codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 13 (f) **CX/FAC 06/38/26**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

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DISCUSSION PAPER ON OCHRATOXIN A IN WINE

Prepared by the European Community with the assistance of Chile, France, Italy, Morocco, United Kingdom, FIVS and OIV

BACKGROUND

1. During its 37th session, which was held from April 25 to 29, 2005, in The Hague, the Codex Committee on Food additives and Contaminants (CCFAC) agreed to establish an electronic working group led by the European Community, with the assistance of Chile, France, Italy, Morocco, the United Kingdom, the International Federation of Wines and Spirits (FIVS), and the International Organization of Vine and Wine (OIV), in order to prepare a discussion paper on a maximum level for Ochratoxin A in wines, for consideration at its forthcoming session[1].

INTRODUCTION

2. Ochratoxin A (OTA) is a mycotoxin present in many foodstuffs, in particular cereals, grape juice, wine, coffee, cocoa, dried vine fruit, spices and beer. Cereals and cereal products represent the main source of dietary exposure, whilst wine, coffee and beer can also be sources of exposure. Dried raisins and grape juice can be important sources of exposure for children, a vulnerable group of the population, due to their high food consumption in relation to their body weight.

3. Ochratoxin A (OTA) is produced by a single *Penicillium* species, *Penicillium verrucosum*, by *Aspergillus ochraceus* and several related *Aspergillus* species, and by *Aspergillus carbonarius* with a small percentage of isolates the closely related *Aspergillus niger*. There are reports of other species of *Penicillium* and *Aspergillus* producing OTA but many of these reports are probably the result of misidentification of the fungi or contamination of cultures. The three groups of species differ in their ecological niche, in the commodities affected, and in the frequency of their occurrence in different geographical regions.

4. *P. verrucosum* grows only at temperatures below 30 °C and at water activity as low as 0.8 and can therefore only be found in cool temperate regions. It is the source of OTA in cereals and cereal products. *A. ochraceus* grows at moderate temperatures and at a water activity above 0.8. It is found sporadically in a wide range of food commodities but is seldom the cause of substantial concentrations of OTA. It is a source of OTA in green coffee beans. *A. carbonarius* grows at high temperatures and is associated with the ripening of fruit, grapes in particular. It is the principal source of ochratoxin A in fresh grapes and the products made from them, i.e. in particular grape juice, wine and dried raisins. It is also a source of OTA in coffee.

CHEMICAL STRUCTURE

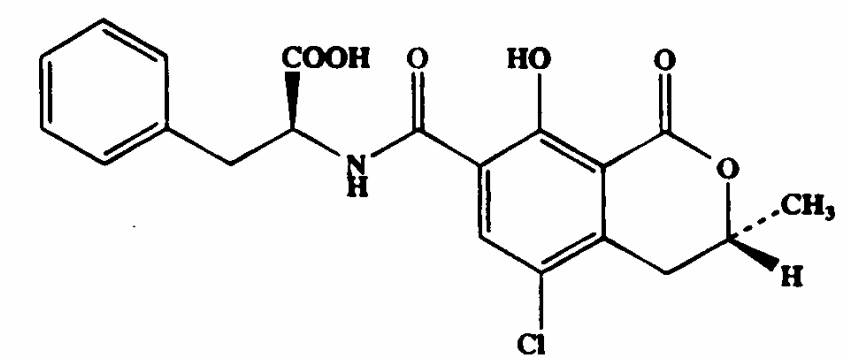

Figure 1: Chemical structure of Ochratoxin A

5. Ochratoxin A consists of a polyketide-derived dihydroiso-coumarin moiety linked through the 12-carboxy group to phenylalanine. Due to its chemical structure (fig. 1), it is soluble in most organic solvents such as alcohols, ketones, benzene, and chloroform, but is not very soluble in water and is insoluble in petroleum ethers and saturated hydrocarbons. It degrades in an alkaline medium, is stable to heat, and resists the cooking and sterilization processes used in culinary practices. It is detectable by blue-green fluorescence in ultraviolet light.

TOXICOLOGICAL EVALUATIONS

6. The toxicological status of OTA has been reviewed several times and detailed monographs have been published by The International Agency for Research on Cancer (International Agency for Research on Cancer) and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

7. The nephrotoxic and carcinogenic properties of OTA have been the major focus of the safety evaluation performed by scientific bodies. Besides the nephrotoxic and carcinogenic properties, OTA has also teratogenic, immunotoxic and possibly neurotoxic properties.

8. The International Agency for research on Cancer (IARC) has classified Ochratoxin A as a possible human carcinogen (group 2B) [2]

9. The JECFA evaluated OTA at its 37th meeting in 1991[3] and a PTWI of 112 ng/kg b.w. was established, on the basis of deterioration of renal function in pigs, for which the lowest-observed-effect level (LOEL) was 0.008 mg/kg b.w. per day and a safety factor of 500. Ochratoxin A was re-evaluated by JECFA at its 44th meeting[4]. At that meeting JECFA reconfirmed the PTWI, rounding it to 100 ng/kg b.w. This figure corresponds to 14 ng/kg body weight per day.

10. The JECFA considered at its fifty-sixth meeting in February 2001 several new studies that had become available since its last evaluation on Ochratoxin A[5]. JECFA concluded that the mechanism by which ochratoxin A causes carcinogenicity is unknown although both genotoxic and non-genotoxic modes of action have been proposed. The JECFA recommended that studies should be conducted to clarify the mechanism by which ochratoxin A induces nephrotoxicity and carcinogenicity and noted that studies to resolve these issues are in progress. JECFA retained the previously established PTWI of 100 ng/kg body weight per week, pending the results of these studies.

11. A group of experts on food toxicology convened under the aegis of the Nordic Council of Ministers made an assessment of OTA in 1991 and proposed a TDI of 5 ng/kg b.w./day based on the carcinogenic properties of OTA and by making use of model based approaches in the calculations[6].

12. An assessment was performed by the Canadian authorities[7] and a PTDI of 1.5 to 5.7 ng/kg b.w. for a life time risk of 10^{-5} was suggested. The evaluations were based on the carcinogenic properties of OTA and both a safety factor and model-based approach were used in the calculations.

13. The Scientific Committee for Food of the European Commission (SCF) expressed on 23 September 1994 an opinion on aflatoxins, ochratoxin A and patulin[8] in food. The Committee concluded that ochratoxin A is a potent nephrotoxic agent, a carcinogen and that it has genotoxic properties The Committee provisionally supported the conclusion that an acceptable safe level of daily exposure would fall in the range of a few ng/kg bw/day.

14. The SCF revised in 1998 the toxicology on ochratoxin A. The Committee noted that the estimates of tolerable daily intake by other scientific bodies based on non-threshold mathematical modelling approaches or a safety factor/threshold approach, have ranged from 1.2 to 14 ng/kg b.w./day. The SCF concluded, in its opinion on ochratoxin A in food on 17 September 1998[9] that there is an increasing concern about potential genotoxicity of ochratoxin A and its mechanism of action as a carcinogen. The Committee was aware that further studies were on-going to elucidate the mechanisms involved in ochratoxin A carcinogenicity Therefore the Committee considered that it would be prudent to reduce exposure to ochratoxin A as much as possible, ensuring that exposures are towards the lower end of the range of tolerable daily intakes of 1.2-14 ng/kg b.w./day which have been estimated by other bodies, e.g. below 5 ng/kg b.w./day.

15. An extensive research project on the mechanisms of ochratoxin A induced carcinogenicity as a basis for an improved risk assessment has been recently finalised[10]. The European Food Safety Authority (EFSA) is currently reviewing the opinion of the Scientific Committee on Food of 17 September 1998 on ochratoxin A in food in the light of results of toxicological studies published since that time (in particular the results of the abovementioned EU-research project), recent analytical results on the occurrence of ochratoxin A in food and exposure assessments and any other scientific information of relevance for the assessment of the risks of the presence of ochratoxin A for human health[11].

16. In the priority list of food additives, contaminants and naturally occurring toxicants proposed by CCFAC for evaluation by JECFA[12], ochratoxin A is listed as high priority for evaluation by JECFA addressing toxicological re-evaluation, exposure assessment (special consideration to developing countries) and effects of processing on residual levels in food.

ANALYTICAL METHODS

17. Reliable, analytical methods, which have been validated by various collaborative studies, have been developed for the analysis of ochratoxin A in maize, barley, rye, wheat, wheat bran, whole wheat flour, roasted coffee, wine and beer. They are based on liquid chromatography with detection by fluorescence.

18. A method for determining OTA in wines was adopted by the Member States of the OIV in 2001[13] and has been adopted by the European Committee for Standardisation.[14] This method, validated on the basis of an international collaborative study, is applicable for the determination of ochratoxin A in red, rosé and white wines (including specialty wines) with concentrations from 0.1 µg/l to 10 µg/l. The principle of this method is based on quantification by HPLC (high performance liquid chromatography) in reverse phase with fluorimetric detection after filtration and purification of the samples on an immunoaffinity column.

FACTORS INVOLVED IN THE PRESENCE OF OTA IN GRAPE WINE

19. *A. carbonarius* and *A. niger* are not pathogens on fruit but saprophytes, and hence they cannot penetrate healthy fruit. However, damage to fruit by any means, mechanical, chemical or by disease micro-organisms, may allow them to enter the fruit, where the low pH, a high sugar content, and often a high temperature provide an ideal habitat for these species. This is especially true for grapes which have a very tough skin. When the grapes are intact, they are resistant to attacks by these fungi, but ideal growth conditions prevail once the skin is damaged. The control of the growth of these fungi species in grapes before the harvest is therefore based on the control of pathogenic fungi and pests, and the control of mechanical damage and control of splitting due to rain just before the harvest. .

20. The presence of *A. carbonarius* in the grape berry increases with ripening (the period from when the grape starts to colour) until harvest. The production of OTA by *A. carbonarius*, if it occurs, increases with the maturity of the grape bunches and is maximal at harvest time.

21. The content of OTA varies naturally during wine making. The concentration increases during maceration by extraction of this mycotoxin from infected berries. For this reason, red wines are more likely to be susceptible to contamination. Whilst white wine grapes are immediately pressed after being picked, red wine grapes are mashed and skin and juice are put aside for several days (skin maceration). The concentration is then close to its maximum, which is reached during alcoholic fermentation. The quantity of OTA in the must then starts to decrease. Certain types of clarification of wines, as well as the adsorption of ochratoxin to the dry active yeasts or inactive yeasts seem to help decrease the toxin concentration during wine making. It is also important to note that the use of oenological charcoal makes it possible to decrease the toxin concentration in the must and in the wine to a very significant degree, but their use is generally prohibited for red wines. The content of OTA also appears to decrease during the ageing of wines. An average reduction of 15-20 % is observed at the end of twenty-one months.

22. Ochratoxin A can be found in different types of wine, in different regions of the world. It is more frequently found, however, and in greater quantities, in red wines than in rosé or white wines. Similarly, wines from the area of the Mediterranean basin appear to be more affected than wines produced in other areas. Regions with a cooler climate seem to be less affected.

23. The level of OTA varies considerably, therefore, among the various types of wines and vine products, the regions and the vintages.

OCCURRENCE IN WINE

24. Occurrence of OTA in wine was reported for the first time in 1995[15]. Concentrations of OTA were measured in table wine from the Swiss retail market:

- white wine : 24 samples, median < 3 ng/l, range: < 3– 178 ng/l
- rosé wine : 15 samples, median 19 ng/l, range <3-123 ng/l
- red wine: 79 samples, median 13 ng/l, range <3-388 ng/l
- dessert wine: 5 samples, median 337 ng/l, range 44-451 ng/l

25. Most of the occurrence data have been generated since 1995 for wine, dried vine fruits and grape juice, especially in the last five years.

26. Ochratoxin A has been analysed in 1997 in 29 wine samples (26 wine samples from France) and ochratoxin A was detected in 50 % of the samples with levels ranging from 0.01 µg/l to 0.27 µg/l, the highest levels been found in red wines from the Mediterranean region[16]..

27. The situation of OTA contamination of wine has been reported by Otteneder and Majerus[17]. OTA was measured in 420 samples.

- white wine : 60 samples, median 0.01 µg/l, range: < 0.01– 1.36 µg/l
- rosé wine : 55 samples, median 0.01 µg/l, range <0.01-2.38 µg/l
- red wine: 305 samples, median 0.02 µg/l, range <0.01 – 3.31 µg/l

An increase of OTA occurrence and concentration in wines from northern to southern regions could be observed e.g. France was reported.

28. Pietri et al[18] analysed 96 red wines and 15 white dessert wines produced in the years 1995-97 in 19 Italian regions for the presence of OTA. The survey showed that the geographic region of origin has a strong influence on OTA contamination both for red and for dessert wines. Wines produced in southern Italy were markedly more contaminated.

- red wine : 96 samples, median 0.09 µg/l, range <0.001 – 3.18 µg/l
- white dessert wine: 15 samples median 0.08 µg/l, range < 0.001 – 3.86 µg/l

29. Visconti et al.[19] analysed commercial and home made red wines coming mostly from southern Italy.

- commercial wine : 27 samples, median 0.90 µg/l, range <0.01-7.63 µg/l
- home made wine: 11 samples, median 0.66 µg/l, range 0.46 – 4.72 µg/l

30. Brera et al1[19] within the Italian project financed by the Ministry of Agriculture, analysed 814 commercial samples of wine (546 red, 222 white, 32 rosè and 14 dessert) produced in the years 1998-2003. The obtained mean results were 0.25 ug/L (red), 0.04 ug/L (white), and 0.28 ug/L (dessert and rosè).

31. Brera et al.[20] analysed 267 commercial wines including 19 dessert, 186 red, 11 rosé and 51 white produced mostly in the years 1997-2002 in Italian and Hungarian regions. The study showed that none of Hungarian wines were contaminated with OTA. As for Italian red wines, (N=208), 84% of the samples were found contaminated at levels ranging 0.01 and 4 ng/ml. Furthermore, OTA was detected in 63% of dessert (maximum level 1,64 ng/ml), in 56% of rosé (maximum level 1,04 ng/ml), and in 19% of white wine (maximum level 0.21 ng/ml). All samples were analysed according to Brera et al. method[21], by the use of an automated HPLC method and immunoaffinity cleanup.

32. A survey for the presence of ochratoxin A was conducted in Greece from 1995 to 1999 on 268 locally produced commercial wines. The OTA concentration in red dry wines (104 samples, median 0.09 µg/l) was not significantly different from that for white (118 samples, median 0.06 µg/l) and rosé (20 samples, median of 0.08 µg/l) wines. Samples of dessert wine (n=18) and retsina wine (n=8) showed higher OTA concentrations with medians of 0.33 and 0.27 µg/l respectively. Also a trend of increasing OTA contamination was observed for red wines from northern to southern Greece[20].

33. Two surveys have been performed on wines produced in France[21].

One survey concerned the analysis of 185 from the vintage 2002 and 2003. 14 % of the red wine samples and 1 % of the white wine samples contained detectable levels of OTA. For the red wines, the average level of samples in which OTA was detected was 0.21 µg/l while the average level in white wine was 0.1 µg/l. The highest level found was 0.5 µg/l.

Another survey was conducted in 2001 and consisted of 982 samples. The average level was 0.12 µg/l with 736 samples (75 %) containing levels lower than 0.2 µg/l, 165 samples (17 %) containing levels between 0.2 and 0.5 µg/l, 55 samples (5.6 %) between 0.5 and 1.0 µg/l and 26 samples (2.7 %) containing levels above 1 µg/l.

34. For the purpose of the assessment of dietary intake of OTA by the population of EU Member States, occurrence data of OTA in 1470 samples were reported [22] The overall mean level of OTA in wine was 0.36 µg/kg. The level in wine from the south of Europe (mean 0.64 µg/l) is higher than in wine from northern Europe (mean of 0.18 µg/l). The content is higher in red wine than in rosé and white wine.

35. In a survey on ochratoxin A in wine originating from Morocco, ochratoxin A was detected in 75 (39 %) from in total 192 samples. The levels found in 60 of 144 samples of red wine ranged from 0.01 to 0.5 µg/l with an average of 0.14 µg/l, in 10 of 25 samples of rosé wine from 0.01 to 0.55 µg/l with an average of 0.25 µg/l and in 4 of 16 samples of white wine from 0.01 to 0.16 µg/l with an average of 0.08 µg/l[23].

36. Surveillance data indicate lower levels in wine from North America compared with European wine. In one survey 180 samples of wine were analysed for OTA. Canadian wines, when compared with imported products showed both a lower OTA occurrence and a lower level of OTA contamination. Wines from the USA contained no quantifiable levels of ochratoxin A[24].

37. Sixty-eight samples were analysed in 2002 and 2003 to assess ochratoxin A contamination in various regions of Argentina and Chile. None of the analysed wines produced in Argentina or Chile were found to be contaminated (with an LOD of 0.008-0.012 µg/l and an LOQ of 0.015 – 0.04 µg/l)[25].

38. A survey of 601 samples of Australian wine for the presence of ochratoxin A was undertaken[26].

- red wine: 344 samples, median: <0.05 µg/l, range <0.05 – 0.62 µg/l.
- white wine: 257 samples, median < 0.05 µg/l, range <0.05 -0.50 µg/l

DIETARY EXPOSURE

39. In its evaluation on OTA in 2001, JECFA calculated the human exposure to OTA from different food sources. The approach followed resulted in a mean total intake of OTA of about 45 ng/kg bw per week, assuming a body weight of 60 kg. From these calculations, it can be observed that wine is the second most important contributor to the human OTA exposure, with an average intake of approx. 9 ng/kg of body weight per week, compared to an intake of 25 ng /kg bw per week from cereals and cereal products, being the most important contributor to the human OTA exposure. Coffee and grape juice contributed for only 2 to 3 ng/kg bw per week to the total OTA exposure.

40. During the examination of the position paper concerning ochratoxin prepared by Sweden, the presence of OTA in wine was highlighted for the first time during the 29th session of the CCFAC[27]. In subsequent sessions (30th, [28] and 31st sessions[29]) discussions continued whereby the dietary exposure from sources other than cereals (e.g. wine (15% of total OTA intake), beer (7.6 % of total OTA intake) grape juice and coffee (12 % of total OTA intake)) were also highlighted. Given the limited data available at that time on the presence of OTA in commodities other than cereals and because cereals and cereal products are by far the most important contributor to human OTA exposure, the Committee agreed to circulate for comment in the Step procedure a maximum level for OTA only for cereals and cereal products[30].

41. In 2002, an assessment of dietary intake of ochratoxin A by the population of the EU Member States was published[31]. In that report the intake of ochratoxin A from wine was assessed.

- For the overall population, the intake of OTA from wine ranged between 0.02 and 0.86 ng/kg of body weight per day
- For consumers only, the intake of OTA from wine ranged between 0.18 and 2.94 ng/kg per body weight and per day.

42. It was concluded that wine contributed 13 % of the mean European total dietary intake of OTA making it the second most important contributor, cereals and cereal products contributing the most (50 %) to the mean European total human OTA exposure.

43. A total diet study performed in France[32] shows that the estimated average ochratoxin A intake of the French population is 2.2 ng/kg b.w./day for adults aged 15 or more, 4.1 ng/kg b.w./day for children aged 3 to 14. The 95th percentile exposure is 3.6 ng/kg b.w./day for adults and 7.8 ng/kg b.w./day for children. The food groups contributing most (>70 %) to the exposure for both population groups are cereals and cereal products. Grape-based products (dried raisins, eating grapes, grape juice and wine) contribute less than 5 % to the total exposure.

PREVENTION OF OTA IN WINE

44. Several research projects have been performed to identify the factors involved in the formation of OTA in wine. One such research project is WINE-OCHRA RISK[33]. The aim of the project is to determine the critical control points for OTA formation during wine production, to specify the critical limits for all identified critical control points and to identify preventive and corrective actions to limit the presence of OTA in wine.

45. Good practices can be identified at all stages of grape and wine production to minimise levels of OTA in all vine based products:
- cultivation practices in vineyards (regional risk information, training of producers, vineyard establishment, plant material, growing techniques, pest and disease control)
- practices at harvest (production of raisins and raisined rapes, production of wine grapes)
- treatments at the winery (operations and pre-fermentation treatments, fermentation treatment, maturing and clarification treatments).

46. Furthermore, during the General Assembly of the International Organization of Vine and Wine (OIV) in October 2005, its Member Countries unanimously adopted a "Code for sound viti-vinicultural practices in order to minimise the levels of Ochratoxin A in vine-based products"[34]. This document establishes and precisely describes the various actions to be taken in vineyards and cellars to help reduce the risks related to the presence of ochratoxin A in vine-based products.

REGULATORY LEVELS FOR OCHRATOXIN A IN WINE

47. The European Union has established a maximum level for ochratoxin in wine (red, white and rosé) and other wine and/or grape must based beverages of 2 µg/l. This maximum level applies to products produced from the 2005 harvest onwards[35].

48. No other countries or regions in the world have set specific regulatory limits for ochratoxin A in wine[36]

49. The OIV adopted in 2002 a standard[37] which sets the maximum content of OTA in wine at the level of 2.0 µg/l from the 2005 harvest onwards.

50. In addition, more and more countries and purchasers test the ochratoxin A content in wines, and impose commercial thresholds (sometimes as low as 0.5 µg/l), which could result in barriers to trade.

CONCLUSIONS AND RECOMMENDATIONS

51. This discussion document on ochratoxin A in wine results in proposing the following recommendations for discussion at the 38th session of the CCFAC:

1. It is recommended that a Code for good practices be established by the Codex in order to prevent and reduce contamination by ochratoxin A in vine-based products, including wines. Given that the OIV has already established such a Code, it would be advisable to use this Code as a basis for the elaboration of the Codex Code, in accordance with the guidelines for co-operation between the Alimentarius Codex Commission and international intergovernmental organisations in the elaboration of standards and related texts, adopted by the Codex Commission in 2005[38]. A draft project paper for this new work is enclosed in Annex II of this discussion paper.

2. To ensure that all climatic and agricultural conditions are considered, it is appropriate that all wine producing countries participate to a drafting working group on the Code of Practice.

3. The necessity of the setting of a maximum level for ochratoxin A in wine in Codex Alimentarius should be considered after the Code of Practice has been developed.

ANNEX I

Project document

Proposal for new work on a "Code of good vitivinicultural practices for the prevention and reduction of ochratoxin A contamination in vine-based products."

1. The purpose and scope of the Standard

To develop a draft Code of good vitivinicultural practices for the prevention and reduction of ochratoxin A contamination in vine based products. The Code will cover cultivation practices in vineyards, practices at harvest and treatments at the winery

2. Its relevance and timeliness

Measures can be taken to prevent and reduce the presence of ochratoxin A in vine based products. Ochratoxin A is a hazard to human health. JECFA concluded in its assessment in 2001 that efforts are needed to ensure that intakes of ochratoxin A do not exceed the PTWI, and this could best be achieved by lowering overall contamination by appropriate agricultural, storage and processing practices. From different dietary exposure studies, it can be observed that wine is a significant contributor to the overall dietary human exposure of ochratoxin A. A code of Practice will provide a means of preventing and reducing the presence of OTA in vine based products, including wine.

3. The main aspects to be covered

The draft Code of Practice will cover all possible measures that have been proven to prevent and reduce ochratoxin A in vine based products. The Code will cover all stages of the production chain (cultivation practices in the vineyard, harvest, transport, pre-fermentation treatments, fermentation treatments, maturing and clarification treatments).

4. An assessment against the Criteria for the establishment of work priorities

This proposal is consistent with the following criteria for the establishment of Work priorities

(a) Consumer protection from the point of view of health (by minimizing consumer dietary exposure to ochratoxin A from vine based products)

5. Relevance to Codex Strategic objectives

This proposal is consistent with the Strategic Vision statement of the strategic Framework 2003-2007.

6. Information on the relationship between the proposal and other existing Codex documents

This new work is recommended in the Discussion paper on ochratoxin A in wine to be presented and discussed at the 38th Session of CCFAC.

7. Identification of any requirement for and availability of expert scientific advice

- Availability of information

* Resolution VITI-OENO 1/2005 – "Code of sound vitivinicultural practices in order to minimise levels of ochratoxin A in vine based products" adopted by the General Assembly of the International Organization of Vine and Wine (OIV) in October 2005.

In accordance with the guidelines on co-operation between the Codex Alimentarius Commission and international intergovernmental organisations in the elaboration of standards and related texts, adopted by the Codex Alimentarius Commission at its 28th session in July 2005, this Code adopted by the OIV can be used as a basis for preparing the proposed draft Code, subject to concurrence of the cooperating organisation.

8. Identification of any need for technical input to the standard from external bodies.

As the International Organization of Vine and Wine (OIV) and the International Federation of Wines and Spirits (FIVS) have "Observer Status" in the Codex Alimentarius Commission and as the OIV and FIVS participate in the activities of Codex Alimentarius Commission in general and of CCFAC in particular, there is no need for additional technical input from external bodies.

9. The proposed time line for completion of the new work, including the start date, proposed date for adoption at Step 5/8, and the proposed date for adoption by the Commission.

If the Commission accepts, in 2006, that the proposal for new work should proceed, the draft Code of Practice will be drafted and will be circulated for consideration at Step 3 at the 39th Session of the CCFAC. Adoption at Step 5 is planned for 2008 and adoption at Step 8 can be expected in 2009.

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