



Directorate-General for Health & Consumers

**Recent developments in European
legislation regarding feed safety
issues with particular focus on
undesirable substances**

Frans Verstraete

OUTLINE PRESENTATION

- Basic principles general food law
- Basic provisions Directive 2002/32/EC
- Regulating contaminants in feed: issues
- Recent developments /case studies
 - Mycotoxins (deoxynivalenol, zearalenone, fumonisins and ochratoxin A)
 - Unavoidable carry-over of coccidiostats into non-target feed
 - Recent developments as regards the review of Annex to Directive 2002/32/EC
- Outlook to future regulatory activities as regards undesirable substances in feed.



General Food Law - 178/2002

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 (feed) 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 178/2002

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 – 178/2002

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 178/2002

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



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)

Directive 2002/32/EC

Scope

- **undesirable substances in products for animal feed**
 - undesirable substance; any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or the the environment or could adversely affect livestock production
 - products intended for animal feed means feed materials, premixtures, additives, feedingstuffs and all other products intended for use or used in animal feed.



Directive 2002/32/EC

Scope

- Without prejudice to the provisions in other Community legislation concerning animal nutrition and concerning veterinary matters
- without prejudice to the provisions on pesticide residue legislation



Directive 2002/32/EC

Basic provision (Art 3)

- 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 particular products for animal feed not complying with the maximum levels established in Annex I are not "genuine, sound and of merchantable quality"

Directive 2002/32/EC

Action level (Art 4)

- Aim of setting action levels: carry out investigations to identify sources of undesirable substances, once identified reduce or eliminate sources of contamination;

Directive 2002/32/EC- Prohibition of mixing /Complementary feedingstuffs

- Non-complying products intended for animal feed may not be mixed for dilution purposes with the same or other products intended for animal feed
- Specific provisions for complementary feedingstuffs in case no specific provisions:
 - taking into account proportion daily ration --
> may not exceed maximum level for complete feed

Directive 2002/32/EC – maximum /action levels - detoxification

- Commission establishes/modifies maximum and/or action levels
 - maximum levels relative to a feedingstuff with a moisture content of 12 %
- Commission may define
 - acceptability criteria for detoxification processes as complement to the criteria provided for the products intended for animal feed undergone such processes
- Member States shall take the measures to guarantee
 - the correct application of detoxification and conformity of detoxified products



Directive 2002/32/EC

Other provisions

- Competent Committee: Standing Committee for the Food Chain and Animal Health - section Animal nutrition.
- Internal market: no stricter rules
- 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
- Community provisions of application for products intended for animal feed to be exported to third countries (except: return/re-export country of origin)

Directive 2002/32/EC Annex undesirable substances

■ Ions and elements

- arsenic, lead, fluorine, mercury, nitrites, cadmium

■ mycotoxins

- aflatoxin B1, rye ergot

■ organic contaminants

- dioxins, dioxin-like PCBs, organochlorine pesticides (aldrin, dieldrin, camphechlor, chlordane, DDT, endosulfan, endrin, heptachlor, HCB, HCH (alpha, beta and gamma isomers))

Directive 2002/32/EC Annex undesirable substances

■ inherent plant toxins

- hydrocyanic acid, free gossypol, theobromine, volatile mustard oil, vinyloxazolidine thione, ...

■ botanical impurities

- (*Lolium temulentum*, *Lolium remotum*) Datura stramonium, Castor oil plant, *Crotalaria* spp, (*apricots*, *bitter almond*,) unhusked beech mast, (*camelina*), mustard (Indian, Sareptian, Chinese, black, Ethiopian), (*Mowrah*, *Bassia*, *Madhuca*), purghera, croton

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 – animal health – sensitive animal species
 - * carry over from feed into food of animal origin – quantitatively – different animal species / different animal products
- > is the basis for the measures to be taken**



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, ...) and considering what is reasonably achievable.

REGULATING CONTAMINANTS IN FEED: ISSUES TO BE CONSIDERED

- Contaminant: effect on public health, animal health, environment → determining the nature of the measure
- Sensitivity /tolerance towards a contaminant (animal health): species specific
- Carry over of contaminants of feed into food of animal origin: species specific
- Feed materials: non species specific
- Compound feed: species specific

REGULATING CONTAMINANTS IN FEED: ISSUES TO BE CONSIDERED

- Bio-availability of contaminant in a certain feed material or additive
- Achievability of certain levels under normal good practice production conditions
- Feed materials: can be by-products of food production, other production processes such as bio-energy...
- Proportion of use of a certain product for feed in comparison with the total production
- Feasibility to decontaminate at a reasonable cost
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MYCOTOXINS IN CEREALS

USE OF CEREALS

Use of cereals, excluding rice, in period 2006-2008 - approximate figures for EU-27 (losses (market) not taken up in the table)

Cereal	% for human consumption	% for animal feed	% for seeds	% for industrial use
total cereals	23-24	63-64	4.1 - 4.3	8.9 – 9.1
common wheat	39-42	45-49	4.4 – 4.9	7.0 – 7.3
durum wheat	86-87	4.1	8.3 – 8.5	1.0
Rye	41-42	30 - 38	9 - 16	11 – 20
barley	0.7	75 - 76	5.3 – 5.6	18-19
Oats	16 - 17	73 -75	6-7	2.4 – 2.5
maize	5.9-6.2	83 - 84	0.6	8.5 – 9.0
other cereals	1.0 -1.3	93 - 95	4 - 5	0.4 – 0.6

MYCOTOXINS IN CEREALS

USE OF CEREALS

- Large part of the production of cereals is used for animal feed
- Cereals for food production: by products → intended for animal feed
- Cereals for bio-energy: by products → intended for animal feed
- Alternative uses for “non-compliant” cereals limited → serious economic impact

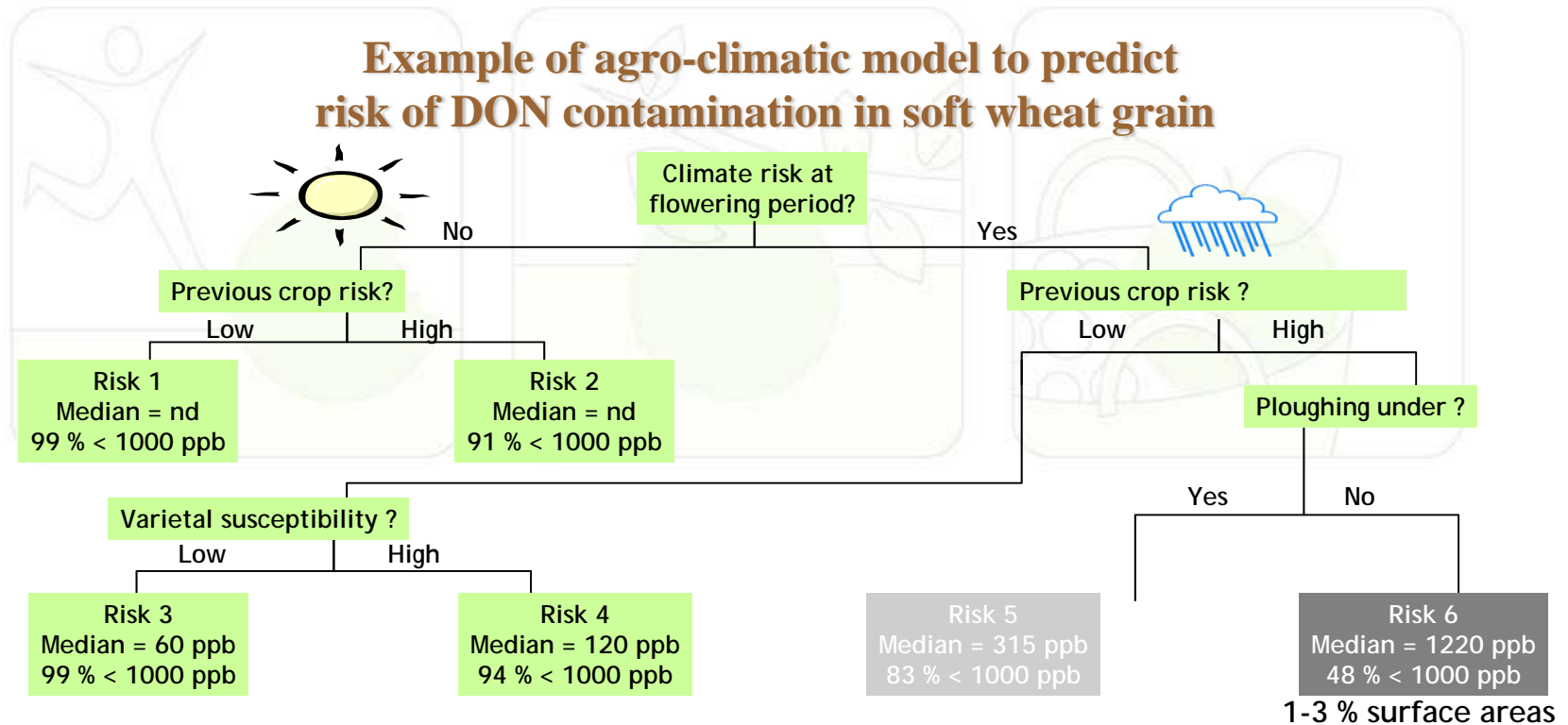
Recommendation

Prevention *Fusarium*-toxins

- Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of *Fusarium* – toxins in cereals and cereal products
 - Risk factors to be considered for inclusion in Good Agricultural Practices (GAP)
 - Contamination by *Fusarium*-toxins of cereals can be imputed to multiple factors
 - integrated approach addressing in a reasoned way all possible risk factors taking into account the local situation

MYCOTOXINS IN CEREALS

FEASIBILITY



MYCOTOXINS IN CEREALS

FEASIBILITY

■ Presence of Fusarium-toxins

- Large year to year variation
- Management measures a relative (limited) impact on presence

■ Presence of ochratoxin A and aflatoxins

- Management measures (storage conditions) major impact on presence



REGULATING MYCOTOXINS IN FEED: considerations

- EFSA opinions on deoxynivalenol (2 June 2004), zearalenone (28 July 2004), fumonisins (22 June 2005), ochratoxin A (22 September 2004)
- Scientific risk assessment concludes that the presence of deoxynivalenol, zearalenone fumonisins and ochratoxin A in animal feed can **endanger animal health and livestock performance** but is of **limited** (ochratoxin A) or **no** (deoxynivalenol, zearalenone and fumonisins) **significance for public health**



Mycotoxins – Feed Recommendation 2006/576/EC

- 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 on achievement of objectives in 2 years time (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 applied to judge acceptability of compound feed and cereal and cereal products for animal feeding
- 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 – “upper guidance values”

Mycotoxins in feed

Particular issues of attention

- Unusual contamination in feed materials previously not known to be contaminated by a certain mycotoxin e.g. zearalenone in soya hulls from Argentina → risk for animal health – responsibility of / risk for the feed business operator
- By products of wet milling industry: no maximum level applicable to maize and maize products used for starch production. Level in starch is no problem but level in by products ??? Intensive monitoring required to avoid animal health problems !!!

Unavoidable carry-over cocciostats - issue

- Broad range of feedingstuffs produced in one feed manufacturing company / different types of products manufactured after each other in the same production line → **carry-over / cross contamination from one batch to another** -- > **technically unavoidable traces of those substances in "non-target feed"**, *i.e.* in feed for which the use of cocciostats or histomonostats are not authorised, such as feed intended for animal species or categories not provided for in the additive authorisation
- Cross – contamination in purchased premixtures, product related cross-contamination, establishment related cross-contamination



Unavoidable carry-over cocciostats – requirements FBO

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for **feed hygiene** provides for **specific requirements for feed businesses using cocciostats and histomonostats** in the production of feed. In particular, the operators concerned have to take **all appropriate measures concerning facilities and equipment, production, storage and transport in order to avoid any cross-contamination**

Unavoidable carry-over coccidiostats – requirements FBO

- The establishment of maximum levels of unavoidable carry-over of coccidiostats and histomonostats in non-target feed in accordance with Directive 2002/32/EC should not interfere with the **primary obligation of feed business operators to apply good manufacturing practices** aiming at **avoiding this cross-contamination**
- **Continued effort is therefore still needed by the operators** concerned in order to avoid the presence of such undesirable substances in animal feed.

Unavoidable carry-over coccidiostats – EFSA (CONTAM)

- The unavoidable carry-over in non-target feed of coccidiostats **should not endanger animal health, human health or the environment.**
- The EFSA adopted scientific opinions on the risks involved for animal health and public health as the consequence of unavoidable carry-over into non-target feed **for the 11 authorised coccidiostats** (decoquinate, diclazuril, halofuginone hydrobromide, lasalocid A sodium, maduramycin ammonium, monensin sodium, narasin, nicarbazine, robenidine, salinomycin sodium, semduramycin sodium).



Unavoidable carry-over coccidiostats – EFSA (CONTAM)

- For each coccidiostat, EFSA's assessment took into account hypothetical carry-over rates of **2 %**, **5 %** and **10 %** from feed produced with the highest authorised dose of the coccidiostats or histomonostats into the afterwards produced non-target feed.
- Considering the conclusions of the individual scientific opinions, it can be stated that generally EFSA concluded that the **presence of the coccidiostats, in non-target feed at levels resulting from an unavoidable carry-over**, and taking into account all prevention measures, is **unlikely to result in adverse animal health effects** and that **the risk to consumers' health from the ingestion of residues in products from animals exposed to cross-contaminated feed is negligible**

Unavoidable carry-over coccidiostats - risk management feed

- The maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed has been established following **the ALARA (As Low As Reasonably Achievable) principle**.
- A carry-over rate of **3 %** compared to the authorised maximum content has been set as regards feed for **less sensitive non-target animal species**, while a carry-over rate of **1 %** compared to the authorised maximum content has been set for feed intended to **sensitive non-target animal species and "withdrawal feed"**, i.e. feed used for the period before slaughter.

Unavoidable carry-over coccidiostats - risk management feed

- The carry-over rate of **1 %** has also been set for cross-contamination of non-target feed for "**continuous food-producing animals**", such as dairy cows or laying hens, where there is evidence of transfer from feed to food of animal origin. The **1 % should also be considered** for other feed for **target species to which no coccidiostats or histomonostats are added**.
- Maximum levels for non-target feed established by Commission Directive 2009/8/EC of 10 February 2009 applicable as from 1 July 2009

Unavoidable carry-over coccidiostats - risk management food

- **Residues in food of animal origin following authorised uses**
 - Maximum residue levels (MRL) established for the specific food of animal origin concerned in the frame of
 - Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (repealing the Regulation (EC) No 2377/90 of 26 June 1990)
 - Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition .

Unavoidable carry-over coccidiostats - risk management food

- **Residues in food of animal origin following carry-over in non-target feed**
 - Maximum levels established for the specific food of animal origin in the frame of the contaminant legislation (Regulation 315/93)
 - Commission Regulation (EC) No 124/2009 of 10 February 2009



Review Annex 2002/32/EC

Background- risk assessments

- Commitment from the Commission in 2002 to review the provisions on undesirable substances on **the basis of updated scientific risk assessments** and **taking into account the prohibition of any dilution of contaminated non-complying products** intended for animal feed.
- Following requests of the European Commission, the Panel on Contaminants in the Food Chain (CONTAM) from the European Food Safety Authority (EFSA) has completed a series of **30 risk assessments** undertaken over the last 5 years on undesirable substances in animal feed reviewing the possible risks for animal and human health due to the presence of these substances in animal feed.

Review Annex 2002/32/EC

Risk assessments

- In most cases, the CONTAM Panel identified **no risks to animal health** resulting from feed intakes at the maximum authorized levels, provided good animal feeding practices are followed. However, **adverse effects on animal health could not be excluded for some substances, such as deoxynivalenol in pigs, mercury in cats, gossypol in sheep and theobromine in dogs and horses.**
- The **risks of adverse human health effects** due to the presence of undesirable substances in products of animal origin – such as fresh meat, eggs and milk – **were generally found to be low** but in some cases EFSA recommended reducing their presence, in particular for persistent organic pollutants such as camphechlor.
- EU legislation on undesirable substances **has undergone recently several changes to take account of these most recent scientific opinions.**

Review Annex 2002/32/EC

Most recent changes

- Commission Directive 2008/76/EC of 25 July 2008 (applicable as from 1 April 2009)
 - increase of the maximum level for fluorine in fish feed from 150 ppm to 350 ppm
 - deleting the specific reference to *Lolium temulentum* and *Lolium remotum* in the provisions limiting the presence of weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances.
 - deleting Apricots – *Prunus armeniaca*, Bitter almond – *Prunus dulcis var. amara*, Camelina – *Camelina sativa*

Review Annex 2002/32/EC

Most recent changes

- Measures voted in Standing Committee on 28/04/2009 (applicable as from 1 July 2010)
 - setting maximum levels for arsenic in additives belonging to the functional group of compounds of trace elements
 - in trace elements: 30 ppm with the exception of
 - copper sulphate and copper carbonate: 50 ppm
 - zinc oxide, manganese oxide and copper oxide: 100 ppm
 - setting a maximum level for arsenic in iron used as tracer (50 ppm).
 - adapting the maximum levels for arsenic in fish meal, fish oil and fish feed following recent developments in technical knowledge
 - Fish meal/fish oil: 15 → 25 ppm (but requirement of maximum 2 ppm inorganic arsenic remains)
 - Fish feed 6 → 10 ppm (but requirement of maximum 2 ppm inorganic arsenic remains)

Review Annex 2002/32/EC

Most recent changes

- Measures voted in Standing Committee on 28/04/2009 (applicable as from 1 July 2010) (cont'd)
 - lowering of the existing maximum levels for theobromine in complete feedingstuffs
 - adult cattle: 700 ppm → 300 ppm
 - Pigs: 300 ppm → 200 ppm
 - Dogs, rabbits, horses and fur animals: 300 ppm → 50 ppm
 - amending the provisions for *Datura* sp,
 - amending the provisions *Ricinus communis* L. and *Croton tiglium* L. combined with introduction of a provision for *Abrus precatorius* L. (seeds and husks as well as their processed derivatives)

Review Annex 2002/32/EC

Most recent changes

- Measures voted in Standing Committee on 18/09/2009 (applicable as from 1 November 2010)
 - change of the maximum level of mercury in fish feed and feed for dogs and cats;
 - Fish feed: 0.1 → 0.2 ppm (given the high proportion of fish meal and fish oil in the feed for which a ML of 0.5 ppm applies)
 - compound feed for dogs, cats and fur animals: 0.4 → 0.3 ppm (because of animal health concerns according to EFSA opinion)
 - decrease of the maximum level of nitrite in fish meal (from 60 to 30 ppm) and establishment of a maximum level of nitrite for all feed materials with the exception of silage;
 - decrease of the existing maximum levels of gossypol in feed for sheep (500 → 300 ppm), including lamb (500 → 60 ppm), and goats (500 → 300 ppm), including kids (500 → 60 ppm);
 - deletion of the provision for *Mowrah*, *Bassia*, *Madhuca*.

Outlook on future regulatory activities at EU level on undesirable substances

- Defining acceptability criteria for detoxification processes
- Non dioxin-like PCBs
- Review legislation on dioxins and dioxin-like, PCBs
 - WHO-TEF-1998 → WHO-TEF-2005
 - Separate level dioxins to be kept ?
 - Reduction of the levels
 - Setting of target levels (?)

Outlook on future regulatory activities at EU level on undesirable substances

- Assessment measures as regards Fusarium toxins and ochratoxin A
- Measures as regards T-2 and HT-2 toxin
- Undesirable substance: ergot alkaloids, pyrrolizidine alkaloids, glucosinolates, ...
- Review of the maximum levels
 - for lead and cadmium in trace elements and binders and anti-caking agents
 - for lead in green fodder
 - for fluorine in vermiculite
 - For camphechlor in fish oil and fish feed

Outlook on future regulatory activities at EU level on undesirable substances

- Speciation heavy metals
 - Total arsenic → inorganic arsenic
 - Total mercury → methylmercury
- Unavoidable carry-over:
 - management of current provisions (e.g. maduramicin)
 - ...
- Melamine (and structural related analogues)
- Emerging contaminants: BFRs, PFCs, Alternaria toxins, ...
- ...