

DRAFT EC REGULATION - AFLATOXIN CONTROL

Submission by India

The following communication was received from India on 13 February 1998.

Comments by India on the proposed EC regulation amending Commission Regulation (EC) No. 194/97 of 31 January 1997 setting maximum levels for certain contaminants in foodstuffs

1. The European Commission's proposed amendment to its existing regulation No. 194/97 of 31 January 1997, which has been circulated as WTO document G/SPS/N/EEC/51 dated 8 January 1998, indicates that the Commission is proposing to adopt a new regulation to establish maximum limits for aflatoxins in certain foodstuffs from March 1998.
2. India has examined the draft EC regulation and considers the proposed maximum limits for aflatoxins in groundnuts, nuts and dried fruit and processed products thereof; cereal and processed products thereof; and for milk and milk products to be unjustifiably low in relation to consumer aflatoxin exposure and the potential risk. India believes that these levels are so low that they will inevitably lead to serious trade disruptions without a corollary increase in consumer protection. Further, the provisions for multiple sampling and analysis will greatly increase handling costs with no appreciable reduction of aflatoxin contamination in consumer products.
3. India is also concerned that these measures have been notified even while the Codex Committee on Food Additives and Contaminants is seized of the matter and had in its previous meeting considered the adoption of suitable international standards for limiting the level of aflatoxin in various food products. In fact this issue figures in the agenda circulated for the 30th Session of the Codex Committee on Food Additives and Contaminants scheduled to be held in The Hague from 9-13 March. We feel that the EC proposal to notify its standards, even while the concerned international body is addressing this issue, is not appropriate, especially since the maximum permissible levels which the European Commission proposes to implement are much higher/stringent than the levels which are under consideration in the Codex Committee.
4. We are also of the view that since the food products covered by EC's proposed regulation are extensively traded, it is important to maintain a balance between the export and import of these items. Setting very low limits of aflatoxin for these products would prove to be a barrier to trade. EC's proposal is contrary to the Codex scientific principle of deciding the values based on acceptable daily intake (ADI). The EC limits are not based on acceptable dietary intake values and the stand taken by the European Commission, that there is no threshold of aflatoxin below which no harmful effect is observed, requires proper scientific justification.
5. India would also like to highlight that Article 3.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures (henceforth referred to as "the Agreement") specifically states that "Members

shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations". Though it can be argued that no international standard exists at present, it is a fact that the Codex Committee is in the final stages of setting an international benchmark in this regard. Even otherwise assuming that there is an imperative urgency for the European Commission to 'harmonize' its international standards, it must be noted that it has been specifically stipulated in the Agreement that where international standards do not exist or where Members fix standards higher than existing international standards, they shall ensure that such measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health. Such a scientific assessment or risk analysis does not appear to have been undertaken.

6. Furthermore Article 5.4 of the Agreement directs that "Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimising negative trade effects". It is obvious that in formulating the present regulation undue reliance has been placed on qualitative assessment which has resulted in a measure which prescribes a higher than appropriate level of protection required. It contravenes the provisions of Article 5.4 which directs Members to keep the objective of minimising negative trade effects firmly in view while determining the appropriate level of sanitary or phytosanitary protection. These measures are also violative of Article 5.6 of the SPS Agreement which states "Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" in as much that they would have a significant negative trade impact.

7. In the above context India would like to bring the following facts to the notice of the European Commission:

- (a) Though an international standard on the acceptable level of aflatoxin in food products does not exist at present, the Codex Committee is seized of the matter and would be considering it in its forthcoming meeting scheduled from 9-13 March 1998. We therefore feel that the timing of the EC's proposed regulation, coming as it does just before the Codex Committee meeting, is inappropriate and that the European Commission should wait for Codex to set the requisite international standards.
- (b) The draft EC regulation does not give any details whatsoever of the risk assessment which may have been carried out taking into account available scientific evidence on the basis of which these levels have been proposed. This is specially important since the European Commission is proposing to set much more stringent levels, as far as the permissible limits of aflatoxin are concerned, in comparison to the standards that are currently being followed internationally.
- (c) The draft EC regulation does not give the details of the proposed sampling procedure. It is, however, learnt that the EC regulation proposes to stipulate the taking of three samples all of which must test less than the permissible limit of aflatoxin, for the lot to be accepted. India feels that the sampling plan is costly, burdensome and unjust; that it will not in any way increase consumer protection and instead will have an adverse impact on the price of the commodity. On the other hand, it would put undue burden on suppliers thereby distorting trade by limiting the volume and number of suppliers who can routinely meet this criteria. Moreover, the sampling plan would mean an unnecessary waste of good material without actually improving consumer safety. The latest JECFA study published in June 1997 shows that an increase in the upper ceiling of total aflatoxin from 10 ppb to 20 ppb would theoretically increase the risk of liver cancer by only two additional cases annually, per one billion population in industrialised countries.

- (d) Moreover, the sampling plan stipulated in the proposed EC regulation has serious negative trade effects as it leads to wastage of material fit for human consumption to the extent of 75 per cent of the quantity and adds to the cost. The sampling plan proposed is, therefore, costly, burdensome and unjust.
- (e) As regards the proposed maximum levels of aflatoxin in milk, it is our view that fixing this at a level of 0.05 ppb is far too stringent and not based on any scientific data or clinical studies regarding risk management. Further, such a protection level appears to be based on unrealistic assumptions. In the case of milk it is understood that the calculation for MI MRLs for all contaminants/pesticides are based on the maximum consumption figures of 1,500 grammes per person per day, which is 7-8 times higher than the world's per capita consumption of milk. Such an evaluation based on exaggerated assumptions would naturally result in unrealistic and impractical standards leading to creation of non-tariff trade barriers. Studies in the United States have shown that a limit of 0.5 ppb in milk is sufficient for the protection of public health. This may also be perhaps the lowest level which can be achieved practically. Further, as milk from animals consuming aflatoxin contaminated feeds may contain aflatoxin M1, it would be more appropriate to first develop a code of practice regarding aflatoxin in feedstuffs. Detailed studies need to be carried out regarding the amount of M1 which will be excreted against the controlled dose of ingested B1. It is only based on the results of such studies that the maximum limit of M1 in milk and milk products should be decided.

8. In conclusion, India would like to reiterate that in its view the proposed maximum levels for aflatoxin are unjustifiably low and that introduction of such rigorous import requirements, without a corollary increase in consumer protection, would lead to significant trade disruption. We therefore urge the Commission to review its proposed amendment of regulation No. 194/97 of 31 January 1997, which has been notified in WTO document G/SPS/N/EEC/51 dated 8 January 1998.

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