

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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Agenda Item 6 (c)

CX/FAC 05/37/8  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

### FOOD ADDITIVES PROVISIONS OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES -GSFA

DRAFT AND PROPOSED DRAFT FOOD ADDITIVES PROVISIONS REQUIRING INFORMATION ON THEIR USE

Comments submitted in response to CL 2004/9-FAC

The following comments have been received from: Brazil, European Community, International Federation of Chewing Gum Associations (IFCGA) and Organisation International de la Vigne et du Vin (OIV)

#### BRAZIL:

INS	Substance	Comentários do GTFAC
901	Beeswax, White and Yellow	Food Category 14.1.4: Clarify if the functional use is included in the functions evaluated by JECFA. Which is the functional use in beverage? If it is considered as a carrier for flavors, this must be specified.
902	Candelilla Wax	Food Category 14.1.4: Clarify if the functional use is included in the functions evaluated by JECFA. Which is the functional use in beverage? If it is considered as a carrier for flavors, this must be specified.
903	Carnauba Wax	Food Category 05.4: Request justification for the functional use of the ML 10000 mg/kg (10g/kg). Brazil considers that there is no technological need for this ML. The ML allowed in Brazil is 10mg/kg. Food Category 12.6: Which is the technological justification? Must be established a ML, because it has a numerical ADI.
210, 211, 212, 213	Benzoates	Food Category 4.1.2.5: The ML in others countries, for similar products, is 500 - 1000mg/kg, what seems to be enough to reach the desired effect Food Category 8.2.1.2: Considering the high use of Benzoic Acid, Brazil suggests the use of Sorbic Acid in the limit of 200mg/kg, for treatment of surfaces, instead of Benzoic acid. Food Category 8.3.2 Which is the technological justification? The processing of heating seems to be enough to reach the technological effect, not having necessity to use benzoates. Food Category 12.5.1: <i>Although in Brazil is permitted the use of preservative (such as sorbic acid) in the limit of 500mg/kg, we do not support the use of benzoates for ready to eat soups</i>

INS	Substance	Comentários do GTFAC
		and broths. Food Category 14.1.1.2: Brazil does not agree with the use of preservatives in this category. Because there is no technological necessity of use benzoates in water.
483	Stearyl Tartrate	No comments.
999	Quillaia Extract	Explain that it concerns the Quillaia type 1.
445	Glycerol Ester of Wood Rosin	The functions that note of standard (adjuvant, bulking agent, emulsifier, stabilizer, thickener) do not coincide with the proposed use – treatment of surface
900a	Polydimethylsiloxane	Food Categories 8.2, 8.3, e 9.2: Which is the technological justification? In the specifications of the JECFA it does not have the letter “a”
1201	Polyvinylpyrrolidone	No comments.
905ci	Microcrystalline Wax	Food Categories 05.1.4, 05.1.5, 05.2 e 05.4: the limits (10000mg/Kg) are too high and can result in one ingest above of the ADI (20mg/Kg).
477	Propylene Glycol Esters of Fatty Acids	The ML is very high. Brazil suggests 5000mg/kg
384	Isopropyl Citrates	No comments.
385, 386	EDTAs	Food Category 4.1.2.8: comparing with the other categories the ML of 650 mg/kg is very high . How and in which categories the EDTA acts as preservative?
310	Gallate, Propyl	The ML of 1000mg/kg is not necessary to reach the desired effect. 200mg/kg seems to be the limit appropriate for the majority of the categories.

### **EUROPEAN COMMUNITY:**

The European Community would like to make the following comments on the circular letter.

#### **CARNAUBA WAX (INS 903)**

For category 05.4 Decorations (e.g. for fine bakery wares, toppings (non-fruit) and sweet sauces level of 10 000 mg/kg is proposed. However, in the EC carnauba wax is used in small products of fine bakery wares coated with chocolate and the maximum level of 200 mg/kg is estimated to be sufficient. Therefore, the EC cannot support the proposed level of 10 000 mg/kg.

#### **BENZOATES (INS 210, 211, 212, 213)**

The European Community would like to maintain the entries for the following food categories:

04.1.2.5 Jams, jellies and marmelades	For this food category, the EC can only support a level of 500 mg/kg
05.3 Chewing gum	1500 mg/kg
08.2.1.2 Cured (including salted) and dried non-heat treated processed meat, poultry, and game products in whole pieces or cuts	GMP Note 3 restricting the use of benzoates to the surface treatment should be added to this food category.
08.3.1.2 Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products in whole pieces or cuts	1000 mg/kg Note 3 restricting the use of benzoates to the surface treatment should be added to this food category.

**GLYCEROL ESTER OF WOOD ROSIN (INS 445)**

The European Community would like to maintain the entry for the food category 04.1.1.2 (surface-treated fruit) as the use of this additive is permitted for surface treatment of citrus fruit in the EC.

**POLYDIMETHYLSILOXANE (INS 900A)**

The European Community would like to maintain the entry for the food category 14.2.2 (cider and perry) at 10 mg/l.

**PROPYLENE GLYCOL ESTERS OF FATTY ACIDS (INS 477)**

The European Community considers the level of 40 000 mg/kg for food category 2.4 fat based desserts to be excessive. In view of EC, the level of 10 000 mg/kg adopted by the CAC at step 8 is sufficient.

**IFCGA:**

The International Federation of the Chewing Gum Association (IFCGA)<sup>1</sup> has been monitoring and participating to the elaboration of the Codex draft General Standard on Food Additives (GSFA) an international non-government observer organisation. On behalf of the IFCGA, we respectfully submit comments, as requested by the 36th session of the Codex Committee on Food Additives and Contaminants (CCFAC) regarding the use of benzoates (INS 210 to 213) in chewing gum.

Under the current draft GSFA standard<sup>2</sup> benzoates are listed at step 6 with a maximum level of use 1500 mg/kg for chewing gum. The last CCFAC meeting requested information as to the use of benzoates in category 5.3 chewing gum, with the understanding that if no information was submitted, the proposed authorisations would be deleted from the draft at the 37th CCAFC session. We understand that the European Commission indicated it would provide information regarding the use of benzoates amongst its members.

**We would also like to provide the Codex CCFAC Secretariat with information regarding the use of benzoates in chewing gum and indicate our opposition to a possible deletion of the GSFA entry for the use of benzoates in chewing gum.**

**Technical justification:**

Benzoates are used as preservatives in chewing gum products. Preservatives are not needed or used in most chewing gum products because chewing gum is relatively dry and inert. Most chewing gum products contain less than 5% water.

However, certain chewing gum products do exist which, because of their high moisture content, require the use of preservatives. Tube gum, for example, contains approximately 15% water.

Without the addition of preservatives, the high moisture content of these products, together with the carbohydrates present, would support microbial growth. High-moisture chewing gum products will be unavailable if preservatives are not authorized in chewing gum.

**Safety justification:**

Benzoates (INS 210 to 213) are currently authorised for use in the EU at a level of 1500 mg/kg in chewing gum under Annex III A of Directive 95/2/EC on miscellaneous additives. Benzoic acid, sodium and potassium benzoates (INS 210 to 212) are authorised for use in food, including chewing gum, under GRAS affirmation regulations at 1000 mg/kg in the United States, as provided under 21 C.F.R.184.1021 and 184.1733 respectively. We also note that benzoic acid, sodium and potassium benzoates are also authorized for use in non-standardized food, including chewing gum, at a level of 1000 mg/kg in Canada.

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<sup>1</sup> The IFCGA is composed of the European Association of the Chewing Gum Industry (EACGI) and the US National Association of the Chewing Gum Manufacturers (NACGM). The two associations include among their membership all major chewing gum, chewing gum base manufacturers and many suppliers of raw materials to the chewing gum industry.

<sup>2</sup> C.f. Appendix IX of Alinorm 04/27/12.

Both JECFA and the EU Scientific Committee for Food have set a group ADI for the benzoates at 5 mg/kg body weight (JECFA evaluation 1996 – ADI maintained in 2001),

SCF Reports 5th Series 1978). Taking the lower ADI, if 1500 mg/kg benzoates were used in a 3 gram piece of chewing gum to be consumed by a person weighing 60 kg, this consumption would amount to only 0,075 mg/kg body weight, which compares favourably with the ADI of 5 mg/kg body weight (1500 mg/kg x 3 g = 4,5 mg per piece; 4,5 mg divided by 60 kg = 0,075 mg/kg body weight).

**We therefore confirm that benzoates are used in certain type of chewing gum with a high moisture content and request that the current proposed authorisation for use at 1500 mg/kg in chewing gum be maintained in the GSFA. Alternatively, we respectfully request that the level of 1500 mg/kg be maintained for chewing gum containing more than 5% water.**

## OIV:

### **COMMENTS Point 13 of the Circular letter CL 2004/9-FAC**

#### **General comments**

More precisely, OIV would like to submit the following comments to point 13 of the CL 2004/9-FAC. These comments update the comments already made for the 36<sup>th</sup> session of the CCFAC (CX/FAC 04/36/9).

The OIV is endeavouring to set out the recommendations and conditions for the use of oenological treatments only necessary to obtain and to preserve grape wines (category 14.2.3) by limiting the use of technologically unjustifiable adjuncts.

OIV supports the decision of the committee to re-establish the newly named Electronic Working Group and to requested it to provide a report with recommendations to the 37th Session of the CCFAC on the draft maximum levels for food additives listed in Appendix X to the report (Alinorm 04/27/12).

The Committee also decided on the discontinuation of work on a number of draft and proposed draft food additive provisions listed in Table 1 of the General Standard for Food Additives (Appendix VIII) (Alinorm 04/27/12).

Furthermore, OIV is fully supportive of the re-installation of the Quality Control Group and hope that this working group will be able to examine technical justification in order to make recommendations for maximum levels of use in the GSFA (list of priority additives)

There still remain certain additives that the OIV would suggest removing from the GSFA, as being unessential to making products that are sound, reliable and true to tradition, and which could be confusing to consumers. Likewise, certain elements that play only a secondary technological role have no reason to figure in the GSFA.

Furthermore, certain additives, like EDTA, have been mentioned in a more general category like alcoholic beverages (14.2), which includes the sub-category « grape wines » (14.2.3). Still with the aim of limiting the use of additives, the OIV proposes that the additives indicated in 14.2 should be specified for each of the sub-categories where technological necessity is claimed.

**Finally, the OIV emphasizes once more that « the CCFAC has taken note of the concerns expressed by the OIV on the overuse of additives in category 14.2.3 and has decided to submit those misgivings for scrutiny by the working committee at the thirty-fifth session of the CCFAC » (alinorm 03/12 § 63).**

#### Specific comments

##### Polyvinylpyrrolidone (Group I)

Name	Nom	Fonction	INS	Food N°	Category	Max level	Not e	Ste p
POLYVINYLPIRR OLIDONE	POLYVINYLPIR ROLIDONE	raffermissant, stabilisant	120 1	14.2. 3	Grape Wines	60	36	6

Only the addition of polyvinylpyrrolidone (PVPP) (INS 1202) to wine in order to lower tannin content or other polyphenols is an œnological practice approved by the OIV (Resolution oeno 5/1987). The PVPP dose used must not exceed 800 mg/l.

As the CCFAC's Electronic quality control working group for the GSFA recommended in its report (CX/FAC 04/36/8) in December 2003, PVP is no longer used as a clarifier and stabilizer in wine and has been largely replaced by Polyvinylpyrrolidone (PVPP S 1202).

PVP and PVPP themselves have been evaluated previously by JECFA, when PVP was allocated an ADI of 0-50 mg/kg b.w. (JECFA, 1987) and PVPP an ADI not specified (JECFA, 1983).

As was already decided by the Commission in 1999 (Alinorm 99/37 § 107), the OIV recommends

- removal of polyvinylpyrrolidone (INS 1201) for category 14.2.3
- the inclusion of polyvinylpyrrolidone (INS 1202) in the GSFA for category 14.2.3 in stage 3 at a dose limited to 800 mg/l.

### **EDTAs (Group III)**

Name	Nom	Fonction	INS	Food N°	Category	Max level	Not e	Ste p
ETHYLENE DIAMINE TETRA ACETATE	EDTAs	antioxydant conservateur	385/386	14.2.3	Grape wines	25	21	6

As indicated by the OIV in 2001 when approving the use of EDTA in stage 8 for category 14.2 (Alinorm 1/41 § 113), the OIV recommends that this additive should be specified for the sub-categories where it is of technological interest and should be excluded from category 14.2.3. (grape-derived wines).

As the CCFAC's Electronic quality control working group for the GSFA recommended in its report (CX/FAC 04/36/8) in December 2003, the technological need for a sequestrant in category 14.2.3. is not clear.

Taking into account available information, it seems that EDTA is not to be used in the wine making process

The OIV recommends

- removal of EDTAs (INS 385 & 386) for category 14.2.3