European Community Comments for the Codex Alimentarius Commission, 24th Session, 2-7 July 2001, Geneva, Switzerland - Agenda Item 10 a) Consideration of Codex standards and related texts – draft standards and related texts at Step 8 or equivalent.

Draft maximum level for Aflatoxin M1 in milk(ALINORM 01/12A–Appendix X)

BACKGROUND

The 23rd session of the Commission (Rome, June 1999) agreed to return the draft maximum level of 0.05 μg/kg for aflatoxin M1 in milk to step 6 for additional comments and further consideration by the CCFAC, with the understanding that information should be provided on the public health and potential economic implications of a higher level or a lower level as proposed as well as the levels of aflatoxin contamination found in milk.

The Codex Committee on Food Additives and Contaminants decided at its 32nd session in March 2000 to return the draft maximum level of 0.05 μg/kg for aflatoxin M1 in milk at step 6 for additional comments and consideration at the 33rd Session of the CCFAC. The Committee requested the 56th Session of JECFA (February 2001) to examine exposure to aflatoxin M1 and to conduct a quantitative risk assessment to compare the levels of 0.05 μg/kg and 0.5 μg/kg in milk.

The Committee forwarded the draft Maximum level of 0.5 μg/kg for aflatoxin M1 in milk to the 24th Session of the Commission for adoption at step 8. The Member States of the European Community present at the meeting and the delegations of Czech Republic, Hungary, Republic of Korea, Norway, Poland, Slovak Republic, South Africa and Switzerland expressed their reservation to this decision.

POSITION:

The European Community supports the maximum level of 0.05 μg/kg for aflatoxin M1 in milk. This limit is considered as being the most appropriate in view of public health and feasibility considerations. Indeed, monitoring programmes in the EU have resulted in a large amount of recent occurrence data (e.g. >7000 in 1999) of aflatoxin M1 in milk. These data clearly indicate that the level of 0.05 μg/kg for aflatoxin M1 in milk is achievable and has to be established as maximum limit following the ALARA (As Low As Reasonably Achievable) principle.

Therefore concern has been expressed at the meeting of CCFAC about the level of 0.5 μg/kg for aflatoxin M1 because in the case of genotoxic carcinogens, exposure at any level might pose a health risk to consumers, in particular to children, and the level should therefore be as low as reasonably achievable.

Discussion:

Toxicology
With regard to the toxicology of aflatoxins, the Scientific Committee for Food (SCF) of the European Community expressed on 23 September 1994 an opinion on aflatoxins (and on ochratoxin A and patulin). (Reports of the Scientific Committee for Food, 35th series). The Committee concluded, 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 Scientific Committee for Food 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. However, because the intakes of milk and milk products by humans can be considerable, particularly among infants and young children, the risks from aflatoxin exposure need careful consideration (paragraph 4 of CX/FAC 97/16)

**Consequences for trade in feedingstuffs**

The claim that a maximum limit of 0.5 µg/kg M1 should be considered as the lowest practicable level considering problems in managing the maximum amounts of aflatoxins in the feed is not in accordance with the recommendations as mentioned in the code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk producing animals. (ALINORM 97/12A, Appendix IX.), as adopted by the Codex Alimentarius Commission \(^2\)

This code of practice recommends, inter alia,

"2.5.3. If aflatoxin B1 is detected, consider one or more of the following options. In all cases ensure that the aflatoxin B1 level of the finished feed is appropriate for its intended use (i.e. maturity and species of animal being fed) and is consistent with national codes and guidelines or qualified veterinary advice.

2.5.3.1. Consider the restriction of AFB1 contaminated feed to a percentage of the daily ration such that the daily amount of AFB1 ingested would not result in significant residues of AFM1 in milk.

2.5.3.2. If feed restriction is not practical, divert the use of highly contaminated feedingstuffs to non-lactating animals only"

**CONCLUSION**

JECFA concluded in its 56\(^{th}\) meeting (Geneva, February 2001) that "according the calculations made, that with worst case assumptions, the additional risks for liver
cancer predicted with use of the proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 µg/kg are very small."

The European Community is of the opinion that in case of genotoxic carcinogens, exposure at any level might pose a health risk to consumers, in particular to children, and the level should therefore be set as low as reasonably achievable.

Extensive amount of data sent to JECFA showed that the level of 0.05 µg/kg is achievable in most regions of the world.

For some regions of the world for which on the basis of the submitted the level of 0.05 µg/kg seemed not to be achievable, the European Community notes that no evidence has been submitted that the recommendations as mentioned in the Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk producing animals, have been followed.

The European Community notes furthermore that no detailed information has been provided on the potential economic implications of the lower level for aflatoxin M1 in milk i.e. 0.05 µg/kg.

The European Community does not accept the level of 0.5 µg/kg for aflatoxin M1 in milk for the reasons mentioned above.

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1 International Agency for Research on Cancer