WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures Original: English

NOTIFICATION G/SPS/N/EEC/51

General reply of the European Communities

The following communication was received from the European Communities on 12 October 1998.

Toxicology of aflatoxins

1. The Scientific Committee for Food of the European Community (SCF) expressed on 23 September 1994 an opinion on aflatoxins, ochratoxin A and patulin (Reports of the Scientific Committee for Food, 35th series).

2. At that time the Committee concluded for aflatoxins, *inter alia*:

> "**Aflatoxins are genotoxic carcinogens.** For this type of carcinogen, it is generally felt that there is no threshold dose below which no tumour formation would occur. In other words, **only a zero level of exposure will result in no risk.**
>
> It agreed with the recent evaluations of IARC[1] (1993) with respect to the carcinogenicity and genotoxicity of the aflatoxins. From the many reports on risk assessment, it can be concluded that **even very low levels of exposure to aflatoxins, i.e. 1 ng/kg b.w./day or less contribute to the risk of liver cancer.**
>
> For aflatoxin M1, the Committee concluded that there is sufficient evidence that aflatoxin **M1 is a genotoxic carcinogen**; its carcinogenic potency is estimated to be approximately 10 times lower than aflatoxin B1."

3. This evaluation is also in agreement with the JECFA[2] evaluation (1987) that for these potent carcinogens (aflatoxins) their presence in food should be limited to "irreducible levels" which it defined as "that concentration of a substance which can not be eliminated from a food without involving the discarding of the food altogether, severely compromising the ultimate availability of major food supplies".[3]

4. At the 49th meeting, held in Rome, Italy from 17 to 26 June 1997, the JECFA reviewed a wide range of studies in both animals and humans that provided qualitative and quantitative information on the hepato-carcinogenicity of aflatoxins. The report of the discussions concerning aflatoxins has been

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[1] International Agency for Research on Cancer.
[2] Joint FAO/WHO Expert Committee on Food Additives.
[3] Evaluation of certain food additives and contaminants; Thirty-first report of the Joint FAO/WHO Expert Committee on Food Additives; WHO Technical Report Series 759, WHO, Geneva, 1987.

disseminated as a draft with the summary report of the meeting. Many notifications of third countries referred to this JECFA report.[4]

5. The Scientific Committee for Food of the European Community (SCF) discussed this recent JECFA evaluation at its 108th plenary session in September 1997[5] merely on the basis of the draft summary report.

6. The Committee (SCF) recognized the great effort made by JECFA to perform a quantitative risk assessment by combining carcinogenic potencies and human exposure data, but noted also the several limitations and assumptions, inherent in this approach, which were clearly set out in the report. The Committee concluded that it was not possible to assess the degree of uncertainty, arising from these limitations and assumptions, in the quantitative risk assessment and felt therefore that it was premature for SCF to draw definitive conclusions on this issue.

7. **The Committee noted that the toxicology of the aflatoxins is not questioned by JECFA "Aflatoxins are amongst the most potent mutagenic and carcinogenic substances known" and that several statements of the JECFA are not incompatible with the SCF opinion on aflatoxins expressed in 1994 and concluded that this opinion remains valid.**

8. On the basis of this assessment it is considered that fixing maximum levels, besides preventive measures to avoid contamination, contribute to the protection of the consumer. These limits must be set at a level as low **as reasonably achievable (= ALARA principle)**.

Maximum limits

9. For groundnuts, nuts, dried fruit, cereals and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs, maximum limits remain at the level of 4 µg/kg aflatoxin total (B_1 +B_2 + G_1 + G_2) and 2 µg/kg, aflatoxin Bl. It is generally accepted that the establishment of an international standard for raw commodities applying to incoming raw materials does not preclude individual countries from establishing more stringent standards for finished products that ultimately reach the consumer.[6]

10. Sorting techniques and other possible physical treatments which reduce the aflatoxin content can be carried out on unprocessed groundnuts, nuts, dried fruit and possibly cereals to obtain the final consumer product. Taking these techniques into account, higher maximum limits for groundnuts, nuts and dried fruit to be subjected to a sorting or other physical treatment, before their human consumption or their use as an ingredient in foodstuffs are proposed.

11. Following modifications have been adopted to the draft measures as notified, taking into account the comments:

12. Maximum limits for unprocessed groundnuts **has been increased from 10 ppb** (aflatoxin total) to **15 ppb**, in line with the limit currently under discussion in Codex Alimentarius.[7] This increase will also be considered for unprocessed nuts, dried fruit if data are provided before 1 July 1999 proving the effectiveness of the sorting techniques or other physical treatments to reduce

[4] Joint FAO/WHO Expert Committee on Food Additives, Forty-ninth meeting, Rome, 17-26 June 1997, Summary and Conclusions, enclosed section.

[5] Minutes of the 108th meeting of the Scientific Committee for Food held on 18-19 September 1997 in Brussels.

[6] CRD 5 of the 28th CCFAC meeting.

[7] ALINORM 99/12, Report of the Thirtieth Session of the Codex Committee on Food Additives and Contaminants, The Hague, The Netherlands, 9-13 March 1998, paras. 64-72 and Appendix X.

an aflatoxin level of 15 ppb in unprocessed nuts and dried fruit to the maximum level set for products intended for direct human consumption or use as an food ingredient.

13. For cereals it cannot be excluded that sorting techniques or other physical treatments can reduce the level of contamination of aflatoxins. In order to be able to check the real effectiveness of the sorting techniques or other physical treatments and, if necessary to fix specific maximum limits for the unprocessed cereal, the maximum limits laid down in the Regulation apply only to the cereals and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs. In the absence of data justifying the fixing of a specific maximum limit for unprocessed cereals, the maximum limit laid down for cereals and processed products thereof intended for direct human consumption or as an ingredient of food, will also apply to the unprocessed cereals from 1 July 1999 on.

14. Aflatoxin M1 is believed to be significantly less carcinogenic than aflatoxin Bl. However, because the intakes of milk and milk products by humans can be considerable, particularly among infants and young children, a maximum limit of aflatoxin M1 for milk has been set at the level of 0.05 µg/kg aflatoxin M1. The maximum limit of 0.05 ppb of aflatoxin M1 for milk and milk products is in line with the standard currently under discussion in the Codex Alimentarius.[8]

Sampling provisions

15. Commission Directive 98/53/EC of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs[9] apply to the competent authorities of the Member States which have to ensure that the sampling, sample preparation and methods of analyses used for the official control of the level of aflatoxins in foodstuffs is carried out in accordance with the provisions laid down in Annexes of this Directive. Therefore the draft directive has not been formally notified to the WTO. As this Directive does not involve direct obligations towards third countries, the draft measure has not been formally notified. However, given the importance of the sampling provisions to determine the aflatoxin content of a lot, the draft measures have been transmitted to the WTO for information.

16. In the comments submitted by Members of WTO, many comments referred to the sampling provisions.

17. Adequate sampling is crucial for estimating lot average levels and is an essential component in the development of any standard for mycotoxins, particularly due to the non-homogeneous distribution of aflatoxin contamination in foods such as grains, nut kernels, pulses and dried fruits (e.g. figs). In such material the distribution is seldom homogeneous. Whereas only a small number of particles may be contaminated, these individual particles may be highly contaminated. In order to describe the expected distribution and to ensure that such isolated "hot spots" are detected adequate sampling is needed (...) (paragraph 5 of CX/FAC 97/16).

18. As the result of the comments made by several Members of WTO, the sampling provisions for the products intended to be subjected to sorting or other physical treatment to reduce the aflatoxin contamination have been modified taking into account the comments from the Members of WTO, while the sampling provisions for final consumer products remained unchanged.

19. As mentioned above, the sampling provisions to control the aflatoxin level in products intended for direct human consumption or use as an ingredient in food remained unchanged. It is

[8] ALINORM 99/12, Report of the Thirtieth Session of the Codex Committee on Food Additives and Contaminants, The Hague, The Netherlands, 9-13 March 1998, paras. 73-75 and Appendix X.

[9] OJ L201, 17.7.98, p.93.

generally accepted that the establishment of an international standard for raw commodities applying to incoming raw materials does not preclude individual countries from establishing more stringent maximum limits for finished products that ultimately reach the consumer.[10] It is consistent with this reasoning that sampling provisions at international level for raw commodities does not preclude more stringent sampling rules at country level for products intended for direct human consumption or use as an ingredient in food. Indeed, the European Communities is of the opinion that the sampling provisions must minimize the consumer's risk, without rendering trade impossible or causing enormous costs for the operators.

20. As already mentioned above, the sampling provisions for the products intended to be subjected to sorting or other physical treatment to reduce the aflatoxin contamination (raw products) have been modified as a result of comments made by Members of WTO. The draft directive, transmitted for information to WTO, stipulated that each subsample of the aggregate sample has to comply with the maximum limit. The modification consists of that the above-mentioned Commission Directive 98/53/EC provides for that in the case of groundnuts, nuts and dried fruit subjected to a sorting or other physical treatment the lot is accepted **if the aggregate sample (in case the available equipment is able to homogenize the aggregate sample as a whole) or the average of the subsamples conforms to the maximum limit.**

21. It can be stated that the sampling provisions fixed for the products intended to be subjected to sorting or other physical treatment are to a great extent in line with the sampling provisions which are currently under discussion in the *Codex Alimentarius*.[11]

22. However some differences remain. The European Communities refers therefore to the relevant comments submitted at the 30th session of CCFAC.[12] These points are reiterated hereafter.

23. The sampling plan currently under discussion in Codex (100 incremental samples, 20 kg sample) provides an approximately equal balance between the producer risk and the consumer risk. Because of the toxicity of the aflatoxins, the European Communities is of the opinion that a sampling plan must minimize the consumer's risk, without rendering trade impossible or causing enormous costs for the operators.

24. The European Commission services notes that in the assumption of a guideline level of 15 µg/kg and using the sampling plan, currently under discussion in Codex[13] for raw shelled peanuts, a lot with aflatoxin concentration of 30 µg/kg (2x guideline level) will be accepted in 32.5 per cent of the cases and a lot with aflatoxin concentration of 60 µg/kg (4x guideline level) in 9.5 per cent (acceptance probabilities on the basis of data contained in the FAO Food and Nutrition Paper 55 (Rome, 1993), "Sampling Plans for Aflatoxin Analysis in Peanuts and Corn".

25. The European Communities consider the acceptance probabilities of lots with such a high aflatoxin content too high and is of the opinion that because of the toxicity of the aflatoxins, the sampling plan must minimize the consumer's risk, without rendering trade impossible or causing enormous costs for the operators.

26. Furthermore in appendix X of ALINORM 99/12 it is stated that the "[Maximum of [15 µg/kg] for total aflatoxins for peanuts intended for further processing, based on a sample size of 20 kg as

[10] CRD 5 of the 28th CCFAC meeting.

[11] ALINORM 99/12, Report of the Thirtieth Session of the Codex Committee on Food Additives and Contaminants, The Hague, The Netherlands, 9-13 March 1998, paras. 64-72 and Appendix X.

[12] CRD 5 - Comments from EC submitted in response to CL 1997/6-FAC.

[13] ALINORM 99/12, Report of the Thirtieth Session of the Codex Committee on Food Additives and Contaminants, The Hague, The Netherlands, 9-13 March 1998, Appendix X.

referenced in the following material obtained from FAO Food and Nutrition Paper 55 (Rome, 1993), "Sampling Plans for Aflatoxins Analysis in Peanuts and Corn"]". However the operating characteristic curves and proposed sample size enclosed refer only to raw shelled peanuts, while the proposed draft maximum level and sampling plan refer peanuts intended for further processing. However from the data provided in the FAO Food and Nutrition Paper 55 it can be concluded that for in-shell peanut a sample size of 27 kg is needed to obtain similar acceptance probabilities as for the 20 kg samples in the case of raw shelled peanuts.

27. Another important remark of the European Communities is that the number of incremental samples to be taken must be defined as a function of the lot size.

28. Linking the number of incremental samples to lot sizes for sampling for aflatoxin contamination is scientifically justified because of the very heterogeneous distribution of aflatoxins within a lot. It is generally recognized that in the case of heterogeneous distribution of the contaminant to be controlled within a lot, the sample size (number of incremental samples) has to be increased as the lot size increases to guarantee an equivalent level of performance.

29. General guidelines on sampling have been considered at the Codex Committee on Methods of Analysis and Sampling since its 19th Session for three consecutive sessions. Paragraph 2.2.9 Lot size and sample size of the document CX/MAS 98/3 which will be discussed at the next session of the Codex Committee on Methods of Analysis and Sampling[14] states that "it is usual to increase the sample size as the lot size increases, especially when the lot is not homogeneous".

30. This principle is also applied in existing. sampling plans currently used in the United States, United Kingdom and the Netherlands where the number of incremental samples to be taken is defined as a function of the lot size.[15]

31. The European Commission services are therefore of the opinion that the sampling plan should specify the lot size to which the sampling provisions apply and has taken up this provision in the sampling plan as described in Commission Directive 98/53/EC. In accordance with the paragraph 71 of the report of the Thirtieth Session of the Codex Committee on Food Additives and Contaminants (ALINORM 99/12), the European Communities has the intention to submit an alternative sampling plan to the Codex Alimentarius Commission for consideration by the twenty-third Session of the Codex Alimentarius Commission in Rome from 28 June to 3 July 1999.

Methods of analysis

32. The European Commission services are of the opinion that a criteria-based approach, whereby a set of performance criteria are established with which the method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specified method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability, coefficient of variation, reproducibility coefficient of variation, and the percent recovery necessary for various statutory limits. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

[14] Agenda item 4(a) of the Twenty-second Session of the Codex Committee on Methods of Analysis and Sampling, Budapest, Hungary, 23-27 November 1998.

[15] Whitaker et al (1995) Evaluation of Sampling Plans Used in the United States, United Kingdom and the Netherlands to test raw shelled peanuts for aflatoxin, Journal of AOAC International Vol. 78, N° 4, pp.1010-1018.

33. The criteria-based approach is also discussed at the Codex Committee on Methods of Analysis and Sampling. Point 2 of the document CX/MAS 98/5 "Criteria for evaluating Acceptable Methods of Analysis for Codex Purposes - Methods of Analysis or Method Criteria" which will be discussed at the next session of the Codex Committee on Methods of Analysis and Sampling[16] states that "The Committee has accepted in principle an alternative approach whereby a defined set of criteria to which methods should comply without specifically endorsing specific methods should be adopted".

34. Furthermore, besides analytical methods based on TLC for aflatoxin quantification as proposed in Codex, HPLC methods are now also commonly used on a routine basis.

35. The European Commission services question also the need to mention "a hammer mill with a # 14 screen (3.1 mm diameter hole in the screen) similar to the type used by the US Department of Agriculture to prepare samples for aflatoxin analysis is specified for peanuts" in an international standard and has adopted a more general requirement such as, that the laboratory sample should be finely ground and mixed thoroughly using a process that has been demonstrated to achieve complete homogenisation.

36. For the above-mentioned reasons the provisions concerning the method of analysis in Commission Directive 98/53/EC are not identical to the provisions outlined in Appendix X of ALINORM 99/12. In accordance with the paragraph 71 of the report of the Thirtieth Session of the Codex Committee on Food Additives and Contaminants (ALINORM 99/12), the European Communities has the intention to submit comments to the provisions concerning the sample preparation and proposed method of analysis to the Codex Alimentarius Commission for consideration by the twenty-third Session of the Codex Alimentarius Commission in Rome from 28 June to 3 July 1999.

[16] Agenda item 5 of the Twenty-second Session of the Codex Committee on Methods of Analysis and Sampling, Budapest, Hungary, 23-27 November 1998.

ANNEX

NOTIFICATION G/SPS/N/EEC/51

COMMENTS RECEIVED FROM MEMBER OF WTO

COUNTRY	**DATE**
INDIA (1)	23.01.1998
IRAN	24.01.1998
GAMBIA	04.02.1998
PHILIPPINES	11.02.1998
MALAYSIA	12.02.1998
AUSTRALIA	12.02.1998
UNITED STATES OF AMERICA	13.02.1998
TURKEY	13.02.1998
ARGENTINA	13.02.1998
SOUTH AFRICA	13.02.1998
SENEGAL	13.02.1998
INDIA (2)	13.02.1998
INDIA (3)	16.02.1998
THAILAND	16.02.1998
BRAZIL	16.02.1998
PERU	25.02.1998
NEW ZEALAND	23.03.1998