



Directorate-General for
Health & Consumers

**Mycotoxins in food: a
continuing challenge for
regulation and science.**

Frans Verstraete



MYCOTOXINS

- Production losses
 - Crops and animal production
 - Economic losses
 - Endangering availability of staple foods
 - Trade problems
 - Quality problems
 - **Endangering FEED AND FOOD SAFETY**
- **Multiple reasons to tackle the issue at all fronts (science, prevention and regulation)**



OUTLINE PRESENTATION

- Overall regulatory framework for feed and food safety legislation
- Regulatory framework for contaminants (mycotoxins)
- Prevention and regulation – challenges
- From risk assessment to risk management
- Risk management tools - challenges
- Sampling and analysis – challenges



OUTLINE PRESENTATION

- Codex Alimentarius
- EU ongoing discussions
- Driving forces for new legislation
- EU future discussions (?)
- Data collections
- Trends
- Conclusions



GENERAL FOOD LAW

Scope and objectives

- Applies to all stages of the production, processing and distribution of food and also of feed produced for, or fed to, food producing animals
- “farm to fork” approach**
- Provides that food law shall pursue one or more general objectives of a **high level of protection of human health** and the **protection of consumers’ interests** and of, where appropriate, **the protection of animal health** and welfare, plant health and the environment



GENERAL FOOD LAW

Objectives

- Provides that food law shall aim to achieve the **free movement** in the European Union of feed and food manufactured or marketed according to the general principles and requirements of food law
- Provides that when **international standards** exist or their completion is imminent, they shall be taken into consideration in the development of food law, except where such standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law



GENERAL FOOD LAW

Risk analysis

- In order to achieve the general objective of a high level of protection of human health, **EU feed/food legislation shall be based on *risk analysis*** (process consisting of three interconnected components: risk assessment-risk management-risk communication) except where this is not appropriate to the circumstances or the nature of the measure (e.g. labelling)
- Risk assessment shall be based on the ***available scientific evidence*** and undertaken in an **independent, objective and transparent manner**



GENERAL FOOD LAW

Risk management

- **Risk management shall take into account the results of risk assessment, other factors legitimate to the matter under consideration and the precautionary principle where appropriate**
- **Mycotoxins: legitimate factor: feasibility and achievability of levels through prevention at reasonable economic cost**



Contaminants food

Council Regulation 315/93

- Regulatory framework for contaminants in food:

Council Regulation (EEC) N) 315/93 of 8 February 1993 laying down Community procedures for contaminants 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, ...)



Regulation 315/93

Provisions

■ General provision:

- food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market

■ Good practice:

- contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages of the production /feed/food chain (ALARA)



Regulation 315/93

Provisions

- When necessary for protecting public health maximum levels shall be established for specific contaminants --> Procedure for setting maximum levels. This can also include a reference to the sampling and analysis methods to be used.
- Obligatory consultation of the European Food Safety Authority (EFSA) Panel on contaminants in the food chain to provide a risk assessment before provisions having effect upon public health shall be adopted.



Risk management Prevention and Regulation

- “prevention is better than cure” to protect the consumer (humans and animals) from the toxic effect of contaminants → need for encouraging preventive actions such as good agricultural practice, good storage conditions, use of improved sorting procedures, good manufacturing practice ...
- Fixing maximum limits is not contrary to prevention. Fixing maximum levels at a reasonably achievable level, stimulates preventive actions at all stages to avoid contamination of the feed/food chain.



Risk management Prevention and Regulation

- Regulatory standards (maximum levels) provide a benchmark against the effectiveness of the successful implementation of prevention programmes and provide a tool for control authorities to control the correct application of prevention measures by each actor in the chain
- If maximum limits are fixed, these should be fixed at a level reasonably achievable but stimulating a preventive approach.

Challenges for science

- Prevention requires knowledge
- Identify factors involved in the development of toxigenic fungi and formation of toxins
- Search for and investigate the different possibilities to “manage” the factors in a viable economic production system to prevent toxigenic fungi development and toxin formation



Setting regulatory limits for contaminants – food

■ Scientific risk assessment:

- assessment of the risks related to the presence of a contaminant in foodstuffs for human health / establishment of a tolerable intake / health based guidance value
- exposure assessment: human exposure (average and 95 percentile) Particular attention to vulnerable groups of population, high level consumers, ...
- Risk characterisation: human exposure assessed in relation to the health based guidance value

--> is the basis for the measures to be taken



Setting regulatory limits for contaminants – food

- Determination of foods/food groups significantly contributing to the exposure
- Occurrence data of the contaminant in the various food/food groups
- Setting a maximum level following the ALARA principle (As Low As Reasonably Achievable - see before prevention versus regulation). The degree of severity of the application of this principle depends on the relation exposure - tolerable intake
- Other appropriate management tools



Risk management tools used for contaminants food

- **Maximum levels:** aflatoxins, ochratoxin A, lead, cadmium, 3-MCPD, nitrates, inorganic tin
- **Maximum levels with regional derogations:** dioxins and dioxin-like PCBs, nitrates in vegetables
- **Maximum levels combined with code of practice for prevention and reduction:** patulin, Fusarium-toxins
- **Comprehensive strategy (feed and food) comprising of a combination of maximum levels, action levels, target levels and source-directed measures:** dioxins and dioxin-like PCBs



Risk management tools used for contaminants food

- **Maximum levels with data collection:** PAH, dioxins
- **Maximum levels combined with dietary advice:** mercury
- **Code of practice:** ethylcarbamate
- **Dietary advice**
- **Data collection:** acrylamide, furan, PFOS/PFOA, ...
- **Tools for reduction of presence:** acrylamide combined with monitoring to monitor effective implementation of tools // indicator values



Mycotoxins regulated in the EU under 315/93 (Food) - Tools

- Aflatoxin B1, Aflatoxin total, aflatoxin M1: maximum levels
- Ochratoxin A: maximum levels
- Patulin: maximum levels and recommendation on prevention
- Fusarium-toxins (zearalenone, fumonisins, deoxynivalenol): maximum levels and recommendation on prevention



Challenges for science

- Determination of toxicity for human health of the different mycotoxins
- Occurrence of mycotoxins in the different foods
- Effect of combined exposure
- Fate of mycotoxin during processing – influence of different food processing procedures on mycotoxin content (exposure assessment)
- Carry-over from feed to food of animal origin → impact on human health
- Possibilities to remove mycotoxin contamination from food (through sorting or through other physical processes)
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Regulatory limits for mycotoxins – sampling

- Adequate sampling procedures are of crucial importance for estimating lot average levels in case contaminants are heterogeneously distributed throughout a lot (as is the case for mycotoxins) and is therefore in these cases an essential component in the development of any maximum level
- In EU and international legislation, maximum levels for mycotoxins are always combined with sampling provisions (and requirements for the methods of analysis)



Regulatory limits for mycotoxins – sampling

- Through sampling procedure, an accurate estimate of the true level of mycotoxin in a batch is pursued
- exporter's risk/producer's risk against importer's risk/consumer's risk: EU policy is that a sampling procedure must be practicable and must minimise the consumer's risk without rendering trade impossible

Challenges for science

- Development of adequate sampling procedures: representative and feasible – heterogeneity – large size batches – estimation of sampling uncertainty
- Methods of analysis + measurement uncertainty
 - Confirmatory
 - Screening
- Screening approach (not only analysis but also sampling): sampling and analysis – very low rate of false negatives – acceptable rate of false positives



CODEX ALIMENTARIUS

- April 2007: first session of the Codex Committee on Contaminants in Food (CCCCF)
- Codex General Standard for Contaminants and Toxins in Food (GSCTF)



CODEX ALIMENTARIUS

GSCTF – General principles

- MLs shall be set only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade.
- MLs shall be set only for those foods that are significant for the total exposure of the consumer to the contaminant or highly contaminated → when identifying the significance of certain foods in the total exposure to the contaminant -→ criteria in the CCCF Policy for Exposure Assessment of Contaminants and Toxin in Food should be consulted



CODEX ALIMENTARIUS

GSCTF – General principles

- MLs shall be set as low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods in order to avoid undue disruptions of food production and trade. Where possible ML's shall be based on GMP and /or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable



CODEX ALIMENTARIUS

Existing MLs on mycotoxins

- 15 µg/kg of aflatoxins total in peanuts for further processing and related sampling provisions
- 15 µg/kg of aflatoxins total in almonds, hazelnuts, pistachios and shelled Brazil nuts for further processing and 10 µg/kg for aflatoxins total in almonds, hazelnuts, pistachios and shelled Brazil nuts ready to eat
- 0.5 µg/kg of aflatoxin M1 in milk
- 5 µg/kg of ochratoxin A in raw wheat, barley and rye
- 50 µg/kg of patulin in apple juice and apple juice as ingredient in other beverages



CODEX ALIMENTARIUS

Codes of practice – mycotoxins

- Prevention and reduction of aflatoxins in peanuts (CAC/RCP55-2004)
- Prevention and reduction of aflatoxins in tree nuts (CAC/RCP 59-2005)
- Prevention and reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk producing animals (CAC/RCP 45-1997)
- Prevention and reduction of Mycotoxin contamination in cereals including annexes on ochratoxin A, zearalenone, fumonisins and trichothecenes (CAC/RCP 51-2003)
- Prevention and reduction of patulin in apple juice and apple juice ingredients in other beverages (CAC/RCP 50-2003)



CODEX ALIMENTARIUS

Codes of practice – mycotoxins

- Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine
- Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs
- Code of Practice for the Prevention and Reduction of Ochratoxin A in Coffee



CCCF- Current discussions on mycotoxins

- Maximum Levels for Fumonisin in Maize and Maize-Products and Associated Sampling Plans
- Maximum levels for aflatoxin total in dried figs
- Maximum levels deoxynivalenol (DON)
- Ochratoxin A in Cocoa (code of practice)



EU – ongoing discussions

- Ochratoxin A in wheat bran
- Ochratoxin A in spices (in particular in Capsicum)
→ assessment of feasibility of lower level by 1 July 2011
- Aflatoxins in nuts (chestnuts)
- Aflatoxins in dried figs (in preparation of Codex Alimentarius)
- Zearalenone in wheat bran
- Doxynivalenol in certain foods (high whole meal flour containing foods)
- T2 and HT toxin



Driving forces for initiating new EU-legislation on contaminants

- **Contamination incidents with “new” (not yet regulated) contaminants:** melamine, mineral oil, ...
- **New (at EU level) risk assessments:** non-dioxin like PCBs, arsenic, ...
- **Updated risk assessments:** cadmium, PAH, mercury, ochratoxin A, lead, zearalenone in wheat bran...
- **Developments in risk assessment approaches**
 - **Risk-benefit assessment:** nitrates in vegetables
 - **Margin of Exposure (MOE):** genotoxic carcinogens such as aflatoxins, PAH



Driving forces for initiating new EU-legislation on contaminants

- **Emerging contaminants:** Brominated flame retardants (BFR), PFOS/PFOA, Alternaria toxins, 3-MCPD esters, enniatins, ...
- **Changing production conditions/ climate change:** *Fusarium* toxins
- **International developments within the Codex Alimentarius :** lead in fish, aflatoxins, melamine, ...
- **Identified problems with current legislation:** *Fusarium* toxins, ochratoxin A in wheat gluten ...

EU – future discussions (?)

- Alternaria toxins
 - Alternariol (AOH), Alternariol monomethyl ether (AME) and altuene (ALT)
 - Tenuazonic acid (TeA)
 - Altertoxins (ATX)
 - Alternaria alternata sp lycopersici toxins (AAL-toxins)
 - Tentoxin
- Ergot alkaloids
- Aspergillus toxins
 - Sterigmatocystin
 - Citrinin

EU – future discussions (?)

- Fusarium toxins
 - Enniatins and beauvericin
 - Diacetoxyscirpenol
 - Nivalenol
 - Moniliformin
- Phomopsins



Ongoing data collection by EFSA

- The integration of newly generated data into existing databases on occurrence data and the creation of new occurrence databases (e.g. *Fusarium* toxins in feed and food) in the field of contaminants in feed and food on a permanent basis → will **ensure continuity of data collection**.
- enables EFSA to access accurate data when quick action is required to handle urgent requests for scientific opinions/statements e.g. in case of contamination incidents and/or requests for scientific opinions where scientific assessments are needed within a short period and separate calls for data would require too much time.



Ongoing data collection by EFSA

- the set up of these permanent data collection exercises will stimulate the generation of occurrence data in accordance with the standard sample description for feed and food and the electronic transmission of data in the appropriate reporting format



Trends (and challenges) in regulation → challenges for science

- Cost – benefit considerations (impact assessment)
- Balance risks of contaminants – benefits of consumption of certain foods (health risk – health benefit considerations)
- New risk assessment approaches: The Margin of Exposure (MOE) approach, threshold of toxicological concern (TTC)
- ...

Conclusions

- **Regulating mycotoxins in food :**
 - **Challenges for risk assessment, risk management, risk communication.**
 - **Challenges for enforcement**
(representative sampling / availability of reliable routine methods of analysis / sampling uncertainty/ measurement uncertainty)
 - **Research/science as driving force for regulation versus science as limiting factor for regulation**