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Directorate-General for
Health & Consumers

Risk management of contaminants in the EU – A policy based on risk analysis

Frans Verstraete

Health and Consumers

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Principles for regulating contaminants in feed and food in the EU

* a **high level of protection of human and animal health** has to be pursued

* **free movement** within the European Union of food compliant with EU legislation

* **international standards** to be taken into account.

* **feed and food placed on the market shall be safe**

* **contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)**

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Principles for regulating contaminants in feed and food in the EU

* 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)

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

* **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

Risk management contaminants – food

Scientific risk assessment:

- assessment of the risks for human health related to the presence of a contaminant in food / 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 hereafter 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 mangement
- 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**

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Risk management 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.

Other appropriate management tools

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 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 regulatory standards are fixed, these should be fixed at a level reasonably achievable but stimulating a preventive approach.

Trends and challenges in EU policy on contaminants in feed and food

Cost – benefit considerations (impact assessment)

Balance risks of contaminants – benefits of consumption of certain foods (feed) (health risk – health benefit considerations)

New risk assessment approaches: The Margin of Exposure (MOE) approach, threshold of toxicological concern (TTC), …

Risk management tools used – to be used (examples food)

Maximum levels: aflatoxins, ochratoxin A, lead, cadmium, 3-MCPD, inorganic tin, citrinin

Maximum levels with regional derogations: dioxins

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 and source-directed measures: dioxins and PCBs

Risk management options used – to be used (examples food)

Maximum levels with data collection: PAH

Maximum levels combined with dietary advice: mercury

Code of practice: ethylcarbamate

Dietary advice only: …

Data collection: acrylamide, furan, PFOS/PFOA, …

Tools for reduction of presence: acrylamide combined with monitoring to monitor effective implementation of tools – indicator values

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Case 1 - Citrinin in food

The CONTAM Panel from EFSA adopted on 2 March 2012 the Scientific Opinion on the risks for animal and public health related to the presence of citrinin in feed and food

Standing Committee – meeting 11 July 2012 agreed the following follow-up:

* Development of performance criteria for the analysis of citrinin in food and feed

* Development of a standard for the analysis of citrinin in feed and food

* Monitoring on the presence of citrinin in feed and food .

Case 1 - Citrinin in food

- Health claim "Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol concentrations" – To obtain claimed effect, 10 mg of monacolin K from fermented yeast rice preparations should be consumed daily (EFSA 2013)

- Citrinin can be produced by some strains of *Monascus purpureus*

- for the intake of 10 mg per day of monacolin K, 4-6 capsules of 600 mg of red yeast rice should be consumed daily.

Case 1 - Citrinin in food

- taking into account the level of no concern for nephrotoxicity in humans of 0.2 µg/kg b.w. per day (EFSA 2012), the maximum exposure for an adult to citrinin should be not more 12 – 14 µg/day.

- this means that the maximum content of citrinin in a capsule of 600 mg of red yeast rice should not be more 2 µg per capsule.

- data indicate that there are capsules of red yeast rice on the market which contain citrinin at much higher levels (up to 114 µg per capsule).

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Case 1 - Citrinin in food

- Therefore a maximum level of citrinin for food supplements based on rice fermented with red yeast *Monascus purpureus* has been established at 2000 µg/kg by Commission Regulation (EU) No 212/2014 of 6 March 2014.

- The level applies since 1 April 2014

- The maximum level is to be reviewed before 1 January 2016 in the light of information on exposure to citrinin from other foodstuffs and updated information on the toxicity of citrinin as regards carcinogenicity and genotoxicity.

Case 2: Regulating certain mycotoxins in feed

EFSA opinions on deoxynivalenol (2 June 2004), zearalenone (28 July 2004), fumonisins (22 June 2005), ochratoxin A (22 September 2004)

Scientific risk assessments conclude 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

Case 2: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 and matrix specific

Feed materials: non species specific

Compound feed: species specific

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Case 2: 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
* ….

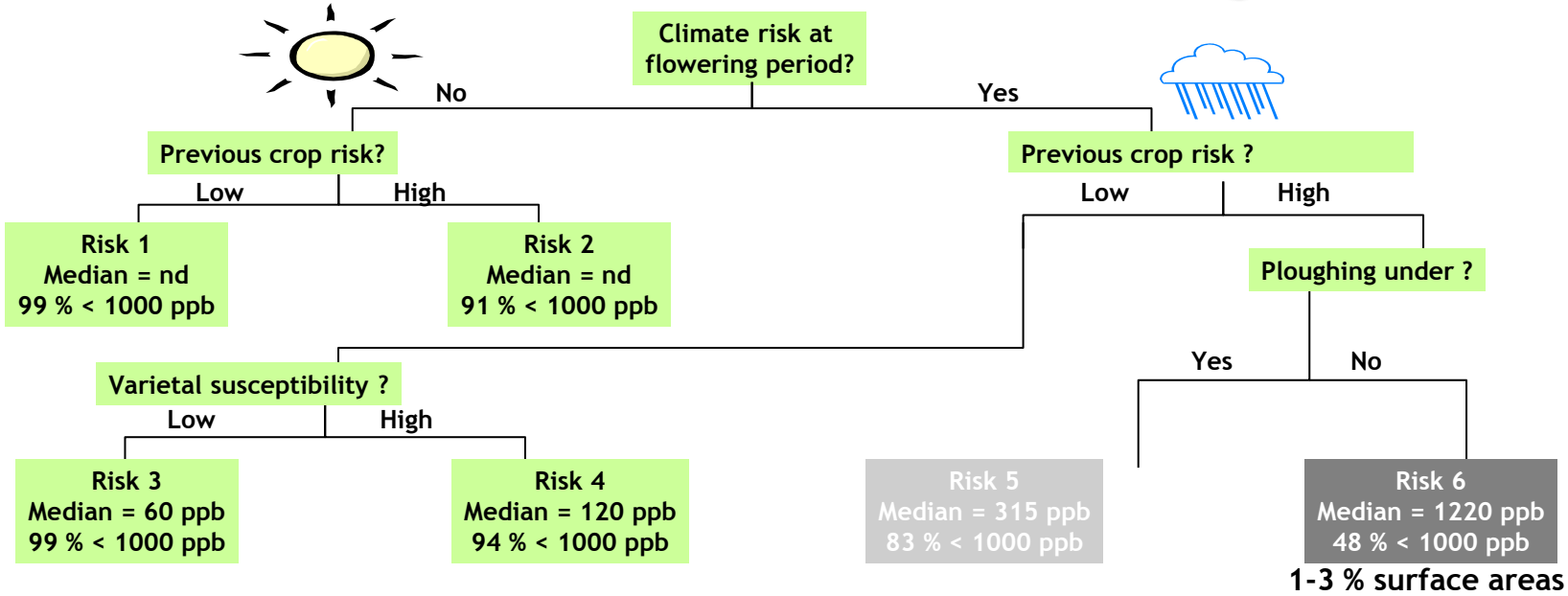
Case 2: Recommendation Prevention *Fusarium*-toxins

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

Case 2: Mycotoxins in cereals - feasibility

Example of agro-climatic model to predict risk of DON contamination in soft wheat grain



ARVALIS - Institut du Végétal en collaboration avec BARRIER-GUILLOT et al., 2004

Case 2: Mycotoxins in cereals feasibility – challenges

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
- Aflatoxins in maize: growth conditions (drought)

Case 2: Mycotoxins in cereals - Use of cereals

Use of cereals, excluding rice, in period 2010-2013 - 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	23.7-24.2	**60.2-61.0**	3.5-3.6	11.0-11.2
Common wheat	40.1-44.0	**41.3-46.2**	3.9-4.3	8.9 – 9.5
Durum wheat	89.5-91.0	**2.2-3.2**	4.5-5.3	1.1
Rye	34.9-43.5	**29.0-40.7**	5.8-7.2	17.4-19.5
barley	0.7-0.8	**74.7-77.9**	4.1-4.8	16.7-19.0
Oats	13.8-14.3	**76.6-77.5**	6.3-6.7	1.3
Maize	6.7-7.4	**77.7-80.0**	0.7-0.8	11.7-13.3
Triticale	0.5	**88.0-88.9**	4.6-5.0	4.6-6.0
Other cereals	0.4-0.5	**88.6-90.2**	5.9-6.8	2.0-2.3

Case 2: 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

Mycotoxins – Feed Recommendation 2006/576/EC

Risk management approach:

* Two-step approach: Recommendation on increased monitoring combined with guidance/orientation values as first step – evaluation on achievement of objectives after 2 - 3 years (2009 -2010) to consider possible further legal measures in the frame of Directive 2002/32/EC
* Evaluation made: objectives achieved with soft legal approach (Recommendation)

Case 2: Mycotoxins – Feed Recommendation 2006/576/EC

* 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"

Case 3: Acrylamide– Monitoring in food and FDE toolbox

* 3-year monitoring programme (2007 – 2009) extended by Recommendation 2010/307/EU – not limited in time, regular assessment of need to continue monitoring

* Regular compilation of monitoring data by EFSA and assessment of results by Commission

* FDE toolbox - leaflets

Case 3: Acrylamide – Monitoring and investigations

* Commission Recommendation on investigations into the levels of acrylamide in food of 10.1.2011 Document C(2010) 9681 final
* Indicative levels triggering investigations until end of 2012, investigations focusing on– application of FoodDrinkEurope (FDE) toolbox – effectivity of the FDE toolbox
* Assessment of the results in 2013

Case 3: Acrylamide – monitoring and investigations

* **Commission Recommendation 2013/647/EU** of 8 November 2013 on investigations into the levels of acrylamide in food

→ Changes indicative values for soft bread, certain breakfast cereals, crispbread, ginger bread, foods for infants and young children (including biscuits and rusks and processed cereal based foods)

-> new indicative levels for coffee substitutes, gingerbread and potato-based crackers

Case 3: Acrylamide – Workshop 13/14 January 2014

Every sector had to present in detail how the FDE-toolbox is implemented in practice in the production process. Each sector had to give concrete information on how the hazard acrylamide is managed within the HACCP system and to provide information on the critical control points, critical limits at critical control points, monitoring procedures at critical control points, corrective actions when monitoring indicates that a critical control point is not under control (Article 5 of Regulation (EC) No 852/2004.

Case 3: Acrylamide – Workshop 13/14 January 2014

Also consumer organisations had to present their initiatives/campaigns towards consumers to make them aware of the good cooking practices to keep acrylamide levels in home prepared foods as low as possible.

Case 3: Acrylamide–Workshop-Outcome

* the major importance of the breeding and agricultural sector was highlighted to control the presence of acrylamide in potato and cereal-based food (low asparagine, low reducing sugar content, fertilisation, storage …)

* sectors provided the requested information at a varying extent of detail (from very detailed to very general)

* presentation by authorities (UK, PL)

Detailed report available at
http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/docs/sum_20140220_en.pdf

Case 3: Acrylamide - Outlook

* EFSA risk assessment on acrylamide
* Public consultation finalised (15/09/2014)
* Final opinion expected to become available in the first half of 2015.
* Further regulatory measures to be discussed after availability of the EFSA opinion

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THANK YOU FOR YOUR ATTENTION !