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Directorate-General for
Health & Food Safety

EU policy on contaminants in food

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

Health and Food Safety

Council Regulation 315/93

- Regulatory framework :

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, …)

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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

Types of contaminants

- Agricultural contaminants
  - **E.g. nitrates, mycotoxins (aflatoxins, ochratoxin A)**
  - **Inherent plant toxins**
- Environmental and industrial contaminants
  - **E.g. heavy metals (mercury, lead, cadmium, etc.), dioxins, PCBs**
- Process related contaminants
  - **E.g. acrylamide, furans, PAHs**
- Other
  - **Unavoidable carry over of coccidiostats in non-target feed**
  - **Residues of biocides (not elsewhere covered)**

Regulation 315/93 Provisions

- General provision:
  - **food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market**
- Good practice:
  - **contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)**

Regulation 315/93 Provisions

- When necessary for protecting public health maximum levels shall established for specific contaminants --> Procedure for setting maximum levels. This can also include a reference to the sampling and analysis methods to be used.

- Obligatory consultation of the European Food Safety Authority(EFSA) Panel on contaminants in the food chain before provisions having effect upon public health shall be adopted.

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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 content

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Regulation 315/93 Provisions

- National measures
  - **possibility to maintain national measures in case they were adopted before 1993 and insofar they are not overruled by EC-legislation**
  - **necessity to adopt new national legislation**
- Notification procedure for new national legislation -- under Regulation 315/93 or 2015/35 (technical standards and regulations)
- Competent Standing Committee: Standing Committee on Plants, Animals, Feed Food and Feed

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From risk assessment to risk management

- 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

- 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 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

or other risk management measures (see further)

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From risk assessment to risk management

- 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

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From risk assessment to risk management

- 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)
  - Feasibility/achievability by applying good practices
  - Analytical achievability/feasibility

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Prevention and Regulation

- "prevention is better than cure" to protect the consumer (humans and animals) from the toxic effect of mycotoxins / 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.

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Instruments to reduce/prevent presence

- Prevention of major importance
- Risk management tools: maximum levels, action levels, guideline levels, benchmark 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

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Maximum / action / guidance / indicative levels

- **Maximum levels**
  - Feed and food placed on the market **shall compl**y with the maximum levels. Maximum levels are safety levels. **Feed and 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**
  - Feed and 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**.

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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 feed and 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/benchmark levels**
  - **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.

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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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**

- **<u>Mycotoxins</u>: 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* ...

- **<u>Heavy metals</u>: lead, cadmium, mercury, inorganic arsenic**, *methylmercury...*

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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, PFAS,…*

- **<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** *…*

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Driving forces for initiating new EU-legislation on contaminants

- **Contamination incidents with "new" (not yet regulated) contaminants:** melamine, …

- **New (at EU level) risk assessments:** non-dioxin like PCBs, inorganic 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

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Driving forces for initiating new EU-legislation on contaminants

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

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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

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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)

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Maximum levels: Commission Regulation (EC) No 1881/2006

- Specific provisions for the application of the maximum levels of groundnuts, nuts, dried fruit and maize, to be subjected to sorting or other physical treatment to reduce the aflatoxin contamination before human consumption or use as an ingredient.
- Specific provisions for the application of MLs of aflatoxins groundnuts, derived products thereof and cereals: double use (for feed or for food)

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Maximum levels: Commission Regulation (EC) No 1881/2006

- Specific provisions for the application of MLs of nitrates in lettuce: open air – under cover
- Derogations: dioxins and non-dioxin-like PCBs for fish from the Baltic region, PAHs in traditionally smoked meat and meat products and traditionally smoked fish and fishery products
- Sampling and analysis
- Monitoring and reporting

Sampling and methods of analysis

- **Mycotoxins: Regulation (EC) 401/2006 of 23 February 2006**

One single sampling method per commodity for the official control of mycotoxins

- **Nitrates: Regulation (EC) 1882/2006 of 19 December 2006**

Particular topics **-** Provision on sampling before harvest, Special attention to extraction procedure

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Sampling and methods of analysis

- **Trace elements and processing contaminants Regulation (EC) 333/2007 of 28 March 2007**

specific sample preparation procedures

- **Erucic acid: Regulation (EU) 2015/705 of 30 April 2015**

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Sampling and methods of analysis – dioxins, dioxin-like PCBs and non-dioxin like PCBs

- **Regulation (EU) 2017/644 of 5 April 2017**
  - Sampling
  - screening method combined with confirmatory method
  - Performance criteria for screening and confirmatory method
  - Screening method
    - detect presence dioxins, furans /DL PCBs at level of interest
    - high sample throughput
    - very low rate of false negatives

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REPORTING OF ANALYTICAL RESULTS

- Corrected or uncorrected for recovery (mycotoxins, nitrates). The manner of reporting and the level of recovery must be reported.
- Corrected for recovery (metals, MCPD and PAH) level of recovery must be reported
- Analytical result to be reported as x +/- U whereby x is the analytical result and U the expanded measurement uncertainty
- Expanded measurement uncertainty, using a coverage factor of 2, which gives a confidence interval of approx. 95 %
- Detailed report on relationship analytical results, measurement uncertainty and recovery: http://ec.europa.eu/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

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INTERPRETATION OF ANALYTICAL RESULTS

- A consignment is considered as non-compliant if analytical result, corrected for recovery exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty

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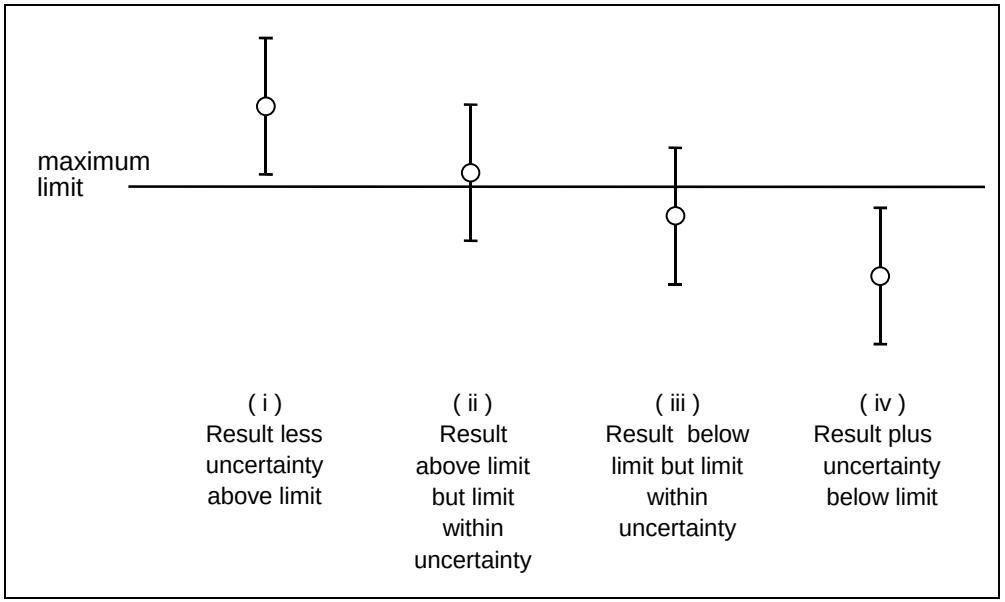
INTERPRETATION OF ANALYTICAL RESULTS

Interpretation of the measurement of uncertainty when considering compliance with a statutory limit, where the circle is the analytical result.



Action: reject accept accept accept

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Acrylamide

COMMISSION REGULATION (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food

Entry into force : 11 December 2017

Entry into application: 11 April 2018

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Acrylamide - Principles – objectives

- The regulation is based upon the **Food Hygiene Regulation**. The objective of the Food Hygiene Regulation is to ensure a high level of consumer protection with regard to food safety, including chemical hazards, through the application of food safety management measures to be applied by food business operators.

- **Imposing of mandatory application** by all concerned food business operators of mitigation measures to reduce the presence acrylamide in food.

- These mitigation measures contain clear obligations for the food business operators and are **integrated in the Regulation.**

- The mitigation measures to be applied **take into account the size and the nature of establishment**

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Acrylamide - Principles – objectives

- **Benchmark levels** reflect the level which can be **achieved** on a consistent basis **by applying mitigation measures** to reduce the presence of acrylamide as low as reasonably achievable.

- The benchmark levels are performance indicators to be **used to measure the efficacy of the applied mitigation measures.** The benchmark levels have been set at a strict level taking into account the most recent occurrence data from the EFSA database.

- Food business operators **are obliged to monitor the effectiveness of the mitigation measures** to reduce the presence of acrylamide by sampling and analysis of their production demonstrating that the levels of acrylamide are below the set benchmark levels

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Acrylamide - Scope

Risk mitigation measures shall be applied with a view to achieving acrylamide levels as low as reasonably achievable by the food business operators producing and marketing the following foods.

(a) French fries, other cut (deep fried) products and sliced potato crisps from fresh potatoes;

(b) potato crisps, snacks, crackers and other potato products from potato dough;

(c) bread;

(d) breakfast cereals;

(e) fine bakery wares;

(f) coffee/ roast coffee / instant (soluble) coffee / coffee substitutes;

(h) baby food and processed cereal-based food intended for infants and young children

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Commission Recommendations on prevention and reduction

- 2003/598/EC: prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages
- 2006/583/EC: prevention and reduction of Fusarium-toxins in cereals and cereal products
- 2013/711/EU: reduction of dioxins, furans and PCBs in feed and food

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Commission Recommendations on prevention and reduction

- (2013/647/EU: investigations into the levels of acrylamide in food)
- 2014/193/EU: reduction of the presence of cadmium in foodstuffs
- 2014/662/EU: good practices to prevent and reduce the presence of opium alkaloids in poppy seeds and poppy seed products
- Recommendation (EU) 2016/22: prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits

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Commission Recommendations on monitoring

- 2007/196/EC: monitoring of the presence of furan in foodstuffs
- 2010/161/EU: monitoring of the presence of perfluoroalkylated substances in foodstuffs
- (2010/307/EU: monitoring of the presence of acrylamide levels in foodstuffs)
- 2012/154/EU: monitoring of the presence of ergot alkaloids in feed and food

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Commission Recommendations on monitoring

- 2013/165/EU: monitoring of the presence of T-2 and HT-2 toxin in cereals and cereal products
- 2014/118/EU: monitoring of brominated flame retardants in food
- 2014/661/EU: monitoring of 2- and 3-monochloropropoane-1,2 diol (2 and 3 MCPD) fatty acid esters and glycidyl fatty acid esters in food
- Recommendation (EU) 2015/682: monitoring of the presence of perchlorate in food

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Commission Recommendations on monitoring

- Recommendation (EU) 2015/976: monitoring of presence of tropane alkaloids in food
- Recommendation (EU) 2015/1381: monitoring of arsenic in food
- Recommendation (EU) 2016/1111: monitoring of nickel in food
- Recommendation (EU) 2016/2115: monitoring of delta9-tetrahydrocannabinol, its precursors and other cannabinoids in food

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Commission Recommendations on monitoring

- Recommendation (EU) 2017/84: monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food.
- Recommendation (EU) 2018/464: monitoring of metals and iodine in seaweed, halophytes and products based on seaweed.

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Commission Recommendations (other)

- Recommendation (EU) 2016/688: monitoring and management of the presence of dioxins and PCBs in fish and fishery products from the Baltic region.

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Safeguard measures

Commission Implementing Regulation (EU) 884/2014

- As the consequence of frequent findings of (high) levels of **aflatoxins** exceeding the maximum levels: Special measures to protect public health as regards pistachios from Iran and Turkey, peanuts (groundnuts) from Egypt, China, India, Ghana, Brazil and Argentina, dried figs from Turkey, hazelnuts from Turkey and Azerbajann, Brazil nuts in shell from Brazil, watermelon seeds from Nigeria, spices from India and Ethiopia, Nutmeg from Indonesia
- Derived, processed and compound foodstuffs included in scope of the Regulation.

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Safeguard measures

- **Commission Implementing Regulation (EU) 2015/175**

Dioxins and pentachlorophenol – guar gum – India

- **Commission Implementing Regulation (EU) 2016/6**

Feed and food from Japan following the accident at the Fulkushima nuclear power plant.

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Approval of pre-export checks carried out by third countries

Commission Implementing Regulation (EU) 2015/949 of 19 June 2015 approving the pre-export checks carried out on certain food by certain third countries as regards the presence of certain mycotoxins

- Aflatoxins – almonds – US
- Ochratoxin A – wheat – Canada

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Thank you for your attention !

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