

# From risk assessment to risk management – focus on contaminants



**Frans Verstraete**  
**European Commission**  
**DG Health and Consumer**  
**Protection**

# GENERAL FOOD LAW



**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**

# GENERAL FOOD LAW OBJECTIVES



- General food law applies to all stages of the production, processing and distribution of food and also of feed produced for, or fed to, food producing animals
- 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



- 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
- 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, the GFL lays down that EU food legislation shall be based on *risk analysis* 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 ANALYSIS



- 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

# 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

## The precautionary principle



- Measures adopted on the basis of the precautionary principle must be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration
- Such measures must be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment



# Contaminants food Council Regulation (EC) 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 (EC) 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 (EC) 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.

# Regulation (EC) 315/93 Provisions



- safeguard clause: as consequence of new information or reassessment of existing information --> suspicion of constituting a health risk although complying EU legislation
- internal market: no restriction on placing on the market for foods complying with EU legislation for reasons relating to their contaminant content
- competent Standing Committee: Standing Committee on the Food Chain and Animal Health

# 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 --> is the basis for the measures to be taken
- exposure assessment: human exposure (average and 95 percentile) assessed against tolerable intake. Particular attention to vulnerable groups of population, high level consumers, ...

# 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). **The degree of severity of the application of this principle depends on the relation exposure - tolerable intake**

# 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

# Contaminants feed Directive 2002/32/EC



- safeguard clause: as consequence of new information or reassessment of existing information --> suspicion of constituting a animal or human health risk although complying EU legislation
- internal market: no restriction on placing on the market for feeds complying with EU legislation for reasons relating to their contaminant content
- competent Standing Committee: Standing Committee on the Food Chain and Animal Health

# Setting regulatory limits for contaminants – 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 // carry over into food of animal origin --> is the basis for the measures to be taken
- Toxic exposure assessment: identification of most sensitive animal species // carry over into food of animal origin ...

# Setting regulatory limits for contaminants – 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 feeds taking into account the factors mentioned above (sensitivity animals, feed materials source of contamination, public health impact ...) and considering what is reasonably achievable.

# Risk management options contaminants food



- **Maximum levels:** aflatoxins, ochratoxin A, lead, cadmium, 3-MCPD, inorganic tin
- **Maximum levels with regional derogations:** nitrates, dioxins and dioxin-like PCBs
- **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

# Risk management options contaminants food



- **Maximum levels with data collection:** PAH, dioxins
- **Maximum levels combined with dietary advice:** mercury
- **Dietary advice alone:**
- **Tools for reduction of presence:** acrylamide combined with monitoring to monitor effective implementation of tools

# Risk management options contaminants feed



- **Maximum levels:** aflatoxin B1, arsenic, lead, fluorine, mercury, cadmium, dioxins and dioxin-like PCBs
- **Guidance values with increased monitoring:** ochratoxin A, deoxynivalenol, zearalenone, fumonisin B1+B2
- **Guidance levels combined with code of practice for prevention and reduction:** Fusarium-toxins
- **Comprehensive strategy (feed and food) comprising of a combination of maximum levels, action levels, target levels and source-directed measures:** dioxins

# Risk management options contaminants feed



- **Indicator levels with data collection:** ergot alkaloids (ergocristine, ergotamine, ergocryptine, ergometrine, ergosine, ergocornine)



# Risk assessment → management New approaches



- Substances which are both genotoxic and carcinogenic
  - No tolerable intake can be established
  - Margin of Exposure : ratio of [the benchmark dose lower confidence limit (BMDL10)]/ [the estimated intake in humans]
  - MOE to be used by risk manager to prioritise different genotoxic carcinogenic contaminants
  - Acceptability of an MOE is a risk management decision
  - Not applicable for substances which are subject to authorisation

# Risk assessment → management New approaches



- MOE's estimated by JECFA for some genotoxic carcinogens (2005)
  - **Acrylamide: 75 – 300**
  - **Ethylcarbamate: 3800 – 20000**
  - **PAH: 10000 - 25000**

# Risk assessment → management New approaches



- Risk-benefit considerations
  - Balance risks of contaminants – benefits of consumption of foods
  - Risk-benefit analysis = risk-benefit assessment + management + communication
  - Qualitative tools available – quantitative assessment confronted with many uncertainties
  - Common scale of measurement

# From risk assessment to risk management

## Aflatoxins



- Risk assessment
  - Aflatoxin are genotoxic carcinogens
  - Animal health risk limited
  - Carry over from feed into milk
- Risk management
  - Food very strict levels
    - B1 stricter than total aflatoxins
  - Feed – strict levels for milk producing animals // less strict levels for non milk producing animals

# From risk assessment to risk management

## Dioxins and dioxin-like PCBs



- Risk assessment
  - TWI of 14 pg WHO-TEQ/kg body weight
  - Considerable proportion of Community population has a dietary intake in excess of the TWI
- Risk management
  - **Strict levels**
  - **Active approach to reduce the levels**
  - **Revisions of maximum levels in view of significant reduction of these levels**

# From risk assessment to risk management

## Fusarium toxins – Food



- Risk assessment
  - TDI for the different toxins
  - Human exposure
- Risk management
  - Maximum levels for the different toxins
  - Level of knowledge as regards the different toxins different

# From risk assessment to risk management

## Fusarium toxins – Feed



- Risk assessment
  - Animal health effects
  - Impact human health limited
- Risk management
  - Increase knowledge – by-products → monitoring
  - Guidance values : most strict for pigs
  - Evaluation of approach within 3 years

# From risk assessment to risk management ochratoxin A in feed and food



- Risk assessment
  - Food: TWI of 120 ng/kg b.w.
  - Food: Dietary exposure below TWI, including consumers of foods containing OTA. No exposure assessment for infants and children
  - Feed: animal health - pigs and poultry
  - Feed: carry over from feed to food limited
- Risk management
  - Food: Commodities to be additionally covered by legislation
  - Feed: guidance values only for poultry and pigs



# From risk assessment to risk management



- PAH
  - Genotoxic carcinogens
  - Contamination through drying and smoking processes and environmental contamination
  - Benz(a)pyrene as indicator for all toxic PAH.
  - Monitoring on all toxic PAH
- Mercury
  - TWI of 1.6  $\mu\text{g}/\text{kg}$  b.w.
  - Risk groups

# Risk assessment → Risk management



- Risk assessment : health based guidance value → new approaches
- Risk assessment always the basis for taking risk management measures related to food safety
- Other legitimate factors: considered on a case by case basis