

# **Update on mycotoxin situation in Europe: regulatory framework strategy, achievements and current and future topics**



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# OUTLINE PRESENTATION



- Overall regulatory framework for feed and food safety legislation
- Mycotoxins in feed
  - **Regulatory framework, risk assessment → risk management, levels, recent developments**
- Mycotoxins in food
  - **Regulatory framework, risk assessment → risk management, maximum levels, sampling and analysis prevention and monitoring**
- Codex Alimentarius: current discussions
- Current and future EU regulatory developments

# EU-FRAMEWORK FEED AND FOOD SAFETY



**Regulation (EC) 178/2002 of the European  
Parliament and of the Council of 28 January  
2002**

**laying down the general principles and  
requirements of food law, establishing the  
European Food Safety Authority and laying  
down procedures in matters of food safety  
“The General Food Law (GFL)”**

# 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 Community 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**
  - **E.g. mycotoxins: legitimate factor: feasibility and achievability of levels through prevention at reasonable economic cost**

# GENERAL FOOD LAW

## The precautionary principle



- The **precautionary principle** provides that where, following an assessment of available information, the **possibility of harmful effects** on health has been identified but **scientific uncertainty** persists, **provisional risk management measures** necessary to ensure the high level of health protection chosen in the EU may be adopted, **pending further scientific information for a more comprehensive risk assessment**

# GENERAL FOOD LAW: Food / Feed Safety requirements



- **If feed and food are unsafe, feed and food shall not be placed on the market and feed shall not be fed to animals**
  - **Food shall be deemed to be unsafe if it is considered to be:**
    - injurious to health,
    - unfit for human consumption.
  - **Feed shall be deemed to be unsafe if it is considered to**
    - have an adverse effect on human and animal health
    - make food derived from food producing animals unsafe for human consumption.

# GENERAL FOOD LAW

## Emergency measures



- In case it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, emergency measures can be adopted to protect public and animal health.

# Contaminants feed Directive 2002/32/EC



- Regulatory framework for contaminants/undesirable substances in feed:
  - **Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed**

(this Directive does not apply to veterinary matters relating to public and animal health regulated by other Community rules)

# Contaminants feed Directive 2002/32/EC



- General provision:
  - **Products intended for animal feed may enter for use into the Community, be marketed and used in the Community only if they are sound, genuine and of merchantable quality and therefore do not represent any danger to human health, animal health or to the environment or do adversely affect livestock production.**
  - **Maximum levels and action levels can be set for contaminants in all products intended for animal feed**

# Contaminants feed Directive 2002/32/EC



- Obligatory consultation of the European Food Safety Authority (EFSA) Panel on contaminants in the food chain before provisions having effect upon public health or animal health or the environment
- Mixing of products intended for animal feed not complying with maximum level with other products intended for animal feeding for dilution purposes is prohibited
- Detoxification is allowed also by chemical treatment

# Setting regulatory limits for contaminants in feed



- Scientific risk assessment: assessment of the risks related to the presence of a contaminant in feed for animal and human health
    - \* establishment of a toxic exposure level for different animal species – animal health – sensitive animal species
    - \* carry over from feed into food of animal origin – quantitatively – different animal species / different animal products (impact on human health)
- > is the basis for the measures to be taken**

# Setting regulatory limits for contaminants in feed



- Determination of the feed materials which are important sources of contamination
- Occurrence data of the contaminant in the various feed materials/feeds
- Setting a maximum levels for feed materials and compound feeds taking into account the factors mentioned above (sensitivity animals, feed materials source of contamination, ...) and considering what is reasonably achievable.

# Mycotoxins regulated in the EU under 2002/32/EC (Feed)



- Maximum levels are relative to a feedingstuff with a moisture content of 12 %
- Maximum levels for aflatoxin B1 and rye ergot (1 g of sclerotia in unground cereals)
- Sampling according Directive 76/371/EC establishing the sampling procedures to be applied in feed for official control (currently under review)

# Mycotoxins – Feed Recommendation 2006/576/EC



- EFSA opinions on deoxynivalenol (2 June 2004), zearalenone (28 July 2004), fumonisins (22 June 2005), ochratoxin A (22 September 2004)
- Animal health effects critical effects – impact public health minor as carry-over from feed to food is limited
- Two-step approach: Recommendation on increased monitoring combined with guidance/orientation values as first step – evaluation in 2009 to consider possible further legal measures in the frame of Directive 2002/32/EC

# Mycotoxins – Feed Recommendation 2006/576/EC



- Cereals and cereal products include also cereal forages and roughages
- Guidance values to be used by feed business operators as guidance for the determination of critical limits in their HACCP system – attention for cereals and cereal products for the production of feed for sensitive animal species - guidance values for cereals and cereal products have been determined for the most tolerant animal species

# Deoxynivalenol (DON) Guidance values feed



- Cereals and cereal products with the exception of maize by products 8 ppm
- Maize by-products 12 ppm
- Complementary and complete feed: 5 ppm
  - **Except for pigs** 0.9 ppm
  - **Except for calves, lambs and kids** 2 ppm

# Zearalenone (ZEA)

## Guidance values for feed



- Cereals and cereal products with the exception of maize by products 2 ppm
- Maize by-products 3 ppm
- Complementary and complete feed
  - For piglets and gilts (young sows) 0.1 ppm
  - For sows and fattening pigs 0.25 ppm
  - For calves, dairy cattle, sheep (including lamb) and goats (including kids) 0.5 ppm

# Ochratoxin A (OTA) guidance values for feed



- Cereals and cereal products 0.25 ppm
- Complementary and complete feed:
  - For pigs 0.05 ppm
  - For poultry 0.1 ppm

# Fumonisin B1 + B2

## Guidance values for feed



- Maize and maize products 60 ppm
- Complementary and complete feed:
  - For pigs, horses, rabbits and pet animals 5 ppm
  - For fish 10 ppm
  - For poultry, calves, lambs and kids 20 ppm
  - For adult ruminants and mink 50 ppm

# Council Regulation 315/93



- Regulatory framework :

Council Regulation (EEC) No 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 (ALARA)**

# Regulation 315/93 Provisions



- When necessary for protecting public health maximum levels shall 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 before provisions having effect upon public health shall be adopted.

# From risk assessment to risk management



- **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 management measures to be taken

# From risk assessment to risk management



- Determination of foods/food groups significantly contributing to the exposure
- Food groups with frequent findings of high level of contamination
- Occurrence data of the contaminant in the various food/food groups
- Setting a maximum level following the ALARA principle (As Low As Reasonably Achievable). The degree of severity of the application of this principle depends on the relation exposure - tolerable intake

# Prevention and Regulation



- “prevention is better than cure” to protect the consumer (humans and animals) from the toxic effect of mycotoxins → need for encouraging preventive actions such as good agricultural practice, good storage conditions, 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.

# 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.

# Sampling



- Adequate sampling procedure is of crucial importance for estimating lot average levels in case contaminants are heterogeneously distributed throughout a lot (as is the case for aflatoxins, ochratoxin A,...) and is therefore in these cases an essential component in the development of any maximum level
- 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

# Method of analysis



- Performance criteria based approach.
  - **Advantage: does not avoid making use of technological progress and newest technologies and laboratories can use the analytical method most appropriate for their facilities**
  - **includes parameters such as detection limit, repeatability, coefficient of variation, reproducibility recovery for various levels**

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



- **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**

# Maximum levels: Commission Regulation (EC) No 1881/2006



- **Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.**
  - Food containing a contaminant exceeding the ML shall not be placed on the market
  - Maximum level does apply to edible part
  - For dried, diluted, processed or compound foodstuffs: concentration/dilution factors, relative proportion of the ingredients apply insofar no specific Community MLs have been established for these dried, diluted, processed or compound foodstuffs

# Maximum levels: Commission Regulation (EC) No 1881/2006



- The specific concentration or dilution factors shall be provided and justified by the food business operator – in the absence thereof competent authority defines the factor based on available information and with the objective of maximum protection of human health.
- prohibition of mixing contaminated with non contaminated consignments and prohibition of deliberate detoxification by chemical treatment

# Maximum levels: Commission Regulation (EC) No 1881/2006



- Specific provisions for the application of the maximum levels of groundnuts, nuts, dried fruit and maize, to be subjected to sorting or other physical treatment to reduce the aflatoxin contamination before human consumption or use as an ingredient.
- Specific provisions for the application of MLs of aflatoxins in groundnuts, derived products thereof and cereals: double use (for feed or for food)

# Sampling and methods of analysis - mycotoxins



- **Regulation (EC) 401/2006 of 23 February 2006**
- Replaces 4 former Commission Directives: 98/53/EC (aflatoxins), 2002/26/EC (ochratoxin A), 2003/78/EC (patulin) and 2005/38/EC (Fusarium-toxin)
- One single sampling method per commodity for the official control of mycotoxins

# Commission Recommendations on prevention



- 2003/598/EC: prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages
- 2006/583/EC: prevention and reduction of Fusarium-toxins in cereals and cereal products

# Commission Recommendations on monitoring



- 2007/.../EC monitoring of the presence of ergot alkaloids in cereals and cereal products for feed and food: ergocristine, ergotamine, ergocryptine, ergosine, ergometrine, ergocornine (where possible also the sclerotia content for establishing if possible a correlation)

# Commission Decision 2006/504/EC of 12 July 2006



- As the consequence of frequent findings of (high) levels of aflatoxins exceeding the maximum levels: Special measures to protect public health as regards pistachios from Iran, peanuts from Egypt, dried figs, hazelnuts and pistachios from Turkey, peanuts from China, Brazil nuts in shell from Brazil, peanuts from Brazil and almonds from US

# CODEX ALIMENTARIUS



- April 2006: last combined Codex meeting additives and contaminants (CCFAC)
- April 2007: first session of the Codex Committee on Contaminants in Food (CCCF)
- 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 ,
- 0.5 µg/kg of aflatoxin M1 in milk
- 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)

# CCCF – Current discussions on mycotoxins



- **Maximum level for aflatoxin total in unprocessed and ready-to-eat hazelnuts, pistachios and almonds**
  - Levels discussed: 15 µg/kg for « further processing » and 8 µg/kg for « ready-to-eat »
  - EFSA opinion on aflatoxins on 25/01/2007: toxicity, influence of different MLs on exposure, MOE
  - Discussion paper on occurrence, risk assessment, sampling, impact codes of practice
  - JECFA assessment in June 2007
  - EU position

# CCCF- Current discussions on mycotoxins



- Maximum level **ochratoxin A (OTA)** in raw wheat, barley and rye
  - **Level discussed: 5 µg/kg**
  - **JECFA assessment in June 2007**
- Code of Practice for the prevention and reduction of OTA in wine,
- Aflatoxins in Brazil nuts and figs
- OTA in coffee and cocoa,

## Current discussions at EU level on mycotoxins in food - guidance



- **provide additional guidance to competent authorities to ensure harmonised application of EU legislation throughout the EU:**
  - **guidance note for competent authorities for the control of compliance with EU-legislation on aflatoxins (available on SANCO-website)**
    - Listing of establishments able to perform physical treatment and sorting to reduce aflatoxin content
    - fate of non compliant lots
    - processed products compound food
  - **guidance note on sampling of large lots (static/dynamic) of cereals for mycotoxins as well developing an screening approach to control a large number of lots in short time.**

# Current discussions on mycotoxins in food - Ochratoxin A (OTA)



- EU research project on the mechanisms of OTA induced carcinogenicity finished spring 2005
- EFSA adopted on 4 April 2006 an opinion on ochratoxin A updating the scientific opinion from SCF in light of these and other new research results
- Based on this updated risk assessment, a review of the OTA measures is ongoing
  - Revision of the ML in dried vine fruit and grape juice in view of a reduction
  - Consideration of setting an ML in green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat and meat products, spices and liquorice

# Current discussions on mycotoxins in food - Ochratoxin A



- Food commodities currently considered for setting a maximum level for OTA in addition to the existing levels for OTA
  - **Spices (chillies, chilli powder, cayenne, paprika, white and black pepper, nutmeg, ginger, turmeric, cloves)**
  - **Liquorice root for herbal infusions**
  - **Liquorice extract for use in liquorice confectionery**

## Current discussions on contaminants in food - Fusarium-toxins in maize



- Regulation (EC) 1881/2006: Anticipated levels for deoxynivalenol in unprocessed maize (applicable from 1 July 2007), zearalenone in maize and maize products (applicable from 1 July 2007), and fumonisins in maize and maize products (applicable from 1 October 2007).
- Not all factors for the formation of Fusarium toxins in maize were known
- A time period to perform investigations was granted

## Current discussions on mycotoxins in food - Fusarium-toxins in maize



- New information on the presence of Fusarium toxins in maize and maize products was provided at the Fusarium-toxin fora (13/01/2006 and 15-16/01/2007)
- These data, in particular as regards the harvest 2006, indicate that a reconsideration of anticipated levels is appropriate (and necessary).

# Fusarium-toxins in maize

## Levels applicable as from 01/10/2007



### – DON:

- Unprocessed maize: 1750 µg/kg
- Milling fractions > 500 µm : 750 µg/kg
- Milling fractions ≤ 500 µm level: 1250 µg/kg

# Fusarium-toxins in maize

## Levels applicable as from 01/10/2007



### – ZEARALENONE

- 350 µg/kg for unprocessed maize,
- 200 µg/kg for milling fractions > 500 µm,
- 300 µg/kg for milling fractions ≤ 500 µm,
- 400 µg/kg for refined maize oil,
- 100 µg/kg for maize intended for direct human consumption, maize-based snacks and maize based breakfast cereals,
- 20 µg/kg processed maize based foods for infants and young children

# Fusarium-toxins in maize

## Levels applicable as from 01/10/2007



### – FUMONISIN B1 + B2

- 4000 µg/kg for unprocessed maize,
- 1400 µg/kg for milling fractions > 500 µm,
- 2000 µg/kg for milling fractions ≤ 500 µm,
- 1000 µg/kg for maize for direct human consumption and maize based foods for direct human consumption
- 800 µg/kg for breakfast cereals and maize based snacksb
- 200 µg/kg processed maize based foods for infants and young childrenb

# Future discussions on mycotoxins in feed and food



- FEED AND FOOD
  - T-2 and HT-2 toxins
  - Nivalenol (?)
  - Ergot alkaloids
  - Alternaria toxins (?)
  - Review of existing maximum levels
- FOOD
  - Review of provisions and control frequencies of Commission Decision 2006/504/EC
  - Review of the provisions on aflatoxins following Codex decisions (?)
- .....