



Directorate-General for
Health & Consumers

**EU legislation for feed and food
safety and socio-economic
considerations with focus on
contaminants**

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Outline of this presentation

- General objectives and principles of food legislation (General Food Law)
- Prevention and Regulation
- From risk assessment to risk management - risk management tools
- Socio-economic considerations regulating contaminants in food – examples
- Socio-economic considerations regulating contaminants in feed – example
- Enforcement: sampling and analysis
- Driving forces for new legislation
- Conclusions



General objectives and principles General Food Law

- The principles and the objectives of the general food law apply 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**
- The 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 shall be pursued by food legislation



General objectives and principles General Food Law

- Food legislation 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 objectives and principles General Food Law

- 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
- Risk assessment shall be based on the ***available scientific evidence*** and undertaken in an **independent, objective and transparent manner**



General objectives and principles General Food Law

- **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
- **Other legitimate factors → socio-economic considerations (for the purpose of this presentation)**
- E.g. mycotoxins: legitimate factor: feasibility and achievability of levels through prevention at reasonable economic cost
- E.g. environmental contaminants



General objectives and principles General Food Law

- The **precautionary principle**: 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 objectives and principles General Food Law

- An **open and transparent public consultation** must be ensured, directly or through representative bodies, during the preparation, evaluation and revision of food legislation, except where the urgency of the matter does not allow it → **during this consultation process particular attention is paid to socio-economic considerations.**
- **Feed and food shall not be placed on the market if it is unsafe**



General Food Law: Responsibilities for feed/food safety

- The GFL clearly establishes **responsibilities for feed/food safety in the EU**. Unsafe feed/food must not be placed on the market and it is the **responsibility of feed/food business operator** to ensure this. It is the **responsibility of the competent authorities to carry out the appropriate controls on feed/food business operators** → official controls → Regulation (EC) 882/2004 on official feed and food controls.



General Food Law: Traceability

- The GFL provides for a general requirement that **feed/food business operators trace feeds/foods under their responsibility.**
- Feed/food businesses are required to know at least from whom a feed/food or feed/food ingredient has been supplied and to whom these may have been supplied. In other words, all businesses, including importers, will have to be able to **identify one step up, and one step down the food and feed supply chain.**



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.



Risk management 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



Risk management 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



Socio-economic considerations – contaminants food

- Socio-economic considerations → result in different management measures for similar problems as regards food safety
 - Protection public health
 - Achievability
 - Risk-benefit considerations
 - Economic consequences
 - **Scale: Macro – micro**



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.



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.



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
- **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
- **Tools for reduction of presence:** acrylamide combined with monitoring to monitor effective implementation of tools



Example 1: dioxins and PCBs in fish from the Baltic region

■ **Maximum levels with regional derogations:**

- Protection public health
- Management measures to reduce presence of dioxins and PCBs limited
- Availability of for consumption
- Sustainability local fisheries
- Derogation for local production and local consumption with consumption advice for the vulnerable groups of the population.



Example 2: nitrates in leafy vegetables

■ **Maximum levels with regional derogations:**

- Protection public health
- Management measures to reduce presence of nitrates in vegetables in poor light conditions → regional differences
- Risk – benefit considerations
- Derogation for local production and local consumption with the requirement to implement strictly GAP to improve the situation.



Example 3: Fusarium toxins in cereals and cereal products for human consumption

- Levels established for products along the chain: unprocessed cereals (marketed for first processing) – intermediate products (e.g. flour) – final consumer products
 - Protection of public health
 - Discussions between the different stakeholders (farmers versus food manufacturers)
 - Achievability and feasibility of levels



Example 3: Fusarium toxins in cereals and cereal products for human consumption

- Levels achievable by farmer/first processing steps
 - 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
- Levels applicable from « unprocessed cereals marketed for first-stage processing »
- Levels achievable from legal levels in raw materials purchased to compliance with legal levels in produced product → main point in the current review.



Example 4: recent changes in legislation on aflatoxins

■ Aflatoxins

- Discussions in Codex
- Changes in risk assessment approach as regards genotoxic carcinogens (MOE approach)
- Increased levels for aflatoxins in pistachios, hazelnuts, almonds and Brazil nuts
- New levels for oilseeds but exceptions for oilseeds for crushing for crude oil for refinement.
- New levels for « raw » rice
- Discussions on aflatoxins in dried figs have started in Codex.



Example 5: recent changes in legislation on ochratoxin A

- Follow-up to EFSA opinion from April 2006
- No EU ML for green coffee, cocoa and cocoa products, beer, meat and meat products, dried fruit other than dried vine fruit.



Example 5: recent changes in legislation on ochratoxin A

<p>Spices (<i>Capsicum spp</i> , <i>Piper spp</i>, nutmeg, ginger, turmeric)</p> <p>Mixtures of spices containing one or more of the abovementioned spices</p>	<p>30 µg/kg as from 01.07.2010 until 30.06.2012</p> <p>15 µg/kg as from 01.07.2012</p>
<p>Liquorice (<i>Glycyrrhiza glabra</i>, <i>Glycyrrhiza inflata</i> and other species)</p> <p>Liquorice root, ingredient for herbal infusion</p> <p>Liquorice extract^(*), for use in food in particular beverages and confectionary</p>	<p>20 µg/kg</p> <p>80 µg/kg</p>

Example 6: Non-dioxin like PCBs

- Protecting public health is main objective
 - other elements considered for setting ML's
 - MLs are upperbound levels – LOQs in routine in many cases 1 ng/g or even 2 ng/g
 - Analytical limit of quantification and requirements for analysis
 - capacity of analysis
 - cost of analysis
 - upperbound levels



Example 6: Non-dioxin like PCBs

- Protecting public health is main objective – other elements considered for setting ML's
 - Farm milk (at the farm !) versus bulk/retail milk --- Farm milk: variation in levels not linked to hot spot contamination
 - River fish versus marine fish
 - Free range/ organic eggs versus cage eggs



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

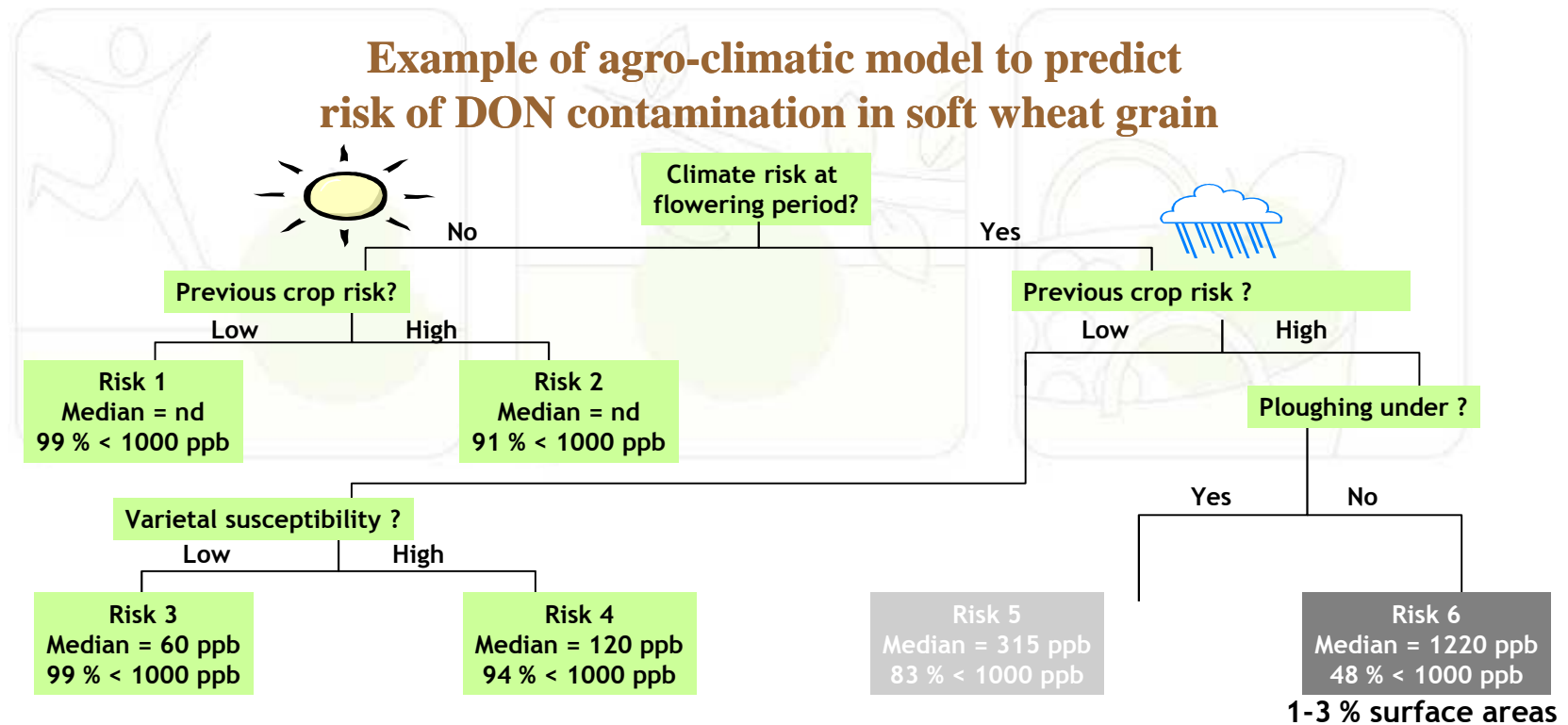


Recommendation

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





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”



Regulatory limits - enforcement 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 in particular 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 contaminants are in most cases combined with sampling provisions (and requirements for the methods of analysis)



Regulatory limits – enforcement Sampling

- Through sampling procedure, an accurate estimate of the true level of contaminant 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



Driving forces for initiating new EC-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, ...
- **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 EC-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 ...

Conclusions

- **Regulating contaminants 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**
 - **All possible options to meet the objectives are considered**