

CODEX ALIMENTARIUS COMMISSION



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Agenda Item 5g

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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DISCUSSION PAPER ON USE OF NOTE 161

(Report of the E-WG on Use of Note 161)

Introduction

1. The 42nd Session of the Codex Committee on Food Additives (CCFA), held in Beijing, China 15 - 19 March 2010, agreed to establish an electronic Working Group (E-WG) chaired by the Netherlands, working in English only, to prepare a discussion paper containing proposals for criteria and conditions of the use of note 161 in the GSFA.

2. On April 21, 2010 the invitation to participate in the E-WG was distributed to all Codex members. Representatives from 19 countries, 7 observers and the EU commission registered to join the group while 6 countries, 3 observers and the EU commission contributed to the task. A complete list of participants can be found in Annex I.

Request for comments¹

First draft documents

3. The first draft document was distributed on July 16, 2010. At the time of the deadline August 30, 2010, representatives from 5 countries, 2 observers and the EU-commission had submitted comments on the first draft.

Second draft document

4. The second draft documents were distributed on October 10, 2010. At the time of the deadline, October 30, 2010 representatives from 3 countries, 2 observers and the EU-commission had submitted comments on the second draft.

Draft final report

5. The report was circulated to the members for minor final comments on December 6, 2010.

Final report

6. The final report was sent to the Codex Secretariat on December 16, 2010

Background information

Note 161

7. Note 161 of the General Standard for Food Additives states: "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble".

¹ All comments submitted on the first and second draft document are available, on request, with the e-WG lead country

Section 3.2 of the Preamble of the GSFA: Justification for the Use of Additives

8. The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:

- a) To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;
- b) To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
- c) To enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;
- d) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

Appendix Codex Procedural Manual: Statements of principle concerning the role of science in the codex decision-making process and the extent to which other factors are taken into account

9. Criteria for the Consideration of the Other Factors Referred to in the Second Statement of principle concerning the role of science in the codex decision-making process and the extent to which other factors are taken into account

- “Recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide.”
- “Only those factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex.”

Article 2.4 of the WTO Agreement on Technical Barriers to Trade (TBT agreement)

10. Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.”

Article 3.3 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

11. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.(2).

12. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

Background on Note 161

13. The inclusion of exemptions for national legislation first appeared in the GSFA in Note 122 (Subject to national legislation of the importing country) as a result of the inclusion of the food additive provisions for fruit juices and nectars subject to the Codex General Standard for Fruit Juices and Nectars (CODEX STAN

247-2005) into the GSFA. At the 3rd Session of the Codex ad hoc Intergovernmental Task Force on Fruit and Vegetable Juices (CTFFVJ), during the discussion of the use of certain additives (primarily antioxidants and preservatives), several delegations noted that countries had the right to keep their own limits for the use of food additives in national legislation, but not to restrict the use of the additives for the purposes of international trade. Other delegations noted the need for certain additives (e.g., preservatives) due to climate. In order to make progress, the European Union proposed, and the CTFFVJ agreed, to introduce a reference to national legislation of the importing country for the use of these additives (ALINORM 03/39A, paras. 31 and 32). Subsequently, the 36th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) endorsed the food additive provisions in the General Standard for Fruit Juices and Nectars, and recommended that the CTFFVJ remove the list of food additives from the General Standard for Fruit Juices and Nectars and replace it with general language that refers to the appropriate food categories in the GSFA.² The 4th Session of the CTFFVJ agreed with the CCFAC's recommendation (ALINORM 05/28/39 paras 13-16). This resulted in the introduction of Note 122, and the concept of exemptions for national legislation, into the GSFA.

14. During the 39th session of Codex Committee on Food Additives (CCFA, 2007) a new Note 161 "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble" was created and added to the 'Notes list' of the GSFA. This new Note 161 could be associated with certain sweetener provisions to make clear that national authorities might establish additional restrictions on the use of sweeteners to ensure that the use of sweeteners in their jurisdictions was technologically justified (ALINORM 07/30/12, para. 102)

15. Furthermore, the use of Note 161 would ensure that the use of sweeteners should not mislead the consumer, had advantages, and is technological justified. The Chair of the *ad hoc* physical Working Group on the GSFA confirmed that this was the intent of Note 161, and also noted the parallel between the use of this note for sweeteners and the situation for additives in general that could arise from regional or national differences.

16. During the 41st session of CCFA (2009) the committee noted that note 161 was added throughout provisions for various food categories for several artificial colours in order to accommodate the concern of some delegations. In this respect, the Committee agreed that the use of Note 161 should be limited as much as possible in order not to undermine the purpose of the GSFA to provide harmonized food additive provisions (ALINORM 09/32/12, para. 87).

17. In view of the concerns expressed by several delegations on the use of colours in specific groups of foods, the Committee agreed that this note would, in principle, be applicable only for provisions for colours for food categories 04.0 "Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds"; 07.0 "Bakery wares"; and 05.1.3 "Cocoa-based spreads, including fillings" and their related subcategories. The Committee noted that the need for note 161 for other food categories could also be examined on a case-by-case basis for the use of a food additive in a specific food category (ALINORM 09/32/12, para. 88).

18. The Committee noted the concerns of several delegations on the possible adverse impact of Note 161 on the objectives of the GSFA and agreed to request comments on the application of this note, in particular, where and when it should be used (ALINORM 09/32/12, para. 89).

19. During the 42nd session of CCFA (2010) the Committee recalled the concern expressed at its previous session by several delegations (Argentina, Costa Rica, the United States of America and the ICGMA) on the possible adverse impact of the extensive use of Note 161 and that it had requested comments on the application of this note, in particular, where and when it was used (ALINORM 10/33/12, para. 70).

20. The delegation of Argentina did not support the use of note 161 in the GSFA because it was noted that the SPS Agreement allowed countries to deviate from the international reference standards only on the basis of scientific evidence and because the use of this note was not in accordance with the purpose of Codex to harmonize food standards and, in their views, it could create unjustified barriers to trade. This view was

² The GSFA food categories for fruit juice (14.1.2.1), concentrates for fruit juices (14.1.2.3), fruit nectar (14.1.3.1) and concentrates for fruit nectar (14.1.3.3) have a direct correspondence with the foods included in the General Standard for Fruit Juices and Nectars.

supported by a number of delegations and observers (Australia, Brazil, India, ICFA and IFAC) (ALINORM 10/33/12, para. 71).

21. Some delegations, while acknowledging that the use of this note could be justified only in some cases in GSFA, were of the view that criteria for the use of this Note should be established in order to avoid its overuse. Some delegations considered that note 161 should not be used simply because a certain food additive was not authorized in a country or in a region or when a member country raised concern regarding exceedance of intake (ALINORM 10/33/12, para. 72).

22. Several delegations were of the view that Note 161 was aimed, in particular, at consistency with Section 3.2 of the Preamble and should always be applied on a case by case basis and only where proposals had the potential of not being in line with the criteria set under section 3.2 of the Preamble of the GSFA (ALINORM 10/33/12, para. 73).

23. Other delegations and observers were of the view that the language of note 161 could be revised to address different technological practices, climate or other conditions and expectations of consumers around the world (ALINORM 10/33/12, para. 74).

24. After some discussion, the Committee agreed to establish an electronic working group, led by the Netherlands and working in English only, to prepare a discussion paper containing proposals for criteria and conditions of the use of note 161 in the GSFA, taking into account comments submitted in response to CL 2009/7-FA, Part B, Point 7³ and the above discussion for consideration at its 43rd Session (ALINORM 10/33/12, para. 75).

25. At the 3rd Session of the Codex Alimentarius Commission, the delegation of the Republic of Korea, supported by other delegations, expressed its concern as to the extensive use of Note 161, which could cause implications in the application of the GSFA (ALINORM 10/33/REP, para 41).

Observations

26. Note 161 has been used as a compromise to move forward with the GSFA. Consequently, the use of Note 161 has become widespread across the provisions for certain food additives, in particular, colours and sweeteners. However, it appears that Note 161 was intended to be used only in cases where there are regional differences in the criteria for the justification for the use of certain food additives. The criteria that have been identified include that the use of the additive should not mislead the consumer, have advantages, and be technologically justified (see e.g., ALINORM 07/30/12, para. 103).

27. Additionally, Note 161 was intended to be applied to only a limited number of food categories (see e.g., ALINORM 09/32/12, para. 88).

28. During the 41st session of the CCFA, initially note 161 was added throughout provisions for various food categories for several artificial colours. The Committee then agreed that the use of note 161 should be limited as much as possible not to undermine the purpose of the GSFA to provide harmonized food additive provisions. The Committee agreed that this note would, in principle, be applicable only for provisions for colours in certain defined food categories. The Committee noted that the need for note 161 for other food categories could also be examined on a case-by-case basis for a combination of a food category and a food additive.

29. The comments submitted in response to CL 2009/7-FA, Part B, Point 7 and the discussion during the 42nd CCFA, indicate that several delegations are of the view that Note 161 is not, in general, necessary, whereas other delegations express a need for the note. In order to move forward on the issue of Note 161, the eWG and the CCFA need to consider a range of options, including the possibility of developing criteria and conditions for the use of Note 161 are necessary to ensure that the note is only used on a limited basis. It may be necessary to periodically review these criteria. These observations are used as a starting point to initiate the discussion there is a need for Note 161 in the GSFA, and if so, the criteria and conditions of the use of Note 161 in the GSFA.

³ CX/FA 10/42/6 (Comments of Australia, Costa Rica, United States of America, ICGA, ICGMA, IFAC; CX/FA 10/42/6 Add.1 (Comments of Argentina, Brazil, European Union, India)

30. It seems that the intended use of note 161 is only in cases where differences in regional approaches/attitudes lead to differences in opinions towards the justification for the use of certain food additives (sweeteners and colours) in certain food categories. This observation is used as a starting point to initiate the discussion for criteria and conditions of the use of note 161 in the GSFA.

First proposal as discussed in the working group

31. In the first draft of the discussion paper it was proposed to establish a shortlist of combinations of types of food additives (e.g. colours, sweeteners) and food categories where Note 161 can be applied. The rationale for this proposal was that the original purpose of the Note was that only for certain additives/food categories, where differences in regional approaches/attitudes lead to differences in opinions regarding consumer perception, advantages and technological justification, national authorities can apply additional restrictions. Since it will be very difficult to clearly define criteria for when differences in views on consumer perception, advantages and technological justification would justify the application of Note 161, it was proposed to restrict the use of Note 161 to the combinations of type of food additives and food categories on the – to be established - shortlist.

32. From the comments received on the first draft, it was clear that the majority of the members were of the view that the proposal to establish a shortlist of combinations of types of food additives and food categories where note 161 can be applied in the first draft of the discussion paper did not meet the mandate of the E-WG to establish criteria and conditions of use, and that clear criteria and conditions of use should be established. Therefore, this initial proposal to establish a shortlist was withdrawn and also the few suggestions received for the shortlist have not been included in the second draft.

33. Based on the comments received, it can be concluded that there is consensus in the E-WG that the use of Note 161 should be reduced.

34. The majority of the members agreed that Note 161 could only be used on a case by case basis for proposals not in line with the preamble, when it is not possible to find a common solution (consensus) for specific food additive provisions. Several members stressed that scientific and technical justification is necessary to conclude whether proposals are in line with the preamble.

35. In the replies to CL 2009/7-FA, Part B, Point 7 and the discussion during the 42nd CCFA, it was mentioned by several delegations that the application of note 161 to specific food additive provisions should not have a permanent character. Members of the electronic working group were invited to submit their views on this point, and to submit suggestions how the application of note 161 to specific food additive provisions should be periodically reviewed. Only one reply was received, and this member of the E-WG was of the view that if there is agreement on the criteria and conditions of use for Note 161, the Note could be considered permanent until new scientific or other information emerges and the criteria are not met anymore.

36. Based on the comments the following proposal '**criteria and conditions on the use of Note 161**' was drafted, and discussed in the WG:

Note 161 should only be used on a case by case basis when consensus can not be reached on whether a proposal for a food additive provision is in line with section 3.2 of the preamble of the GSFA, i.e.:

- i. When the proposal leads to discrepancies in relation to whether it presents an appreciable health risk to consumers*
- ii. When the proposal leads to discrepancies in relation to its technological need.*
- iii. When the proposal leads to discrepancies in relation to its potential misleading of consumers.*

And i) It should be justified that:

- a. the prerequisites to conclude on health risk are not fulfilled (e.g. no evaluation by JECFA or an out-of-date evaluation by JECFA, no appropriate intake assessment and/or no intake assessment for high risk subpopulations is/are available) OR*
- b. a national scientific intake assessment for the additive under consideration demonstrated an appreciable health risk to the consumer.*

37. Note 161 has a permanent character, and review of the application of Note 161 should be undertaken when new scientific or other information emerges and when the criteria listed above are not met anymore.

Discussion in the electronic working group following the second proposal

Comments on the proposal ‘criteria and conditions on the use of Note 161’

38. All members but one commented on the proposal in the second draft. Some comments requested small changes, other comments suggested significant changes, whereas one comment agreed with the proposal while another rejected the proposal. The range of the requested changes and remarks is such that no possibility for compromise is in reach. Therefore it can be concluded that the proposal is rejected by the E-WG.

39. Additionally a majority of the same comments received also pointed out that existing documents such as the Codex Procedural Manual, the GSFA or the WTO Agreement on Technical Barriers to Trade offer enough guidance for members to reach consensus and still take into account local circumstances that justify applying additional measures.

40. Additionally some members pointed out that Note 161 should not have a permanent character but should be on a temporary basis and should be used sparingly.

41. Other comments not strictly within the scope of the working group have been included in ‘Suggestions on how the use of Note 161 could be reduced, besides setting clearly defined criteria and conditions of use’

Suggestions on how the use of Note 161 could be reduced, besides setting clearly defined criteria and conditions of use.

42. Although not fully in the scope of this E-WG, during both comments round several suggestions were received on how the use of Note 161 could be reduced, besides setting clearly defined criteria and conditions of use. The E-WG suggests that a discussion on possible actions, which could be followed by the CCFA aiming at reducing the use of Note 161, could be valuable, and the suggestions listed below can be used in this discussion.

43. Several members indicated that there is too little time in the working group on the GSFA for exchange of views and for negotiations to reach consensus when delegations are of the opinion that section 3.2 of the preamble is not fulfilled. Allowing more time for discussion could reduce the use of Note 161.

44. Another member was of the view that the use of note 161 could be reduced when the procedures for consideration of the entry and review of food additive provisions in the general standard for food additives described in section II of the Procedural Manual are more strictly followed.

45. This member also indicated that the “Denner Paper” mentioned that the future GSFA should contain a list of food “which shall contain no additives at all”, and that establishment of such a list could also reduce the need for use of Note 161.

46. Some members indicated that the motivation for development and use of footnote 161 has been differences of opinion between delegations as to when some proposed additive uses/use levels meet some of the criteria in section 3.2 of the Preamble of the GSFA. Therefore, to look at the delegations’ current views on these criteria (what is required as sufficient justification for technological need, what use will mislead consumers?) and discussing these in the plenary of the CCFA should lead to a greater understanding of differences in opinions and could reduce the need for use of Note 161.

47. Three members indicated that elimination or deletion of Note 161 should be considered.

48. One member proposed that the revision of Note 161 be presented to the Committee as an alternative approach.

Conclusion

49. The members of the E-WG did not reach agreement on the proposal ‘criteria and conditions on the use of Note 161’. However, although not within the scope of the E-WG, several alternative approaches in ‘Suggestions on how the use of Note 161 could be reduced, besides setting clearly defined criteria and

conditions of use', were offered that might offer possible solutions to reach consensus on food additive provisions.

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