

DRAFT EC REGULATION - AFLATOXIN CONTROL

Submission by Australia

The following communication was received from Australia on 5 March 1998.

EC Notification G/SPS/N/EEC/51: Comments by Australia

1. The following comment by Australia in respect of G/SPS/N/EEC/51 has been forwarded to the EC enquiry point.
2. The notification relates specifically to the setting of maximum limits for aflatoxin B1 and total aflatoxins in groundnuts, dried fruit, cereals, milk and processed products thereof. The stipulated rationale for this sanitary measure is public health.
3. It is considered unlikely that the proposed maximum levels for aflatoxins will result in a significant reduction in health risk to EC consumers. A draft report of the evaluation of aflatoxin-related health risk undertaken by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) in June 1997 supports this position. The report, while stating that aflatoxin levels should be reduced as low as reasonably achievable, also emphasizes the significant role of hepatitis B infection in the population as a factor in aflatoxin-induced human liver cancer, and the importance of vaccination in reducing the incidence of liver cancer. The report states that populations with a low prevalence of hepatitis B individual and/or with a low mean intake (less than 1 ng/kg/ bw/day) are unlikely to exhibit detectable differences in population risks for standards in the range 10-20 µg/kg. Thus, in Europe, the proposed change to the standard is unlikely to significantly reduce the risk of liver cancer.
4. The proposed sampling procedure is unduly onerous and likely to be costly. Under the proposed sampling plan it is estimated that up to 75 per cent of lots rejected would be "good lots". In general, the sampling statistics of aflatoxin detection are exceptionally difficult, especially given that the uncertainty of Type 1 and Type 2 errors increases significantly with lower limits. We are of the view that 15 µg/kg is the lowest level that can be practically and reliably met in any environment which has effective regulatory surveillance.
5. Due to the increased statistical uncertainty, the cost of attempted conformance increases disproportionately to the proposed decreased maximum level. This cost relates to both the increased number of good lots rejected coupled to the loss in yield and increased cost of processing. We are of the opinion that the number of disputes will increase dramatically due to the increased Type 2 error. Moreover, the ability of the European Communities to apply the same rigour to their domestic retail surveillance is questionable.

6. FAO/WHO through the Code Committees on Food Additives and Contaminants (CCFAC) and Cereal, Pulses and Legumes (CCCPL) have attempted to harmonize aflatoxin sampling plans and legal limits for peanuts and other commodities. An FAO/WHO Technical Consultation on Sampling Plans for Aflatoxin Analysis in Peanuts and Corn evaluated the performance of 35 aflatoxin sampling plans using two sample sizes (5 and 20 kg) and five accept/reject limits ranging from 5 to 30 µg/kg total aflatoxin. As a result of this process, the aflatoxin sampling plan now pending before CCFAC to test raw shelled peanuts for aflatoxin in the export/import market uses the 20 kg sample and a 15 µg/kg (total aflatoxin) accept/reject limit.

7. In the EC notification there are no details of a risk assessment which was undertaken to justify the reduction in aflatoxin level from the Codex draft limit of 15 µg/kg. It is therefore not possible to establish that the level of protection afforded by the proposed EC standard is materially different to that of the Codex draft norm presently under development, and underpinned by the JECFA risk assessment. Accordingly, we invite the Commission to reconsider its position in relation to this proposed standard.

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