

**European Community Comments for the
CODEX COMMITTEE ON FOOD ADDITIVES
AND CONTAMINANTS**

Beijing, People's Republic of China, 20-24 March 2000

CL 1999/13-GEN - CX 0016 FAC - Agenda item 16a

Draft Maximum Level for Aflatoxin M1 in milk

By CL 1999/13-GEN a maximum level of 0.05 µg/kg for aflatoxin M1 in milk at step 5 is proposed (ALINORM 99/37, paras 103-105).

The European Community appreciates the opportunity to reiterate its opinion on this matter.

POSITION:

The European Community supports the maximum level of 0.05 µg/kg for aflatoxin M1 in milk.

The limit of 0.05 µg/kg for aflatoxin M1 is of application for liquid milk. This limit is also applicable to milk products which are dried or processed, taking into account the concentration caused by the drying process or by processing.

DISCUSSION:

Toxicology

With regard 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 IARC¹ (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.”

¹ International Agency for Research on Cancer

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At the 49th meeting, held in Rome, Italy from 17 to 26 June 1997, 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 Scientific Committee for Food (SCF) discussed this recent JECFA evaluation on the basis of the draft summary report of the meeting and recognised the great effort made by JECFA to perform a quantitative risk assessment by combining carcinogenic potencies and human exposure data. But the Committee 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 to draw definitive conclusions on this issue.

The Committee (SCF) noted that several of JECFA's statements are not incompatible with the SCF opinion on aflatoxins expressed in 1994 and concluded that this opinion remains valid.

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 Commission²

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”

² Alinorm 97/37 Report of the Twenty-second Session of the Joint FAO/WHO Codex Alimentarius Commission, Geneva, 23-28 June 1997, Appendix III, Part I.

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Taking the above mentioned recommendations into account, it is acknowledged that feeding dairy cattle with supplementary feedingstuffs, containing low levels of aflatoxin B1, no longer constitutes a problem.

Following maximum limits for aflatoxin B1 for feed materials and feedingstuffs are applied within the European Community.

Feedingstuff	Maximum content in µg/kg relative to a feedingstuff with a moisture content of 12 %
For the feed materials groundnut, copra, palm kernel, cotton seed, babassu, maize and products derived from the processing thereof	20
For feed materials, other than those mentioned above	50
Complete feedingstuffs for dairy cattle	5
Complementary feedingstuffs for dairy cattle	5

The European Community would appreciate to receive the scientific evidence, which supports the claim, as mentioned in one of the comments in CX/FAC 00/16, that “a maximum limit of 0.05 µg/kg aflatoxin M1 in milk is a *de facto* limit of 4 µg/kg of aflatoxin B1 in feed ingredients”.

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