCFA47 agreed on a three-step approach to address the issue of the secondary food additives: (i) to consider the proposed definition in detail with a view to have at this stage a working definition which would facilitate the understanding of the issue; (ii) to further analyse the Preamble of the GSFA and whether all aspects of the working definition were already covered; and (iii) to analyse the impact of these gaps, if any, to the GSFA ([REP15/FA](#), para. 145). At that meeting the Committee addressed point (i) and endorsed the working definition of secondary food additives.

Mandate of the EWG

6. To continue its work on this matter (i.e. Step ii and iii as indicated above), the Committee agreed to establish an EWG, led by the European Union, open to all Members and observers and working in English only, to:

- (i) Compare the working definition with the Section 4 in the Preamble of the GSFA;
and if the analysis under (i) establishes that Section 4 does not appropriately cover all the aspects of the definition
- (ii) Analyse what would be the impact of the definition on the GSFA.
The report of the EWG will be considered by CCFA48, which will decide on the way forward (REP15/FA, paras. 148-149).

Discussion by the EWG

7. Two rounds of consultations were undertaken within the EWG. In the first round the EWG was tasked to compare the working definition with Section 4 of the Preamble to the GSFA based on the analysis outlined in the first circular. The analysis focused on (a) whether and how the Preamble addresses the preparations of food additives, enzymes, flavourings, nutrients or substances with physiological effect that are formulated particularly for commercial use (hereafter “preparations”) listed in the definition; and (b) how the use of secondary additives relates to the principles on how food additive provisions are currently accounted for in the GSFA and whether the Preamble (and Section 4 in particular) provides with any indication on how to deal with secondary food additives in the GSFA.

8. In the second round the EWG members were requested to consider the impact of the definition on the GSFA based on the analysis contained in the first circular and on the comments received from the EWG members. Reflecting the comments three options were outlined in the second circular and the EWG members were requested to express their opinions on the appropriateness and impact of those options.

9. The following parts of the discussion paper summarise the content of the two circulars and the comments submitted by the EWG members.

First round of the consultation

Relation of carry over principle to the definition of secondary food additives

10. Carry-over is a broad term to describe the transfer of an additive from raw materials or food ingredients whether or not the additive is functional in the food to which it is transferred. The meaning of the term “secondary food additive” is explained in its definition, which clarifies that secondary additives are food additives exerting a technological function in preparations and not having a technological function in the food in which those preparations have a function. It should be noted that secondary additives are present in foods as a result of carry-over from preparations.

11. CCFA47 agreed to the following working definition of secondary food additives ([REP15/FA](#), para. 147):

“Secondary food additive means any food additive that: (i) is used in preparations of food additives, enzymes, flavourings, nutrients or substances with physiological effect that are formulated particularly for commercial use; (ii) exerts a technological function in those preparations (e.g. to facilitate their storage, standardisation, dispersion, dilution or dissolution); and (iii) does not have a technological function in the food in which those preparations have a function. 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.”

12. The members of the EWG offered some comments¹ on the working definition which could deserve further reflection; however, they were not considered further taking into account that the definition was extensively discussed and agreed at CCFA47 and that this issue was not under the mandate of the EWG.

¹ The comments included:

- Suggestion to add preparations of processing aids in the definition,
- To indicate that it is “the intention” of secondary food additives to have a function in food additive preparations,
- Amending the definition to reflect that flavourings are considered food additives (i.e. to amend the text of the definition as follows....*(i) is used in preparations of food additives (including flavourings), enzymes,...*),
- Amending the wording “*nutrients or substances with physiological effect...*” to “*nutrients and other substances with physiological effect...*” taking into account that nutrients are substances with a physiological effect as well or

13. One EWG member pointed out that certain functional classes (i.e. colours, flavour enhancers and sweeteners) should not fall within the secondary food additive uses because they do not meet the definition (they do not exert a technological function in the preparations). Another EWG member was of the view that it should be clarified which functional classes are needed for the use in preparations. It was noted that most commonly secondary food additives are used as carriers and that Table 3 additives would cover the vast majority of food additive uses in preparations.

14. Section 4 of the Preamble to the GSFA explains the principle of carry-over of food additives into foods. It has three parts as follows:

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.*

4.2 Special conditions applying to the use of food additives not directly authorised in food ingredients and raw materials

An additive may be used in or added to a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard, including that any maximum level applying to the food is not exceeded.

4.3 Foods for Which the Carry-over of Food Additives is Unacceptable

Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.

- a) 13.1 - *Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.*
- b) 13.2 - *Complementary foods for infants and young children.*

Interpretation of Section 4.1

15. Section 4.1 explicitly refers to the use of secondary food additives in food additive preparations (see the text “(including food additives)”). The interpretation of the wording “*other ingredients*” is crucial to consider whether the carry-over principle also covers other types of preparations listed in the definition. Only if there is a common understanding that “*other ingredients*” cover other types of preparations the carry-over principle would be generally applicable to all ingredients used in foods including preparations of enzymes and nutrients or substances with physiological effect.

16. The vast majority of the EWG members were of the view that “*other ingredients*” cover all preparations listed in the definition, however, that such understanding is not obvious and that an amendment of Section 4.1 may be required to provide better clarity and to avoid confusion. One EWG member noted that the ingredient definition² in paragraph 2 of *General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)* could be applied for the interpretation of that term in Section 4.

17. The majority of the EWG members acknowledged that there is a gap in the GSFA since according to Section 4.1 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. It was noted that the current food category system does not contain any food category for preparations, which would legitimise the use of secondary

to refer just to “*nutritional substances*” taking into account that the term “*substances with physiological effect*” is not recognized in other Codex texts,

- Request for clarification of the wording “*...are formulated particularly for commercial use*” and
- Request for clarification of the scope of the applicability of the definition as regards enzymes.

² “Ingredient” means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form.

food additives. Therefore, some EWG members suggested considering the Option 1 in Recommendation 2 proposed in CX/FA 15/47/19 (i.e. the establishment of a new food category on preparations) to close the gap.

18. Some other EWG members were of the view that there is no gap in the GSFA. According to them Table 3 additives could be used in preparations (Table 3 lists additives permitted for use in food in general except for foods listed in Annex to Table 3) and the provisions for additives with numerical ADIs could be addressed via the reverse carry-over principle laid down in Section 4.2, i.e. an additive may be used in or added to a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard, including that any maximum level applying to the food is not exceeded.

19. One EWG member suggested that the history of the wording of the Preamble needs to be considered to interpret the intent of Section 4. According to that EWG member CX/FA 11/43/14³ suggests that additives carried over to the finished food which are non-functional in it do not require a provision in the GSFA. However, it seems that the sentence⁴ in CX/FA 11/43/14 relates only to a composite food and not to the ingredients from which additives are carried over and for which the authorisation would be required according to Section 4.1.

20. Another EWG member, whose view was echoed by other two EWG members, was of the view that secondary food additives are not food additives and therefore they should not be addressed within the GSFA. It should be noted that such view contradicts the working definition as agreed by the Committee (i.e. “*Secondary food additive means any food additive...*”) and the wording of Section 4.1 which explicitly refers to the use of food additives in food additives according to the Standard.

Interpretation of Section 4.2

21. Divergent views were expressed on the relevance of Section 4.2 to secondary food additives. Some EWG members considered that Section 4.2 can only partially cover some secondary food additive uses – i.e. cases in which a food additive permitted for use and needed in foods falling within the categories 1-16 is at the same time needed for use as a secondary food additive in preparations added to those foods.

22. Other EWG members were of the view that Section 4.2 applies / should be used to address the use of food additives in preparations.

23. Some other EWG members were of the view that section 4.2 is not applicable to secondary food additives. They pointed out that there are inconsistencies between the definition of secondary food additives and Section 4.2 (i.e. the technological need for secondary food additives is not based on final foods but on the nature of the commercial preparations) and that following the logic of Section 4.2 would be too complicated since it would require secondary food additives to be permitted in all final foods in which preparations are used.

Interpretation of Section 4.3

24. Apart from one EWG member, who questioned the whole concept of secondary additives and another EWG member, who asked for further investigation and discussion as regards applicability of Section 4.3 to secondary additives, all other EWG members agreed that the secondary food additive uses have to meet the requirements of Section 4.3 (i.e. uses of food additives in preparations must be listed in Tables 1 and 2 for the food categories 13.1 and 13.2).

25. Some EWG members outlined that there is a legitimate need for some secondary food additive uses in preparations added to foods of categories 13.1 and 13.2 and that the currently permitted additives in those categories do not cover all those uses. Two EWG members pointed out that a revision might be needed to allow carry over for secondary food additives. It should be noted that the work on the GSFA has not been finalised and therefore the mentioned food categories might not include all food additives for which there is a legitimate technological need.

Concerns expressed in the comments to the first circular

26. Whilst analysing the impact on the GSFA was envisaged to be addressed in the second circular some EWG members provided their feedback already in reply to the first one. In their view, the exposure to secondary food additives is very low and they should not be addressed within the GSFA because they are not food additives, their technological purpose do not fall within the GSFA, and several of the preparations listed in the definition do not fall within the GSFA. They considered that a common understanding on how the

³ [Discussion paper on the revisions of Section 4 of the Preamble to the GSFA](#)

⁴ “It was noted that if an additive has no functional effect in a composite food, its presence does not require an authorization; and if it does have an effect, then it must be authorized for use in that food.” see CX/FA 11/43/14, para. 8

Preamble to the GSFA applies to secondary food additives should be developed in Guidelines following the approach of *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).

Second round of the consultation

27. The analysis carried out in the first circular and the comments of the EWG members indicated certain views on the relation between Section 4 and the use of food additives in preparations. Those views were formulated in the options A, B and C below. In the second circular the members of the EWG were requested to consider the appropriateness and the impact of those options. It should be noted that the options were similar to Recommendation 2 and 4 of CX/FA 15/47/19.

- A) The wording of Section 4 implies the need for a food category "Preparations" - i.e. Option 1 in Recommendation 2 proposed in CX/FA 15/47/19.
- B) Apart from Table 3 additives (which can be used in preparations according to the GSFA) additives with numerical ADIs should be addressed in the current food category system 1-16 by adding notes - i.e. Option 2 in Recommendation 2 proposed in CX/FA 15/47/19.
- C) Secondary food additives are not food additives and their use does not fall within the GSFA. They should be addressed in separate Guidelines following the approach of CAC/GL 66-2008.

Impact of option A on the GSFA

28. Option A received a significant support from the EWG members. Even those EWG members who preferred option C acknowledged that option A is the least disruptive option if the Committee decides to address secondary food additives within the GSFA.

29. The comments on the impact of option A included:

- (+) It would close the gap as regards the use of additives in preparations in line with the GSFA Preamble and the principles for the use of food additives as laid down in the Procedural Manual.
- (+) More pragmatic option than option B - relating the use of secondary food additives to preparations and requiring to address only food additives with the numerical ADIs (i.e. in comparison to option B not requiring the inclusion of Table 3 additives used in preparations in the food categories listed in Annex to Table 3).
- (-) It would require significant changes to the GSFA – the establishment of a new food category which would be too broad, increase in the number of new provisions to be included, broadening the scope of the GSFA.
- (-) Not commensurate to the lower exposure risk associated with the use of secondary additives.

Impact of option B on the GSFA

30. Whilst option B was formulated based on the comments received in the first circular this option was not supported in reply to the second circular. It should be noted that this option was followed in the past when some secondary food additive uses were included in the GSFA via notes 12, 65 and 131.

31. The comments on the impact of option B included:

- (+) It was followed by the CCFA in the past.
- (+) Unless Section 4.3 of the Preamble is fundamentally amended it will need to be followed for the categories 13.1 and 13.2 anyway.
- (-) The use of secondary food additives is linked with preparations not directly with foods in the food categories 1-16.
- (-) Too complex comparing to option A leading to unnecessary proliferation of the provisions and notes.

Impact of option C on the GSFA

32. Option C received a significant support in particular from the Codex Observers. However, most of the EWG members in favour of this option were of the view that secondary food additives are food additives and their use fall within the GSFA.

33. The comments on the impact of option C included:

- (+) Pragmatic approach using the experience of CAC/GL 66-2008 and having a low impact on the GSFA (not expanding its scope) and the CCFA resources.

- (+) Possibility to address all issues related to secondary additives (e.g. scope, conditions of use, relevant functional classes, exposure) in the Guidelines which would recognise and legitimise their use.
- (-) Not appropriate - the use of additives in preparations should be handled in the same manner as any other additive uses, otherwise the principles on food additives in the Procedural Manual would be undermined.
- (-) In conflict with several sections of the Preamble (e.g. section 1.2 stating that the GSFA should be the single reference point for food additives; section 4.1 explicitly referring to the use of food additives in additives according to the Standard).

Concluding remarks

34. The EWG members expressed divergent views as regards the relation of the working definition to the interpretation of Section 4 and as regards the impact of the different options on how to address the use of additives in preparations.

35. There was a consensus of the EWG that the wording of Section 4.3 should be respected and that all food additive provisions (i.e. including the provisions for the uses of food additives in the preparations) for the food categories 13.1 and 13.2 must be listed in Tables 1 and 2 of the GSFA. Therefore, an action should be taken and option B should be followed for those food categories.

36. There was no consensus of the EWG as regards the overall approach on the use of food additives in preparations. One significant group of the EWG members supported the establishment of a new food category "Preparations" and addressing the use of secondary additives in the GSFA in accordance with the principles on the use of food additives as laid down in the Preamble to the GSFA and in the Procedural Manual. Another significant group of the EWG members supported the development of Guidelines and addressing the use of secondary additives outside of the GSFA following the approach of the *Guidelines for the Use of Flavourings*.

37. Following different options would imply different consequences as regards the amendments needed in the Preamble to the GSFA and as regards the implications for the provisions for secondary food additives both adopted and in the step process.

Recommendations

Recommendation 1

38. The Committee is invited to follow **option B**, i.e. addressing the use of secondary additives by use of notes within the current GSFA food category system, for the food categories listed in Section 4.3 (i.e. 13.1 – Infant formulae, follow-up formulae, and formulae for special medical purposes for infants and 13.2 – Complementary foods for infants and young children).

Recommendation 2

39. Based on the outcome of the discussions in the EWG the Committee is invited to further discuss and consider how to address the use of secondary food additives on the basis of the following options:

Option A

Establishment of a new category in the GSFA food category system to address the use of secondary additives.

This option would require new work on the establishment of the food category "Preparations". The adopted provisions for secondary food additives (4 provisions – one associated with note 12 and three with note 131) would be revoked. The provisions in the step process would be either automatically covered by the establishment of the new food category (Table 3 additive uses in preparations which are currently proposed for the inclusion in the food categories listed in Annex to Table 3) or would need to be included in the new category (food additives with numerical ADIs).

Option C

Development of separate Guidelines for the use of secondary additives following the approach of CAC/GL 66-2008.

This option would require new work on the establishment of the Guidelines. In addition, changes to the Preamble to the GSFA (in particular to Section 4) might be necessary as well. The adopted provisions for secondary additives would be revoked and the provisions in the step process discontinued.

Recommendation 3

40. In case no consensus is reached as regards the overall approach on the use of secondary food additives (Recommendation 2) the Committee is invited to continue addressing this issue following the approach taken in the past (**option B**), i.e. by addressing the use of secondary additives by use of notes within the current GSFA food category system.

41. No new work would be required for this option. The adopted provisions for the secondary food additive uses would be kept. Provisions in the step process will be considered by CCFA and included within the current GSFA food category system 1-16 associated with the relevant notes.