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Autor: Verstraete, Frans
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EU legislation on mycotoxins in food and feed*

Frans Verstraete

European Commission

DG Health and Consumer protection, Brussels, Belgium

E-mail: frans.verstraete@cec.eu.int

The EU harmonisation of legislation on contaminants, including mycotoxins, in food fulfils two essential objectives: the protection of public health as major objective but also to ensure the proper functioning of the internal EU-market.

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food is the framework for the Community action on contaminants, including mycotoxins, in food. This Regulation does not apply to contaminants which are the subject of more specific Community rules such as pesticide residues, veterinary drug residues, ...

This Framework Regulation provides that:

- food containing a contaminant in an amount which is unacceptable from the public health viewpoint shall not be placed on the market
- contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all stages of the production chain (ALARA)
- in order to protect public health, maximum levels for specific contaminants shall be established where necessary (by comitology)
- provides for mandatory consultation of a scientific body (EFSA) for all provisions which may have an effect upon public health.

A scientific risk assessment comprises a hazard identification, toxicological evaluation and risk characterisation. A tolerable intake is the level of intake at which no harmful effects are expected to occur. In cases of genotoxic compounds, no safe level can be identified and therefore no tolerable intake can be set.

Through the exposure assessment the foods/food groups contributing significantly to the exposure are determined. The human exposure is assessed against the tolerable intake in order to define the measures to protect public health.

*Summary of the lecture presented at the 117th annual conference of the society of Food and Environmental Chemistry on 8 and 9 September 2005

Based on the provisions and principles laid down in this framework Regulation, maximum levels for the following mycotoxins have been established at EU level: aflatoxin B₁, aflatoxin total (B₁, B₂, G₁ and G₂), aflatoxin M₁, ochratoxin A, patulin and the *Fusarium*-toxins deoxynivalenol, zearalenone, fumonisin B₁+B₂ and T-2 and HT-2 toxin.

Besides the establishment of maximum levels, also detailed rules for the sampling and methods of analysis for the official control have been established.

Besides the setting of maximum levels, codes of practice have been elaborated (patulin) or are under elaboration (*Fusarium* toxins) to ensure a high level of consumer protection

As the consequence of frequent findings of high levels of aflatoxins in some products originating from some third countries, specific safeguard measures have been taken imposing special conditions as regards the import of these products.

Directive 2002/32/EC of 7 May 2002 of the European Parliament and of the Council on undesirable substances in animal feed is the framework for the Community action on undesirable substances, including mycotoxins, in feed.

This Framework Directive provides that:

- products intended for animal feed may enter for use in the Community from third countries, be put into circulation and/or used in the Community only if they are sound, genuine and of merchantable quality and therefore when correctly used do not represent any danger to human health, animal health or to the environment or could adversely affect livestock production
- in order to protect animal and public health and the environment, maximum levels for specific undesirable substances shall be established where necessary (by comitology)
- provides for mandatory consultation of a scientific body (EFSA) for all provisions which may have an effect upon public health
- products intended for animal feed containing levels of an undesirable substance that exceed the established maximum level may not be mixed for dilution purposes with the same, or other, products intended for animal feed and may not be used for the production of compound feed.

Based on the provisions and principles laid down in this framework Directive, maximum levels for aflatoxin B₁ and rye ergot have been established at EU level.

Guidance values are under discussion for ochratoxin A and the *Fusarium*-toxins deoxynivalenol, zearalenone and fumonisin B₁+B₂ in cereals and cereal products intended for animal feeding and for compound feedingstuffs (for sensitive animal species).

Furthermore discussions are ongoing to replace the current provisions on rye ergot (sclerotia) by specific maximum levels for some ergot alkaloids.

In the presentation, particular attention was paid to the regulatory framework for mycotoxins in food and feed, the procedure for setting maximum levels (decision-making process) and the specific provisions on mycotoxins in food and feed.