CODEX ALIMENTARIUS COMMISSION







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Agenda Item 5d

CX/FA 17/49/10 December 2016

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Ninth Session

Macao SAR, China, 20-24 March 2017

DISCUSSION PAPER ON THE USE OF FOOD ADDITIVES IN THE PRODUCTION OF WINE

Report of the Electronic Working Group chaired by the European Union and co-chaired by Australia

Background

- 1. The 45th CCFA agreed to establish an electronic Working Group (EWG), led by France, open to all members and observers, and working in English only, to prepare recommendations on the horizontal approach to the use of food additives in these food categories with the technological function of "acidity regulator" and "emulsifier, stabilizer, thickener," as well as recommendations for provisions and proposals for new provisions listed in food category 14.2.3 and its sub-categories in CX/FA 13/45/12 and Appendices 2 and 3 of CX/FA 13/45/7.¹
- 2. For the 46th CCFA, the EWG prepared proposals for the horizontal approach for both "acidity regulators" and "emulsifiers, stabilizers, thickeners"², which were considered at the physical Working Group (pWG) on the GSFA at the 46th CCFA. The pWG agreed to the recommendation that food additives with "acidity regulator" and "emulsifier, stabilizer and thickener" function should be considered on a case-by-case basis in food category 14.2.3 (Grape wines) and its sub-categories, and therefore, considered each provision in these food categories on an individual basis.³
- 3. The 47th CCFA noted that the concern for specific provisions of food category 14.2.3 was not about the safety but about the technological justification of the provisions.⁴ The 47th CCFA agreed to establish an EWG, chaired by France and co-chaired by Australia, open to all members and observers, and working in English only, (i) to provide clarity and specificity on the general concerns of wine identity, wine stability, global applicability of limitations for the use of food additives in wine and innovation in wine production and (ii) to perform an examination on the effect of expressing a maximum use of additives in wine.⁵
- 4. Considering the recommendation of the EWG, to set the maximum use level of wine additives having ADIs "not specified" at GMP with an appropriate footnote, the 48th CCFA generally agreed that "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine". ⁶

EWG Mandate

5. The 48th CCFA agreed to establish an EWG, chaired by the European Union and co-chaired by Australia, open to all members and observers, and working in English only, with the following terms of references:⁷

¹ REP 13/FA, para. 76.

² CX/FA 14/46/10.

³ FA 46/CRD 2, REP 14/FA, para. 67.

⁴ REP 15/FA, para 77

⁵ REP 15/FA, para 78

⁶ REP 16/FA, para 93-93

⁷ REP 16/FA, para 97

Taking account of the issues identified in CX/FA 16/48/13, and the positions expressed at the CCFA48 and in the various CRDs, including the EWG co-chair recommendations for food additives in wine (FC 14.2.3):

- (i) Develop and analyse recommendations for the amendment of the GSFA with respect to food additives in wine.
- (ii) Consider provisions for food additive belonging to the following functional classes: acidity regulators, stabilizers and antioxidants.

EWG Participants

6. 31 Members and 7 Observers expressed their interest to participate in the EWG: Argentina, Australia, Austria, Brazil, Canada, Chile, China, Cyprus, Czech Republic, Ecuador, European Union, France, Germany, Greece, Hungary, India, Italy, Japan, Malaysia, Mexico, New Zealand, Paraguay, Poland, Portugal, Russia, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom, United States of America, CEFIC (European Chemical Industry Council), ELC (Federation of European Specialty Food Ingredients Industries), FIVS (International Federation of Wines and Spirits), ICGMA (International Council of Grocery Manufacturers Association), IFAC (International Food Additives Council), OENOPPIA (International Association of Oenological products Manufacturers and marketers), OIV (International Organisation of Vine and Wine).

Discussion within EWG

- 7. Two rounds of comments occurred with a high level of participation⁸. Comments on the first circular were received from 18 Members and 4 Observers. Comments on the second circular were received from 18 Members and 5 Observers. In total, 45 comments were received from Argentina, Australia, Austria, Brazil, Canada, Chile, Cyprus, Czech Republic, European Union, France, Germany, Greece, Hungary, Italy, Japan, Malaysia, New Zealand, Poland, Russia, Slovak Republic, Spain, United States of America, FIVS (International Federation of Wines and Spirits), ICGMA (International Council of Grocery Manufacturers Association), IFAC (International Food Additives Council), OENOPPIA (International Association of Oenological products Manufacturers and marketers), OIV (International Organisation of Vine and Wine).
- 8. The two circulars focussed the discussion on 2 points:
 - GMP + footnote for the maximum use level for additives with an Acceptable Daily Intake "not specified" or "not limited",
 - Possible additives in food category 14.2.3 and its subcategories.

GMP + footnote for the wine additives with an ADI "not specified" / "not limited"

- 9. Several EWG participants recalled their initial position: some were in favour of a maximum level set as GMP and other were in favour of a numerical limit. Both groups developed and reiterated their arguments in favour of their respective positions. Mainly: (i) the maximum level should be set as GMP as there is no safety issue and (ii) the maximum level should be a numerical value to guarantee consistency with the OIV limits.
- 10. Several EWG participants have shown their willingness to find a compromise in exploring the possibilities of a second sentence in the footnote associated to GMP considered at the 48th CCFA. From the first circular, the following footnote was identified as a possible compromise and was presented in the second circular:
 - GMP* *: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine <u>and shall be established with reference to science-based recommendations of the OIV or any other international intergovernmental organisations with recognised expertise in the field of vitiviniculture. They may in no case be more restrictive than such recommendations."</u>
- 11. Three mains elements in the second sentence were discussed in the second round of comments: (i) "shall be established", (ii) "any other international intergovernmental organisations" and (iii) "may in no case be more restrictive than".
- 12. "shall be established": several EWG participants insisted on a strong link to OIV confirming their willingness to maintain a "shall", while several others did not want a mandatory link with some accepting "should be established".

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⁸ Comments are attached to the present document in ZIP files

13. "any other international intergovernmental organisations": most of the EWG participants did not believe it relevant to list these other international intergovernmental organisations as none were identified. Some EWG participants wanted to expand to other organisations while others wanted to restrict or to define those organisations further.

- 14. "may in no case be more restrictive than": some of the EWG participants, among the ones supporting a strong link to OIV and the ones opposing to such link, were against this last sentence.
- 15. Considering the numerous comments from the EWG participants, the chair and co-chair suggest two options which might be acceptable as a compromise or discussed further by the CCFA:
 - **A**: GMP* *: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine and should be consistent with those of the International Organisation for Vine and Wine (OIV).
 - **B:** GMP* *: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine. <u>This maximum level may be further specified to be consistent with those of the International Organisation for Vine and Wine (OIV).</u>

Possible additives in food category 14.2.3 and its subcategories.

- 16. The following additives used in wine considered for adoption may be separated in different groups according to their status and the comments received:
 - 1) Additives with ADI not specified by JECFA and authorised by OIV: Citric acid (INS 330); Lactic acid L-, D-and DL- (INS 270); Malic acid DL- (INS 296); L(-) Malic Acid (INS 296); Ascorbic acid (INS 300); Gum arabic (INS 414) and Sodium carboxymethylcellulose (INS 466). Most of the EWG participants agreed to support the adoption of these seven additives with a Maximum Level set at GMP with an appropriate footnote.
 - 2) Additives with ADI not specified by JECFA but not authorised by OIV: Fumaric acid (INS 297), Erythorbic acid (INS 315) and Calcium sulfate (INS 516). Some EWG participants support the adoption of these additives with a Maximum Level set at GMP with an appropriate footnote, but others prefer to have a maximum level for Calcium sulfate (Max 2000 mg/kg as currently proposed at step 7 in the GSFA) and for Erythorbic acid (ADI specified by European Food Safety Authority: 6 mg/kg bw, 250 mg/kg as currently proposed at step 7 in the GSFA). Other EWG participants do not support the adoption of such additives as they are not authorised by the OIV.
 - **3)** Additives with ADI specified by JECFA and authorised by OIV: Tartaric acid (L+) (INS 334), ADI between 0 and 30 mg/kg bw. Several EWG members agreed to support the adoption of this additive with a Maximum Level set at GMP with an appropriate footnote. Some EWG members suggested a specific note regarding the natural content of tartaric acid in grape wine and others supported a Maximum Numerical Level.
- 17. DL-Malic Acid (INS 296) was included in the group ADI for malic acid and its sodium, potassium and calcium salts; it was evaluated in 1969 and has an ADI not specified. (http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=5163). Extract from the 13th Report on the Joint FAO/WHO Expert Committee on Food Additives9: "In connexion with the evaluation of calcium stearoyl lactylate, the Committee reviewed DL-lactic acid and DL-malic acid, the evaluation of which was given in the ninth report. A conditional acceptable daily intake was then set for the D-isomers of these acids, whereas no limit was set for the L-isomers, on the ground that they are metabolized to a lesser degree than the D-isomers. On the basis of further evidence indicating that adults do metabolize D-lactic and D-malic acids, it was not considered necessary to maintain the distinction previously drawn between the enantiomorphs of the two acids for use by adults. Accordingly, the Committee decided to convert the evaluation for the D-enantiomorphs from a conditional acceptable daily intake value to use limited only by good manufacturing practice. However, the restriction on the use of these acids in the diet of very young infants remains." Based on this, the chair of the EWG suggested to L-Malic Acid might be considered to be included in the DL-Malic Acid (INS 269).

Outcomes and Recommendations

18. **Recommendation 1**: Endorsement by CCFA of the principle that, if JECFA recommends an additive with ADI not specified, the Maximum Level of this additive authorised in grape wine is set at GMP with the reference to one of the following footnotes:

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⁹ http://apps.who.int/iris/bitstream/10665/40773/1/WHO_TRS_445.pdf

A: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine <u>and should be consistent with those of the International Organisation for Vine and Wine (OIV)."</u>

- **B:** "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine. <u>This maximum level may be further specified to be consistent with those of the International Organisation for Vine and Wine (OIV)."</u>
- 19. **Recommendation 2**: Endorsement by CCFA of the additives for the Food Category No. 14.2.3 Grape wines in the GSFA at step 5/8 as listed below:

Additive	INS	Step	Year	Max Level	Notes
ASCORBIC ACID, L-	300	5/8		GMP	XXX
CITRIC ACID	330	5/8		GMP	XXX
FUMARIC ACID	297	8		GMP	XXX
GUM ARABIC (ACACIA GUM)	414	5/8		GMP	XXX
LACTIC ACID, L-, D- and DL-	270	5/8		GMP	XXX
MALIC ACID, DL-	296	5/8		GMP	XXX
SODIUM CARBOXYMETHYL CELLULOSE (CELLULOSE GUM)	466	5/8		GMP	XXX

Note xxx: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine [and should be consistent with those of the International Organisation for Vine and Wine (OIV)] / [.This maximum level may be further specified to be consistent with those of the International Organisation for Vine and Wine (OIV).]

20. **Recommendation 3**: Endorsement by CCFA of the additive for the Food Category No. 14.2.3 Grape wine in the GSFA at step 5/8 as listed below

Additive	INS	Step	Year	Max Level	Notes
ERYTHORBIC ACID (ISOASCORBIC ACID)	315	5/8		GMP	XXX

Note xxx: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine [and should be consistent with those of the International Organisation for Vine and Wine (OIV)] / [.This maximum level may be further specified to be consistent with those of the International Organisation for Vine and Wine (OIV).]

21. **Recommendation 4**: Endorsement by CCFA of the additive for the Food Category No. 14.2.3 Grape wine in the GSFA at step 5/8 as listed below

Additive	INS	Step	Year	Max Level	Notes
TARTRATES	334; 335(i),(ii); 336(i),(ii); 337	5/8		GMP	128, xxx

Note xxx: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine [and should be consistent with those of the International Organisation for Vine and Wine (OIV)] / [.This maximum level may be further specified to be consistent with those of the International Organisation for Vine and Wine (OIV).]

22. **Recommendation 5**: Endorsement by CCFA of the additive for the Food Category No. 14.2.3 Grape wine in the GSFA at step 5/8 as listed below

Additive	INS	Step	Year	Max Level	Notes
MALIC ACID, DL-	296	5/8		GMP	xxx, yyy

Note yyy: "including Malic acid L(-) (INS 296)"

Note xxx: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine [and should be consistent with those of the International Organisation for Vine and Wine (OIV)] / [.This maximum level may be further specified to be consistent with those of the International Organisation for Vine and Wine (OIV).]

23. **Recommendation 6**: Endorsement by CCFA of the additive for the Food Category No. 14.2.3.3 Fortified grape wine, grape liquor wine, and sweet grape wine in the GSFA at step 8 as listed below

Additive	INS	Step	Year	Max Level	Notes
CALCIUM SULFATE	516	8		GMP	XXX

Note xxx: "The Maximum level of the additive in grape wine set as Good Manufacturing Practice must not result in (i) the modification of the natural and essential characteristics of the wine and (ii) a substantial change in the composition of the wine [and should be consistent with those of the International Organisation for Vine and Wine (OIV)] / [.This maximum level may be further specified to be consistent with those of the International Organisation for Vine and Wine (OIV).]