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Directorate-General for
Health & Food Safety

EU policy on contaminants in feed and food.

Frans Verstraete

Health and Consumers

European Commission

GENERAL PRINCIPLES FEED AND FOOD SAFETY REGULATION

Health and Consumers

Principles for regulating contaminants in feed and food in the EU

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

* **free movement** within the European Union of feed and 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)**

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 and animal health, **EU feed and 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

CONTAMINANTS FOOD
PRINCIPLES AND LEGISLATION

Council Regulation 315/93

Regulatory framework for contaminants in food :

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
Definition contaminant

Contaminant means any substance not intentionally added to food which is present in such food as a result of the production, manufacture, processing preparation treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination

Regulation 315/93 Provisions

General provision:

- **food containing a contaminant/mycotoxin 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/mycotoxin levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)**

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Regulation 315/93 Provisions

When necessary for protecting public health maximum levels shall established for specific contaminants/mycotoxins --> 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 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/mycotoxin content

From risk assessment to risk management -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 management measures to be taken

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From risk assessment to risk management - FOOD

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/mycotoxin 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

From risk assessment to risk management - FOOD

Risk assessment : health based guidance value → new approaches (The Margin of Exposure (MOE) approach, threshold of toxicological concern (TTC)…)

Risk assessment always the basis for taking risk management measures related to food safety

From risk assessment to risk management - FOOD

Other legitimate factors: considered on a case by case basis

* Cost – benefit considerations (impact assessment)
* Balance risks of contaminants – benefits of consumption of certain foods (health risk – health benefit considerations)
* Analytical achievability

Instruments to reduce/prevent presence

* Prevention of major importance
* Risk management tools: maximum levels, action levels, target levels, source-directed measures, codes of practices, encouraging GAP, GMP, …
* EU-Measures to reduce the contaminant level in food are determined on a case by case basis (dependent of the nature of the contaminant), are divergent and can be a combination of several approaches into one strategy.
* maximum levels are at EU level always combined with sampling provisions and requirements for the methods of analysis

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, 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**

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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

Maximum / action / guidance / indicative levels

- **Maximum levels**
  - Food placed on the market **shall comply** with the maximum levels. Maximum levels are safety levels. **Food not compliant** with the maximum levels (taking into account the measurement uncertainty) **shall not be placed on the market** or withdrawn/recalled from the market.

- **Guidance values**
  - Food placed on the market **should comply** with the guidance levels. Guidance for accepting or rejecting lots. Guidance levels are established taking into account the toxicity for humans, sensitivity of different animal species. **Some flexibility possible in enforcement**.

Maximum / action / guidance / indicative levels

- **Action levels**
  - Action levels are established **in combination with maximum levels**. Action levels are set at a lower level than a maximum level in order **to stimulate a pro-active approach to reduce the presence of the contaminant in food**. These action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination.
- **Indicative values**
  - **Indicative levels are not safety levels**. **Exceedance of the indicative values trigger actions /investigations** to be undertaken: investigations on the sources and the reasons for the increased levels and related mitigation measures, on the fate during processing and any other relevant investigations.

Driving forces for initiating new EU-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 EU-legislation on contaminants

* **Emerging contaminants:** Brominated flame retardants (BFR), PFOS/PFOA, Alternaria toxins, 3-MCPD esters, enniatins, …

* **Changing production conditions/ climate change:** Mycotoxins, phytotoxins (?)

* **International developments within the Codex Alimentarius :** lead in fish, aflatoxins, melamine, …

* **Identified problems with current legislation:** Fusarium toxins **…**

Contaminants regulated / possibly to be regulated under 315/93 (1)

(bold – maximum level established for certain foods
Italics – other risk management measures discussed)

Nitrates, melamine

Mycotoxins: **aflatoxins**, **ochratoxin A**, **patulin**, **Fusarium-toxins (zearalenone, fumonisins, trichothecenes: Deoxynivalenol**, *T-2 and HT-2 toxin*), **ergot sclerotia,** *ergot alkaloids*, *Alternaria toxins,* **citrinin**, *phomopsins, sterigmatocystin, beauvericin and enniatins* **...**

Heavy metals: **lead, cadmium, mercury**, **inorganic arsenic**, *methylmercury...*

Contaminants regulated / possibly to be regulated under 315/93 (2)

<u>Other environmental contaminants</u>: **dioxins**, **dioxin-like PCBs, PAH**, **non-dioxin-like PCBs,** *BFRs, PFOS,...*

<u>Processing/industrial contaminants</u>: 3-MCPD, **inorganic tin, PAH,** *acrylamide, furan, ethylcarbamate, 3- MCPD esters and glycidyl esters, …*

<u>Inherent plant toxins</u>: **erucic acid** *opium alkaloids*, *pyrrozolidine alkaloids,* **tropane alkaloids** *...*

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 EU 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-non contaminated consignments and prohibition of deliberate detoxification by chemical treatment (mycotoxins)

CONTAMINANTS FEED PRINCIPLES AND LEGISLATION

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 Union 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

Risk assessment → Risk management measures 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 (impact on human health)

-→ is the basis for the measures to be taken

Risk assessment → Risk management measures 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.

* Other appropriate risk management measures

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 contaminantsof 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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Directive 2002/32/EC Annex undesirable substances

* **inorganic contaminants and nitrogenous compounds**
  - Arsenic, cadmium, fluorine, lead, mercury, nitrite, melamine
* **mycotoxins**
  - Aflatoxin B1, Rye ergot
* **inherent plant toxins**
  - Free gossypol, hydrocyanic acid, theobromine, volatile mustard oil

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Directive 2002/32/EC Annex undesirable substances

* organochlorine compounds, including dioxins and PCBs

- Aldrin, dieldrin, camphechlor, chlordane, DDT, endosulfan, endrin, heptachlor, hexachlorobenzene, hexachlorcyclohexane (alpha, beta and gamma isomers)
- Dioxins, dioxins + dioxin-like PCBs, non-dioxin like PCBs (maximum levels and action levels)

Directive 2002/32/EC Annex undesirable substances

* harmful botanical impurities

- Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances – specific provision for *Datura sp.*
- *Crotalaria* spp
- Seeds and husks from *Ricinus communis, Croton tiglium, Abrus precatorius*
- Unhusked beech mast
- Purghera (*Jatropha curcas)*
- Seeds from Indian, Sareptian, Chinese, Black and Ethiopian mustard
- Seeds from *Ambrosia spp.*

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Directive 2002/32/EC Annex undesirable substances

* **authorised feed additives in non-target feed following unavoidable carry-over**
Decoquinate, diclazuril, halofuginone hydrobromide, lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, nicarbazin, robenidine hydrochloride, salinomycin sodium, semduramicin sodium

Unavoidable carry-over coccidiostats – Background

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 coccidiostats 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

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Unavoidable carry-over coccidiostats – requirements FBO

The establishment of maximum levels of unavoidable carry-over of coccidiostats and histomonostats in non-target feed 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.

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Unavoidable carry-over coccidiostats – Why tolerances ?

However, even if all prevention measures are applied, including the use of flushing batches, the carry over of residues is unavoidable.

Therefore the setting of tolerances for these unavoidable residues of coccidiostats in feedingstuffs for non-target species was considered in the frame of Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed.

→providing legal certainty/security to feed business operators applying good practices

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Unavoidable carry-over coccidiostats – Why tolerances ?

Such tolerances for feed for non-target species **should be set following the ALARA principle (As Low As Reasonably Achievable)** taking into account good manufacturing practices.

Such tolerances in feed for non-target species should **not have a pharmacological activity and not endanger animal health and public health**, as in some cases the tolerances for feed for non-target species could result in residues in products of animal origin.

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Unavoidable carry-over coccidiostats – EFSA opinion

The EFSA / Panel Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) adopted between **September 2007 and May 2008** scientific opinions **for the 11 coccidiostats** (decoquinate, diclazuril, halofuginone hydrobromide, lasalocid A sodium, maduramycin ammonium, monensin sodium, narasin, nicarbazin, robenidine, salinomycin sodium, semduramycin sodium) authorised as feed additive in accordance with Regulation (EC) 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition

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Unavoidable carry-over coccidiostats –Outcome EFSA opinions

Animal health impact on non-target species

- Risks of adverse effects for non-target species after consumption of cross-contaminated feed was negligible in most cases

- Exceptions were salinomycin and monensin in horses for which potential cardiovascular adverse effects may occur after consumption of cross-contamination feed at 2% and 5% of the maximum levels for target species respectively.

Unavoidable carry-over coccidiostats –Outcome EFSA opinions

Human health impact

The CONTAM Panel concluded that **the risk for human health** resulting from residues in food products from animals exposed to cross-contaminated feed up to a hypothetical level of 10% of the maximum authorised level was considered to be **negligible**

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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.

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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.**

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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

Intended to be a two-step approach: Recommendation on increased monitoring combined with guidance/orientation values as first step – evaluation after a period of implementation to consider possible further legal measures in the frame of Directive 2002/32/EC

Mycotoxins – Feed
Recommendation 2006/576/EC

Evaluation has taken place: Recommendation to be continued

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

Feed: Criteria for detoxification processes

Article 8 – Directive 2002/32/EC: The Commission may define acceptability criteria for detoxifciation processes as a complement to the criteria provided for products intended for animal feed which have undergone such processes.

It is also provided that Member States shall ensure that measures are taken to guarantee the correct application of any acceptable detoxification process on products intended for animal feed and the conformity of those detoxified products with the provisions of Annex I of that Directive.

Commission Regulation (EU) 2015/786 of 19 May 2015 : Criteria for detoxification processes

* In order to ensure a uniform assessment across the European Union of the acceptability of detoxification processes, acceptability criteria for detoxification processes are established at Union level.

* Detoxification of a contaminated batch of feed can be performed by a physical, chemical or (micro-) biological detoxification process.

* The acceptability criteria ensure that the detoxified feed should not endanger animal and public health and the environment and that the characteristics of the feed should not be adversely altered by the detoxification process

Commission Regulation (EU) 2015/786 of 19 May 2015 : Criteria for detoxification processes

* The detoxification process has to be performed in an establishment approved for that purpose in accordance with Article 10 (3) of Regulation (EC) No183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene.

* From the scope of this Regulation are excluded the physical detoxification process through which the contamination by an undesirable substance is reduced or eliminated solely by cleaning, sorting or mechanical removal of certain parts as such a process is in many cases part of the usual production process.

Commission Regulation (EU) 2015/786 of 19 May 2015 : Criteria for detoxification processes

* A detoxification process shall only be applied **if the EFSA has performed, on request of the Commission, an scientific assessment of the detoxification process**, concluding that **the detoxification process complies with the acceptability criteria.**

*** It applies as from 1 July 2017**

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Contaminants feed – current issues

* gossypol in cotton seed and complete feed for dairy cows
* mercury in fish ingredients in in pet food
* arsenic in peat
* nitrites and nitrates
* ….

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MYCOTOXINS

RECENT DEVELOPMENTS AND OUTLOOK FEED-FOOD

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Challenges as a consequence of changing weather conditions – mycotoxins

- Tension between MLs based on the application of prevention / ALARA versus changing climate/weather conditions and year to year variation
- Approach to tackle the year-to-year variation of *Fusarium* toxins/mycotoxins from a legal point of view
- Increasing prevalence of aflatoxins in Europe (increased levels of aflatoxins in the South-East of Europe in 2012 – 2013)
- Increased levels of Fusarium toxins in maize in (large parts of the) EU in harvest 2013 and 2014
- …

Major challenge for the future - MYCOTOXINS

- Conference at the occasion of Milan EXPO 2015 on 5 June 2015 "Regulatory challenges following increased prevalence of mycotoxins in feed and food following climate change"
- Observations: Increased prevalence of mycotoxins at higher levels in cereals produced in the EU. Major cause is climate change and in particular the extreme weather conditions during critical growth stages of cereals in particular maize. However also other causes (agricultural practices) might contribute → in depth root-cause analysis appropriate
- Conclusion: For a sustainable solution, it was concluded that it would be appropriate to elaborate a comprehensive EU mycotoxiin (prevention) approach, including agricultural and environmental aspects

Most recent developments

- Commission Regulation (EU) 2015/1940 of 28 October 2015 amending Regulation (EC) 1881/2006 establishing a maximum level of 0.5 g/kg for ergot sclerotia in unprocessed cereals with the exception of corn and rice (food)

  → Includes also a provision that before July 2017: maximum levels for ergot alkaloids have to be established

- New guidance values for deoxynivalenol, zearalenone and ochratoxin A in pet food.

Developments in the future

- Parent compound -> parent compound + metabolites + modified (masked) mycotoxins
- Deoxynivalenol: updated risk assessment from EFSA expected mid-2016 : feed and food, acetylated derivatives, modified deoxynivalenol → regulatory follow-up, including analytical aspects

Developments in the future

- Review of Health Based Guidance Values (HBGV) by EFSA for zearalenone, fumonisins and T-2 and HT-2 toxins considering the metabolites and the modified forms → regulatory follow-up including analytical aspects

- Sterigmatocystin, citrinin: more occurrence data needed , more data on toxicity (genotoxicity and carcinogenicity)

- "Emerging" mycotoxins: enniatins, Alternaria,…

- Moniliformin, diacetoxyscirpenol: EFSA opinions awaited

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PLANT TOXINS

Health and Consumers

Pyrrolizidine alkaloids (PA)

The CONTAM Panel of EFSA adopted on 5 October 2011 the Scientific Opinion on Pyrrolizidine alkaloids in feed and food

Standing Committee – meeting 11 July 2012 agreed the following follow-up to be given to the conclusions and recommendations of the scientific opinion:

- Active co-operation on the development of a CODEX Code of Practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed.

- The CONTAM Panel identified the following PAs (including the tertiary amine as well as the corresponding *N*-oxide forms) of particular importance as regards the monitoring of their presence in food and feed:

Pyrrolizidine alkaloids (PA)

- **Senecionine-type PAs**: acetylerucifoline, erucifoline, integerrimine, jacobine, jacoline, jaconine, jacozine, retrorsine, senecionine, seneciphylline. These PAs occur particularly in the Senecioneae (Asteraceae family), but are also found in Crotalaria spp. (Fabaceae family).
- **Lycopsamine-type PAs**: acetylechimidine and isomers, echimidine and isomers, echivulgarine, lycopsamine and isomers, vulgarine. These PAs occur in the Boraginaceae family and in the Eupatorieae (Asteraceae family).
- **Heliotrine-type PAs**: europine, heliotrine, lasiocarpine. These PAs occur in Heliotropium spp. (Boraginaceae family).
- **Monocrotaline-type PAs**: fulvine, monocrotaline, retusamine, trichodesmine. These PAs occur in Crotalaria spp. (Fabaceae family).

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Pyrrolizidine alkaloids (PA)

- LC-MS/MS is the method of choice

- the relevant Limits of Quantification (LOQ) to be achieved for the individual pyrrolizidine alkaloids is

- 1 ng/g for honey

- 0.01 ng/g for milk and milk products

- 0.1 ng/g or µg/kg for other food and feed

<u>Issue for regulatory follow-up</u> : findings of high levels of pyrrolizidine alkaloids in herbal infusions and tea and in food supplements → Standing committee on 21/10/2013: particular atttention to be paid in the monitoring – data will be assessed end 2015/early 2016 for follow-up

Pyrrolizidine alkaloids (PA)

* Currently discussion on possible regulatory measures as regards the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements

* Specific exposure assessement currently undertaken by EFSA

* Also recent JECFA assessment indicated that the presence of pyrrolizidine alkaloids in honey and tea are of health concern.

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Opium alkaloids in poppy seeds

* A Commission Recommendation 2014/662/EU has been adopted on 10 September 2014 on good practices to reduce the presence of opium alkaloids in poppy seeds.

* The purpose of the Recommendation is to give guidance to poppy seed producers and processors to prevent and to reduce the presence of opium alkaloids as much as possible

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Opium alkaloids in poppy seeds

Recent RASFF notifications on the presence of morphine in poppy seeds → public health and internal market issue

→ Discussion on the possibility to establish maximum levels for morphine (opium alkaloids) in poppy seeds to be resumed

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Erucic acid Regulation(EU) 696/2014

* Council Directive 76/621/EEC establishes a maximum level for erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats.

* A stricter maximum level for erucic acid in infant formulae and follow-on formulae has been established by Commission Directive 2006/141/EC.

* To simplify legislation it is appropriate to integrate these maximum levels for erucic acid in Regulation (EC) 1881/2006.

Erucic acid
Regulaiton (EU) 696/2014

Vegetable oils and fats	50(*)
Foods containing added vegetable oils and fats with the exception of the foods referred to below	50(*)
Infant formulae and follow-on formulae	10(*)

(*)

(*) the maximum level refers to the level of erucic acid, calculated on the total level of fatty acids in the fat component in food

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Erucic acid
Regulation (EU) 696/2014

Measures adopted on 24 June 2014.

* Applies as from 1 July 2014

* A more in depth examination of the measures itself will take place once the EFSA scientific opinion on the risk assessment of the presence of erucic acid in feed and food is available.

Erucic acid
Commission Regulation (EU) 2015/705

Commission Regulation (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs and repealing Commission Directive 80/891/EEC

→ sampling provisions

→ performance criteria for the method of analysis

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Tropane alkaloids

* Following the conclusions and the recommendations of the EFSA opinion on tropane alkaloids the Commission adopted Recommendation (EU) 2015/976 of 19 June 2015 on the monitoring of tropane alkaloids in food

* Method of choice: preferably HPLC-MS/(MS) or, if HPLC-MS/(MS) not possible, GC-MS

Tropane alkaloids

* LOQ should not be higher than of 10 µg/kg for hyoscyamine/atropine and scopolamine and preferably below 5 µg/kg for agricultural commodities, ingredients, food supplements and herbal teas and should be preferably lower than 2 µg/kg for finished foods and 1 µg/kg for cereal based foods for infants and young children

Tropane alkaloids

Foods to be targeted for monitoring

- **Cereals and cereal derived products in particular (in order of priority)**
  - Buckwheat, sorghum, millet, maize and their flours
  - Cereal based food for infants and young children
  - Breakfast cereals
  - Grain milling products
  - Grains for human consumption
- **Gluten free products**
- **Food supplements and teas and herbal infusions**
- **Legumes vegetables (without pods), pulses and oilseeds and derived products**

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Tropane alkaloids

Commission Regulation (EU) 2016/239 of 19/02/2016 setting maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children

Processed cereal-based foods and baby foods for infants and young children, containing millet, sorghum, buckwheat or their derived products

* atropine 1.0 µg/kg
* scopolamine 1.0 µg/kg

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TETRAHYDROCANNABINOL (THC)

* EFSA was asked to deliver a scientific opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin.

* Opinion adopted on 5 June 2015

* THC, more precisely delta-9-tetrahydrocannabinol (Δ^9-THC) is derived from the hemp plant Cannabis sativa. In fresh plant material, up to 90 % of total Δ^9-THC is present as the non-psychoactive precursor Δ^9-THC acid.

European Commission

TETRAHYDROCANNABINOL (THC)

* The CONTAM Panel derived an acute reference dose (ARfD) of 1 µg Δ^9-THC/kg b.w.

* Based on intake scenario's, acute exposure to Δ^9-THC from the consumption of milk and dairy products ranged between 0.001 and 0.03 µg/kg body weight (b.w.) per day in adults, and 0.006 and 0.13 µg/kg b.w. per day in toddlers.

The exposure estimates are at most 3 % and 13 % the ARfD, in adults and toddlers, respectively.

European Commission

TETRAHYDROCANNABINOL (THC)

* The CONTAM Panel concluded that exposure to Δ^9-THC via consumption of milk and dairy products, resulting from the use of hemp seed-derived feed materials at the reported concentrations, is unlikely to pose a health concern.
* A risk assessment resulting from the use of whole hemp plant-derived feed materials is currently not feasible due to a lack of occurrence data.
* The CONTAM Panel could also not conclude on the possible risks to public health from exposure to Δ^9-THC via consumption of animal tissues and eggs, due to a lack of data on the potential transfer and fate of Δ^9-THC.

European Commission

TETRAHYDROCANNABINOL (THC)

Follow-up discussions feed and food:

FEED:

* No immediate action as regards use of hemp derived feed materials in feed (only hemp with less than 0.2 % THC can be used)
* WHY: Food of animal origin no major contributor compared to hemp-derived foods, foods containing hemp derived products (for people consuming those foods)
* Consumption of milk and other dairy products unlikely to be a health risk (based on hempseed derived feed materials)
* No occurrence data on presence of Δ^9-THC in food of animal origin know which would indicate a possible concern for public health

European Commission

TETRAHYDROCANNABINOL (THC)

Follow-up discussions feed and food:

FOOD:

* Monitor the presence of Δ^9-THC in food of animal origin → need to regulate ?

* Discuss the appropriateness of setting maximum levels for hemp derived foods

European Commission

OUTLOOK PLANT TOXINS

EFSA scientific opinion requested on

- erucic acid in feed and food
- hydrocyanic cid in apricot kernels (acute risks)
-

Possible request to EFSA on

- glyco-alkaloids (solanine, chaconine etc)
- Quinolizidine alkaloids

European Commission

PROCESSING CONTAMINANTS

RECENT DEVELOPMENTS AND OUTLOOK FOOD

Health and Consumers

PAH – Commission Regulation(EU) No 1327/2014 of 12/12/2014

Derogation from the stricter levels (applicable as from 1 September 2014: 2,0 µg/kg for B(a)P and 12,0 µg/kg for PAH4) for local production and consumption :

- for traditionally smoked meat and smoked meat products: IRL, ES, HR, CY, LV, PL, PO, RO, SK, FIN, SV and UK
- and for traditionally smoked fish and smoked fishery products: IRL, LV, RO, FIN, SV and UK

PAH – Commission Regulation(EU) No 1327/2014 of 12/12/2014

*Levels from before 01/09/2014 remain applicable, i.e. 5,0 µg/kg for B(a)P and 30,0 µg/kg for PAH4

* Re-assessment before 1 September 2017 → specific list of smoked meat and meat products, smoked fish and fishery products for which the derogation should be continued without time limit

PAH – Commission Regulation(EU) No 2015/1125 of 10/07/2015

- *Katsuobushi:* traditional Japanese food product made from bonito – smoking drying process over combusting woods: 5,0 µg/kg for B(a)P and 30,0 µg/kg for PAH4
- "*Sprotid":* can contain smoked sprat and smoked Baltic herring depending on the season and availability → levels for small smoked Baltic herring (≤ 14 cm) are aligned with the existing levels for smoked sprats (i.e. 5,0 µg/kg for B(a)P and 30,0 µg/kg for PAH4

PAH – Commission Regulation(EU) No 2015/1933 of 27/10/2015

- Cocoa fibre and products derived from cocoa fibre, intended for use as an ingredient in food: 3,0 µg/kg BaP and 15 µg/kg for PAH4 on a **product basis**
- Banana chips**:** 2,0 µg/kg BaP and 20 µg/kg for PAH4
- Food supplements containing botanicals and their preparations, food supplements containing propolis, royal jelly, spirulina and their preparations: 10,0 µg/kg BaP and 50 µg/kg for PAH4

PAH – Commission Regulation(EU) No 2015/1933 of 27/10/2015

- Dried herbs: 10,0 µg/kg BaP and 50 µg/kg for PAH4
- Dried spices with the exception of cardamom and smoked *Capsicum* spp.: 10,0 µg/kg BaP and 50 µg/kg for PAH4

PAH – amendment to Regulation (EC) No 333/2007

- Fat content in cocoa and cocoa derived products: determination of the fat content to be done in accordance with AOAC Official method 963.15 for the determination of the fat content of cocoa beans and derived products. Equivalent fat determination procedures can be applied.

Acrylamide - Investigations

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

→ Changes in 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

Acrylamide - Outlook

* EFSA risk assessment on acrylamide published early June 2015: current presence of acrylamide in food is a concern for public health

* It is acknowledged that food industry has done already considerable efforts to reduce the presence of acrylamide in certain foods. However further efforts are needed to reduce further the presence of acrylamide in food.

Acrylamide - Outlook

Therefore there is a need for a general application by all relevant food business operators of mitigation measures to reduce the presence of acrylamide in food as much as possible to provide a high level of human health protection.

Acrylamide - Outlook

The current voluntary approach, while having resulted in the application of mitigation measures by certain food business operators and consequently resulted in a reduction of acrylamide levels, has not resulted in a general application of the necessary mitigation measures by all relevant food business operators (outcome of the investigations in application of Commission Recommendation 2013/647/EU)

Acrylamide - Outlook

Further risk management measures are therefore needed to be established at EU level to ensure that acrylamide levels in food are consistently as low as reasonably achievable by the application of the appropriate mitigation measures by all food business operators all along the food chain. These risk management measures must be credible and enforceable and result in a measurable reduction of the presence of acrylamide in the food.

Furan

* Ongoing data collection under Commission Recommendation 2007/196/EC
* Annual reports on the monitoring results by EFSA
* JECFA risk assessment 2010
* Toxicological studies on furan now finalised (NTP studies)
* Request to EFSA to provide risk assessment on the presence of furan in food
* Following availability of opinion: discussion on risk management measures

EU Recommendation ethyl carbamate

* Recommendation 2010/133/EU on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on the monitoring of ethyl carbamate in these beverages

* Contains a Code of Practice (CoP) and a 3-year monitoring recommendation (2010-2012)

EU Recommendation ethyl carbamate

* Assessment of monitoring results (EFSA report April 2014)

* Update of the recommendation with the experiences gained and to align it on certain aspects with the Codex Code of Practice on ethyl carbamate contamination in stone fruit distillates (CAC/RCP 70-2011)

→ Commission Recommendation (EU) 2016/22 of 7 January 2016

MCPD esters and glycidylesters

- Collection of occurrence data on 3-MCPD -esters in different foodstuffs → EFSA report on occurrence became available in September 2013
- EFSA has been requested for a risk assessment
- Recommendation 2014/661/EU on monitoring adopted on 10 September 2014.
- The monitoring of the presence of 2 and 3-MCPD, 2 and 3-MCPD esters and glycidyl esters is recommended in a whole range of foodstuffs (LOQ of 100 µg/kg)

European Commission

HEAVY METALS METALLOIDS

RECENT DEVELOPMENTS AND OUTLOOK FOOD

Health and Consumers

Lead amendment (EU) 2015/1005

- *Increased and extended protection for infants & young children*
  - **Increased: lowered existing MLs**
  - **Extended: setting of MLs for additional food commodities destined and infants and young children**
- *Harmonised ML for honey*
- *Additional changes*
  - **Cephalopods: lowered to general fish ML**
  - **Lowering MLs for fruit juices & wine**
  - **Fine-tuning of MLs for vegetables**

Lead

			Previously
3.1.1	Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products	0,020	**Identical**
3.1.2	Infant formulae and follow-on formulae		**0,020**
	marketed as powder (8) (29)	0,050	**(0,160)**
	marketed as liquid (8) (29)	0,010	**(0,020)**
3.1.3	Processed cereal-based foods and baby foods for infants and young children (3) (29) other than 3.1.5	0,050	**No ML**
3.1.4	Foods for special medical purposes (9) intended specifically for infants and young children		
	marketed as powder (29)	0,050	**No ML**
	marketed as liquid (29)	0,010	**No ML**
3.1.5	Drinks for infants and young children labelled and sold as such, other than those mentioned in 3.1.2 and 3.1.4		
	marketed as liquids or to be reconstituted following instructions of the manufacturer including fruit juices (4)	0,030	**No ML**
	to be prepared by infusion or decoction (29)	1,50	**No ML**

Cadmium amendment (EU) 488/2014

- *Additional MLs for major dietary contributors*
  - **Chocolate and cocoa products (> 1/1/2019)**

    Differentiated MLs depending on cocoa content
  - **Foods for infants and young children**

    Differentiated MLs for soy-based products due to natural uptake from soil

    Processed cereal based and other baby foods

    Food for special medical purposes for infants
- *Fine tuning of existing MLs*
  - **specific vegetables (salsify, parsnips, celery, horseradish) and fish species**

Cadmium monitoring 2014/193/EU

- *Immediate reduction of MLs for important contributors to dietary exposure difficult to achieve due to highly variable cadmium content*
  - **growing area (cadmium presence in soil)**
  - **availability / transfer of cadmium (pH and other soil components)**
  - **plant variety**
  - **anthropogenic factors (agricultural use of sewage sludge, manure, phosphate fertilisers…) " 2014/193/EU**

Cadmium monitoring 2014/193/EU

- *Three aspects:*
  - ***Progressive implementation of available mitigation measures* especially for cereals, vegetables and potatoes**
  - **Carry out investigations/research to fill gaps in knowledge**
  - **Monitor progress by collecting occurrence data on cadmium levels in food**
- *Running 2015 + 3y after which Commission to reassess the situation with a view to deciding about further appropriate measures*

Arsenic amendment (EU) 2015/1006

- *MLs for inorganic arsenic defined as "sum of As(III) and As(V)"*

Food commodity	Maximum level
Non-parboiled milled rice (polished or white rice)	0,20mg/kg
Parboiled rice and husked rice	0,25mg/kg
Rice waffles, rice wafers, rice crackers and rice cakes	0,30mg/kg
Rice destined for the production of food for infants and young children	0,10mg/kg

Arsenic monitoring (EU) 2015/1381

- *EFSA: speciation data for different food commodities should be generated to refine the risk assessment of inorganic arsenic*
- *During 2016 + 2y*

  Cereal grains, cereal based products (including bran and germ), fruit and vegetable juices, drinking water (including bottled water), coffee, dry tea leaves, beer, fish and sea food, vegetables, algae products (including hijiki), milk & dairy products, food intended for infants and young children, food for special medical purposes, food supplements

Mercury (discussions on-going)

- *Review of existing MLs and pesticide MRL enforcement problems*
- *MLs for fish and food supplements*
  - **Review of existing MLs for fish: 0,5 mg/kg "default value" and 1,0 mg/kg "predatory fish"**
  - **Explore additional differentiation for MLs for fish**
  - **Online petition condemning 2,0 mg/kg for top predatory fish**
- *Food supplements*
  - **Reduction from current 0,1 mg/kg seems feasible**

Mercury (discussions on-going)

- *Pesticides (PPP) MRL enforcement problem*
  - **Mercury containing PPP phased out > 35 years**
  - **Mercury = environmental contaminant (natural and anthropogenic sources)**
  - **PPP MRLs set at LOD (0,01 or 0,02 mg/kg)**
  - **PPP MRLs very close to background levels**
- *➔ explore setting of MLs solely under contaminants legislation*

Chromium

- *EFSA Scientific Opinion on the risks to public health related to the presence of chromium in food and drinking water*
  - **No immediate need for MLs for chromium in food due to environmental contamination**
  - **Mineral waters and food contact materials are more important**
  - **Food supplements merit attention**

Nickel

- *EFSA Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water*
- *Explored options:*

  Consumption advice for sensitive consumers

  Recommendation on data collection (& research)

  Indicative values for high nickel food

  Maximum levels in combination with action levels

European Commission

DIOXINS AND PCBs

RECENT DEVELOPMENTS AND OUTLOOK FEED AND FOOD

Health and Consumers

Dioxins and PCBs – Recent issues

Analytical criteria

Food: Regulation (EU) 589/2014 of 2 June 2014

Feed: Regualtion (EU) 709/2014 of 27 June 2014

Non-dioxin like PCBs in dog fish

Regulation (EU) 2015/704
Level of non-dioxin-like PCBs is 200 ng/g weight

Dioxins in fish from the Baltic region

- the establishment of a common database
- the level of contamination of the different fish species from the different ICES zone from the Baltic region.
- the common risk management measures

Request to EFSA

* The Commission asked EFSA for scientific and technical assistance to assess and explain the differences in health based guidance value established by different organisations as regards dioxins and dioxin-like PCBs.

* A statement on the health-based guidance values for dioxins and dioxin-like PCBs has been issued in May 2015

Request to EFSA

→ a comprehensive risk assessment on the risks for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food, taking into account the recent occurrence data on the presence of dioxins and dioxin-like PCBs in feed and food.

is needed.

* EFSA opinion expected to be available by mid 2017

European Commission

OTHER POPs

RECENT DEVELOPMENTS AND OUTLOOK FOOD

Health and Consumers

Perfluoroalkylated substances

- 2008 EFSA scientific opinion on PFOS, PFOA and their salts in food
- 2010-2011 EU-wide PFOS / PFOA monitoring exercise
- 2012 EFSA dietary exposure report: dietary exposure is highly unlikely to exceed health-based guidance values
- No specific action was envisaged at EU level. Member States monitoring perfluorinated substances in food continue providing data to EFSA

- 2015 mandate to EFSA for (updated) scientific opinion on perfluoroalkylated substances in food

Brominated Flame Retardants

- 2014 – 2015 EU wide monitoring (2014/118/EU)
- Wide range of BFRs
  - Polybrominated diphenyl ethers (PBDEs) (BDE-47, 49, 99, 100, 138, 153, 154, 183, 209), Hexabromocyclododecanes (HBCDDs) (α, β, γ), Tetrabromobisphenol A and its derivatives (TBBPA), Brominated phenols and their derivatives, certain emerging and novel BFRs
- Variety of commodities
  - eggs, milk, meat and derived products; animal and vegetable fats and oils; fish and other seafood; products for specific nutritional uses and food for infants and young children.

European Commission

MINERAL OIL

RECENT DEVELOPMENTS AND OUTLOOK FOOD

Health and Consumers

Mineral oil

2012 EFSA *Scientific Opinion on mineral hydrocarbons in food*: important pathways of mineral oil entering in the food chain

- **use as de-dusting agent on cereals to prevent explosions of silos**
- **use as glazing agent for confectionery and fruit**
- **use as an ingredient in pesticides**
- **migration from printing inks to the packaged food and**
- **contamination of the food during harvesting or further processing.**

No urgent action needed in relation to mineral oil under the contaminants legislation

European Commission

SPECIFIC TOPICS

Health and Consumers

European Commission

Measures as regards feed and food from Japan

Health and Consumers

European Commission

Sequence of events

* Incident occurred on 11 March 2011
* Japanese authorities informed the Commission that radionuclide levels (Iodine-131, caesium-134 and caesium-137) in certain food products in Japan exceeded the action levels in food applicable in Japan
* On 15 March 2011, Commission recommended via RASFF to the Member States to carry out analysis of radioactivity in feed and food from Japan.

European Commission

Sequence of events

* On 25 March 2011, the Commission adopted, as a precautionary measure, Implementing Regulation (EU) N° 297/2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station, based on Article 53 of Regulation (EC) 178/2002.
* Regulation regularly amended /replaced
* Regulation (EU) No 322/2014 of 28 March 2014 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station
* Measures applicable since 1 April 2014

European Commission

Regulation (EU) 322/2014 Scope

Article 1(2) of Council Regulation No 3954/87

* "foodstuffs": products which are intended for human consumption, either immediately or after processing
* "feedingstuffs" products which are intended only for animal nutrition

Not in scope:

* products which left Japan before 28 March 2011
* products which have been harvested and/or processed before 11 March 2011

European Commission

Regulation (EU) 322/2014 Scope

Not in scope:

* alcoholic beverages

* personal consignments of feed and food of animal origin covered by Article 2 of Com. Reg. (EC) No 206/2009

* personal consignments of feed and food other than of animal origin which are non-commercial and destined to a natural person for personal consumption and use only (in case of doubt, burden of proof lies with the recipient of the consignment).

European Commission

Regulation (EU) 322/2014 Maximum levels

* As the maximum levels in Japan for the sum of caesium-134 and caesium-137 are stricter than EU levels, the levels applicable in Japan are applicable for feed and food imported from Japan into the EU

European Commission

Regulation (EU) 322/2014 Measures

Each consignment must be accompanied by a

* declaration that product is not originating from a prefecture for which an analytical bulletin is required "declaration of origin"

* declaration + analytical bulletin (sampling and analysis required for each consignment intended to be exported to the EU) for certain products from certain prefectures (see next slide) "declaration of compliance"

* special case of tea: no declaration required except for tea from Fukushima

European Commission

Regulation (EU) 322/2014 "Declaration of compliance"

Declaration of compliance required for products covered in Annex IV

- All products originating in prefecture Fukushima
- List of products originating in the prefectures Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Chiba or Iwate
- Mushrooms and few wild edible plants (and derived products) originating in Akita, Yamagata and Nagano
- Mushrooms (and derived products) originating in Yamanashi, shizuoka, Niigata or Aomori.

- Compound products containing more than 50 % of the products listed above or of which the origin of more than 50 % of the ingredients is unknown.

European Commission

European Commission

Regulation (EU) 322/2014 Declaration + signature

* Declaration to be drawn up in accordance with the model in Annex I.

* signed by an authorised representative of the competent Japanese authority ("declaration of compliance" or by an authorised representative of an instance authorised by the competent Japanese authority ("declaration of origin")

* list of authorised representatives available via RASFF system.

Regulation (EU) 322/2014 Points of entry and prior notification

* Products of non animal origin: DPE (Regulation (EC) No 669/2009.

* Products of animal origin (Directive 97/78) : BIPs

* Prior notification

- CED (Reg (EC) No 669/2009)

- products of animal origin: CVED (Annex III Commission Regulation (EC) No 136/2004)

European Commission

Regulation (EU) 322/2014 Controls at import

* Documentary checks on all consignments for which a declaration is required
* random identity checks and random physical checks
* all costs resulting from official controls to be borne the feed and food business operators.

European Commission

Regulation (EU) 322/2014 Release for free circulation

* Release for free circulation only after presentation (physically or electronically) by the feed or food business operator or their representative to the custom authorities of a CED duly completed by the competent authority once all offcial controls have been carried out.
* Custom authorities shall only release the consignment for free circulation if a favourable decision by the competent authority is indicated in box II.14 and signed in box II.21 of the CED

European Commission

Regulation (EU) 322/2014 Non-compliance

* Products which do not comply with this Regulation shall not be placed on the market
* Such products shall be safely disposed of or returned to Japan

Regulation (EU) 322/2014 Review and transitional provisions

* Regulation to be reviewed before 31 March 2015
* transitional provisions:
  - consignment left Japan before 1 April 2014 or after 1 April 2014 but before 1 May 2014 and accompanied by a declaration issued before 1 April 2014 (compliance with Regulation (EU) No 996/2012**)**

Regulation (EU) 2016/6 of 5 January 2016

The Regulation provides for a very significant alleviation of the measures in place before 9 January 2016 and results in a significant reduction in administrative burden for the Japanese authorities.

The current restrictive measures (i.e. each consignment exported to the EU has to be tested and sampled before export to the EU and has to be accompanied by a declaration) relates to

- for the prefecture Fukushima, the pretesting is **only maintained** for mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Giant butterbur (fuki), Koshiabura, Japanese butterbur scape, Aralia spp., bamboo shoot, bracken, Japanese royal fern and Ostrich *fern*

Regulation (EU) 2016/6 of 5 January 2016

The Regulation provides for a very significant alleviation of the measures in place before 9 January 2016 and results in a significant reduction in administrative burden for the Japanese authorities.

Regulation (EU) 2016/6 of 5 January 2016

The current restrictive measures (i.e. each consignment exported to the EU has to be tested and sampled before export to the EU and has to be accompanied by a declaration) relates to

- for the prefecture Fukushima, the pretesting is only maintained for certain products such as mushrooms, fish and fishery products, rice, soybeans, (Japanese) persimmon, Giant butterbur (fuki), Koshiabura, Japanese butterbur scape, Aralia spp., bamboo shoot, bracken, Japanese royal fern and Ostrich fern.

Regulation (EU) 2016/6 of 5 January 2016

- For the prefectures within the "zone with restrictions" (Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Iwate and Chiba), the pretesting requirement is only maintained for mushrooms, fish and fishery products, and listed edible wild plants Aralia sprouts, bamboo shoot, bracken, Koshiabura, Ostrich fern and Japanese royal fern and the processed and derived products thereof. No pretesting would be required anymore for rice, soybeans, Uwabamisou and buckwheat.

Regulation (EU) 2016/6 of 5 January 2016

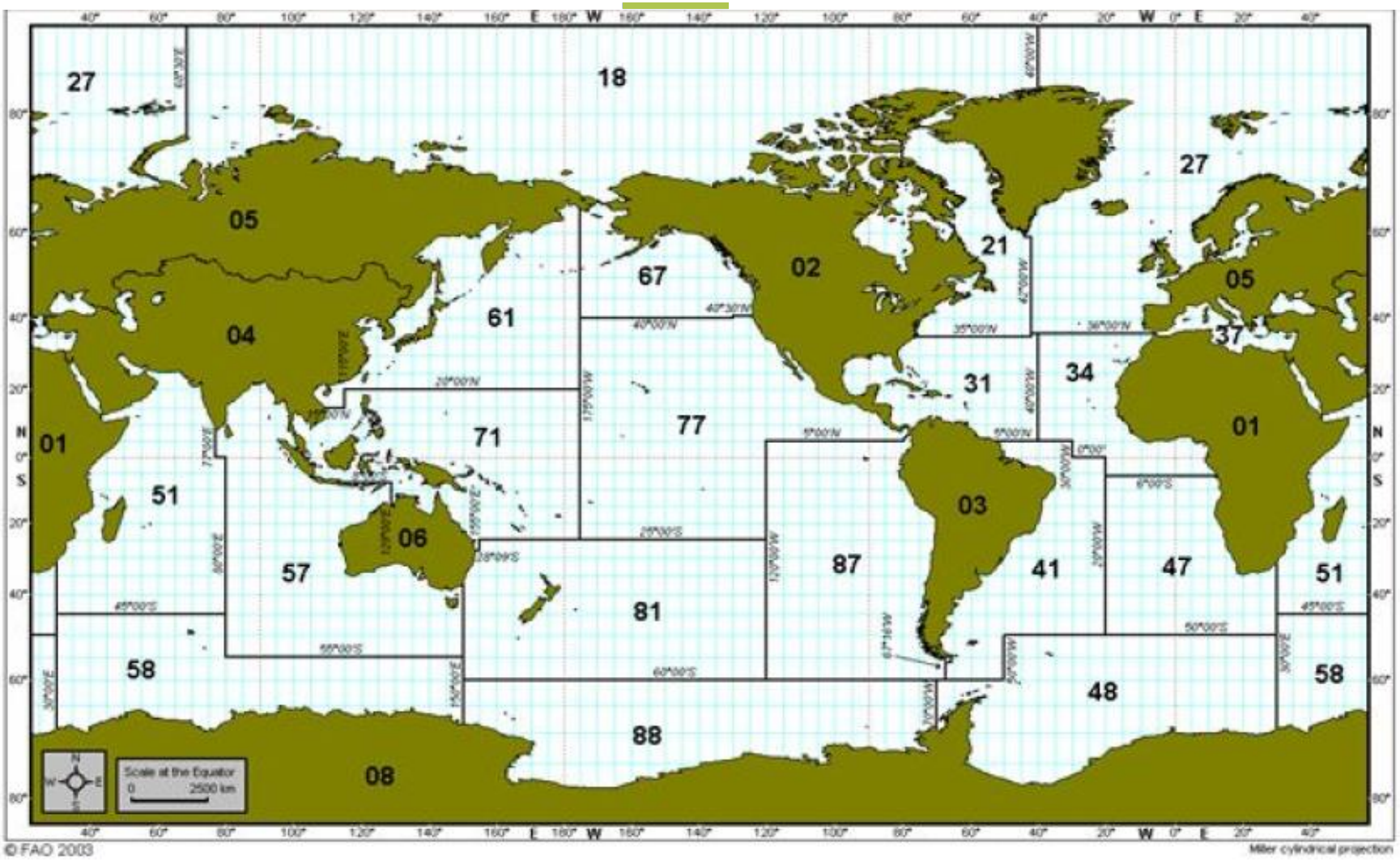
- For the prefectures Akita, Yamagata and Nagano, the pretesting requirement is maintained for mushrooms and listed edible wild plants Aralia sprouts, bamboo shoot, Japanese royal fern bracken and Koshiabura and the processed and derived products thereof.

- For the prefectures Shizuoka, Yamanashi and Niigata, the pretesting requirement for mushrooms and Koshiabura is maintained

Monitoring - RASFF notification 11-653-add11–dd 16/04/2011

The European Commission recommends the Member States to monitor on an at random basis for the presence of Iodine-131, Caesium-134 and Caesium-137 the following feed and food products (in order of importance) :

- fish, fishery products and other marine products caught in FAO Major Fishing Area 61 and derived/processed products thereof
- fish, fishery products and other marine products caught in FAO Major Fishing Areas 67, 71 and 77 and derived/processed products thereof
- feed and food, processed from fish and fishery products or containing fish and fishery products, (possibly) originating in/caught in the Pacific region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Miller cylindrical projection

European Commission

Monitoring recommendation

RASFF message 27/04/2011

- Preliminary risk assessment on the possible contamination by radionuclides of fish and fishery products in the Pacific region following the accident at Fukushima nuclear power plant. The assessment has been performed by the Directorate-General for Maritime Affairs and Fisheries.
- This assessment has to be seen in relation with the recommendation on the monitoring of the presence of I-131, Cs-134 and CS-137 in fish and fishery products (and derived/processed products) originating in/caught in certain fishing areas of the Pacific region.
- Following the conclusions of this preliminary assessment the monitoring should focus by preference on pelagic fish species in FAO Fishing zone 61 (e.g. mackerel, anchovy, sardines, tuna, …) in particular the albacore tuna.

European Commission

Monitoring recommendation

RASFF message 03/01/2012

In replacement of previous RASFF notifications, it was recommended that Member States to monitor on an at random basis for the presence of Cs-134 and Cs-137 migratory pelagic fish in FAO major fishing Area 61 and derived/processed products thereof

Migratory pelagic fish species of relevance are the
- tuna (albacore, bluefin, bigeye and skipjack)
- billfishes (swordfish and marlin)

European Commission

Some final remarks

* The requirement for analysis was/is limited to (iodine-131 and) caesium-134 and caesium-137, as there was/is not any evidence of contamination of feed and food at significant levels by other radionuclides (like Strontium, Plutonium).

European Commission

MEASURES MELAMINE INCIDENT

Health and Consumers

European Commission

Melamine in feed and food from China

15 September 2008: press reports as regards the presence of melamine in infant formula in China and the resulting health problems affecting infants (kidney problems) in China

Why this contamination ? Is there a risk for EU consumers ?

Why? Melamine intentionally (fraudulently) added to milk to increase the apparent protein content.

Risk for EU consumer ? Milk and milk products from China are not allowed for import into the EU, but products containing milk and milk products can be imported → request on **19/09/2008** to EFSA for urgent scientific advice assessment of the risks for public health.

European Commission

Melamine in feed and food from China

- EFSA statement on **24/09/ 2008** on melamine: estimated exposure does not raise concerns for the health of adults in Europe. However, children with high daily consumption of milk toffee, chocolate or biscuits containing high levels of milk powder would exceed the TDI.
- On **25/09/2008:** extra-ordinary emergency meeting with Member States to discuss situation and measures

European Commission

Melamine in feed and food from China

- On **26/09/2008**: Commission adopts emergency measures*:*
  - Ban on all products originating from China for infants and young children containing any percentage of milk (infant formula, follow on formula and other products).
  - Impose 100 % testing on all imported feed and food products from China containing milk and milk products and random testing on such products already on the EU market.
  - Random testing of feed and food with high protein content
  - Action level of 2.5 mg/kg to distinguish food and feed with an acceptable unavoidable background contamination products fraudulently adulterated

Melamine in feed and food from China

- October 2008: measures **extended** with random testing of all feed and food containing high level of protein.
- November 2008:Following RASFF notifications, initial measures **extended** to ammonium bicarbonate (100 % testing) and to products containing soya and soya products (ban baby food, 100 % testing feed and other food).
- Since January 2009, **significant decrease** of RASFF notifications → **measures alleviated** in November 2009: 100 % controls at import decreased to 20 %, other provisions remain unchanged in place.
- **Measures were lifted by** Regulation (EU) 2015/170 of 04/02/2015

Melamine in feed and food from China
Further follow-up

- EFSA requested to provide scientific opinion on the risk for public and animal health of the presence of melamine (with cyanuric acid) in feed and food
- Maximum levels for melamine have been set in feed and food in the EU and worldwide (Codex Alimentarius)

European Commission

Dioxin incidents in feed and food

Health and Consumers

European Commission

Dioxin contamination incidents in the EU

1998: citrus pulp pellets from Brazil

- Source: use of lime used in the production process of acetylene

1999: PCB/dioxin contamination incident in Belgium

- Source: recycled animal and vegetable oil mixed with PCB-oil

1999: kaolinitic clay from Germany

- Source: contamination of geological origin

2000: choline chloride from Spain

- Source: use of pentachlorophenol treated saw dust as carrier

European Commission

Dioxin contamination incidents in the EU

2002: Carbosan copper from the US

- Source: Production of "protected copper" by processing through heating chlorine containing algae with copper generating high levels of dioxins

2003: Dried bakery waste, green meal pellets used for animal feeding in Germany

- Source: Direct drying process whereby the combustion gases come in direct contact with the product to be dried and whereby inappropriate burning materials are used such as waste wood, other waste, insufficient dried wood,

2003: contamination of milk / mozzarella in Italy

- Source: illegal burning of waste resulting in an environmental contamination: pastures, silage, …

European Commission

Dioxin contamination incidents in the EU

2004: potato pulp – kaolinitic clay in the Netherlands

- Source: use of highly contaminated kaolinitic clay (see incident 1999) as "potato-separator-clay"

2006: animal fat - hydrochloric acid in Belgium

- Source: animal fat as by-product from gelatine production making use of non-filtered hydrochloric acid

2006: Contamination of eggs and poultry in Portugal

- Source: use of wood pellets/dust made of burned wood from forest fires as bedding (litter)

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Dioxin contamination incidents in the EU

2007: guar gum from India

- Source: technical guar gum preserved with pentachlorophenol marketed as food grade

2008: mozzarella in Campania region in Italy

- Source: illegal burning of waste resulting in an environmental contamination: pasture, silage,…

2008: pork from Chile

- Source: zinc oxide very highly contaminated→ use of filter residue

2008: pork/beef from Ireland

- Source: dried bakery waste → direct heating process → transformer oil (PCBs) in fuel

2010: feed and food of animal origin from Germany

- Source: contaminated technical fatty acids from biodiesel production used as feed fat

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Dioxin contamination incidents in the EU

After 2010 :

* free-range, organic eggs → different sources: historical contamination, building waste with PCB-sealants, …
* chicken meat, fattening chickens in Partulgal (2011)
* by-products of vegetable oil processing such as palm fatty acid distillate, coconut fatty acid distillate, sunflower cake, sunflower fatty acid, tocopherols, soybean meal expeller,
* sunflower seeds (2010), pea seeds (2013) rapeseed (2013) corn (2014) from Ukraine
* molassed sugar beet pellets in Germany (2011)
* minerals: zinc oxide, copper carbonate, calcium iodate, copper sulphate, iron carbonate, dicalcium phosphate, green clay, picking stones for pigeons,

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Dioxin contamination incidents in the EU

After 2010 (cont'd) :

* cod liver, fish oil, fish meal,
* dried basil, paprika powder, marigold powder, caritinoides from Tagetes erecta, passion flower extract,
* hardened fat
*lamb liver, cheese, sow carcasse, dried egg yolk powder, ostrich meat
* spiny dogfish, Baltic salmon, bluefin tuna, eel, crab,
* Leonardite,
* dried apple pomace pellets

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MANAGEMENT AT EU LEVEL OF CONTAMINATION INCIDENTS

Health and Consumers

European Commission

Role of the Commission contamination incident in MS

* Ensure that competent authority of the Member State concerned takes the necessary measures to protect public health, to manage the contamination incident (source identification, measures to reduce/eliminate the source, tracing/tracking of contaminated farms/food/feed/animals and block the contaminated products)
* Assessment of the measures (are they sufficient, effective ?)

European Commission

Role of the Commission contamination incident in MS

* Ensure that competent authorities provide the necessary information related to the contamination incident and in particular the distribution of contaminated product through the Rapid Alert System for Feed and Food (RASFF)

* In case measures are assessed as insufficient, ineffective and no sufficient information is provided, Commission can take in accordance with article 53 of the General Food law a safeguard measure to protect public health

European Commission

Role of the Commission contamination incident in MS

* Information of the Member States through the RASFF on the contamination incident / distribution of potentially contaminated feed/food

* Information to Third Countries as regards the contamination incident, distribution of contaminated products to these third countries (via RASFF), providing guarantees to avoid restrictive measures

* Assist the competent authority in the management of the contamination incident

- EURL, …

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Role of the Commission contamination incident in MS

Provide recommendations to the Member States as regards measures to be taken as regards potentially contaminated feed and food to ensure an uniform enforcement approach across the EU

- guidelines
- important role of EFSA (public health aspect)
- Role of EURL (analytical aspects)
- guidelines based on EFSA assessment ensure consumer protection and are more widely accepted (in MS and TC)

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Role of the Commission contamination incident in MS

After contamination incident and in case third countries have taken safeguard measures, provide the necessary guarantees to these countries in order to enable them to lift the measures

Lessons to be learned, initiation of new legal measures as the consequence of contamination incident

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Role of the Commission contamination incident in TC

* Request guarantees that TC concerned takes the necessary measures to protect public health, to manage the contamination incident (source identification, measures to reduce/eliminate the source, tracing/tracking of contaminated farms/food/feed/animals and block the contaminated products)
* Ensure that TC provides the necessary information related to the contamination incident and in particular the distribution of contaminated product to the EU through the Rapid Alert System for Feed and Food (RASFF)

European Commission

Role of the Commission contamination incident in TC

* Information of the Member States through the RASFF on the contamination incident / distribution of potentially contaminated feed/food
* Assessment of the measures (are the measures sufficient, effective)
* In case measures are assessed as insufficient and ineffective and no sufficient information is provided, Commission can take in accordance with article 53 of the General Food Law a safeguard measure to protect public health

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Important tools for efficient management of food safety incidents

* Legal basis to adopt emergency measures
* Urgent scientific advice → EFSA
* Rapid exchange of accurate information → RASFF

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Important tools for efficient management of food safety incidents

* **Maximum levels** are necessary for a efficient management of contamination incidents
* **Traceability** is of major importance to enable a quick, precise and reliable containment of the contamination incident
* **Responsibility of feed and food business** operators.

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Additional information on RASFF (if time allows)

Health and Consumers

Members of the RASFF

Austria	Greece	Poland	Iceland
Belgium	Hungary	Portugal	Norway
Cyprus	Ireland	Slovakia	Liechtenstein
Czech Republic	Italy	Slovenia	
Denmark	Latvia	Sweden	
Estonia	Lithuania	Spain	
Finland	Luxembourg	United Kingdom	
France	Malta	Bulgaria	
Germany	Netherlands	Romania	
Croatia			

- **European Food Safety Authority**
- **European Commission**
- **EFTA Surveillance Authority**

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Alert Notifications

- **Food or feed for which a serious risk has been identified**
- **Product is on the market**
- **Immediate action is required by members of the network**

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Informations Notifications

- **Food or feed for which a serious risk has been identified but no rapid action required on the product**

Or

- **Not a serious risk but useful for food/feed control in other member countries**

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Informations Notifications

- **Information notifications for follow-up**: are related to a product that is or may be placed on the market in another member country
- **Information notifications for attention:** are related to a product that

(a) Only present in the notifying member country; or

(b) Has not been placed on the market; or

(c) Is no longer on the market

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Border Rejections Notifications

- **Any rejection, related to a direct or indirect risk, of a batch, container or cargo of food or feed at a border post**

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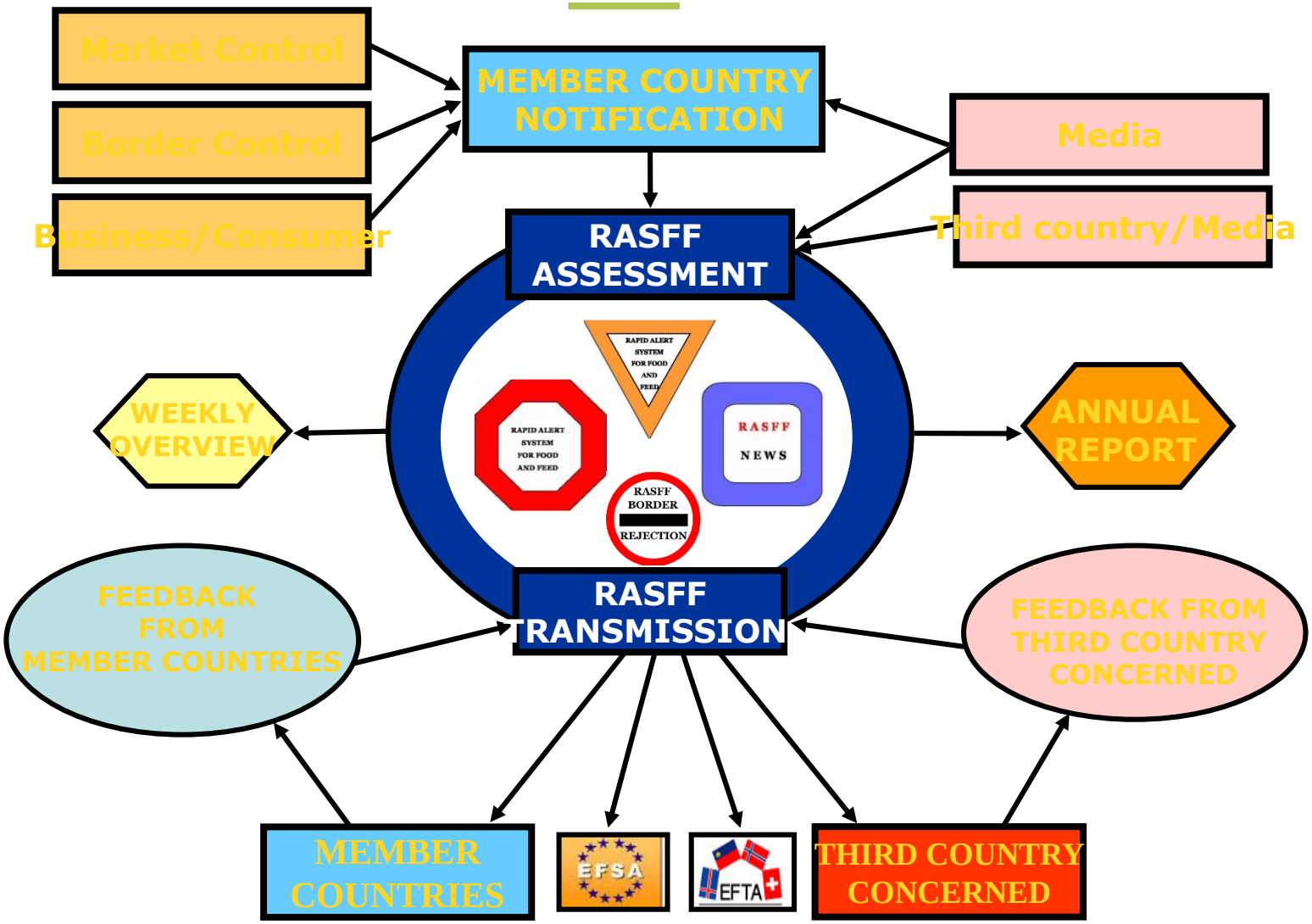
News Notifications

- **Information related to the safety of food/feed**
- **Not communicated as an 'alert' or an 'information'**
- **But judged interesting for the control authorities**


Market Control
Border Control
Business/Consumer
MEMBER COUNTRY NOTIFICATION
Media
Third country/Media
RASFF ASSESSMENT
RAPID ALERT SYSTEM FOR FOOD AND FEED
RAPID ALERT SYSTEM FOR FOOD AND FEED
RASFF NEWS
RASFF BORDER REJECTION
WEEKLY OVERVIEW
ANNUAL REPORT
RASFF TRANSMISSION
FEEDBACK FROM MEMBER COUNTRIES
FEEDBACK FROM THIRD COUNTRY CONCERNED
MEMBER COUNTRIES
EFSA
EFTA
THIRD COUNTRY CONCERNED

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Thank you for your attention !

Health and Consumers