BETTER TRAINING FOR SAFER FOOD

MODULES DESCRIPTION and SYLLABUS

Version 24 September 2019

Organisation and implementation of training activities on the

Controls on contaminants in food

under the "Better Training for Safer Food" initiative

Course 2: Official control plans and systems for the control of contaminants

Service Contract 2016 96 05 – Phase 2

NSF

INRA SCIENCE & IMPACT

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TOPIC 1 – From risk assessment to the establishment of contaminants level

Specific objectives of Topic 1:

At the end of Topic 1, participants will be able to:

- examine the outcomes of risk assessment and EFSA opinions, and consider them for the risk management of contaminants
- consider other factors / approaches for the risk management as regards contaminants in feed and food

Module 1.1: Participants presentation

Tutor(s): Carlo Brera
Duration: 30 min
Format: Open discussion

Summary of contents	Activities
• go around the table	• participants introduce themselves and share their individual expectations for the training session; • groups for the integration activity are formed; • the integration activity content is presented; • throughout the training session, the participants will receive the necessary information to solve the problem posed for the integration activity and will present the results on the last training day.

Modules 1.2 – 1.3: Risk assessment and risk management in the risk analysis cycle – Reminders on risk management measures at EU level

Tutor(s): Isabelle Oswald
Duration: 45 min
Format: Presentation

Module Description
• Reminders of risk assessment principles and practical implications on risk management measures; • Presentation of EFSA opinions (e.g. aflatoxins in feed, dioxins in feed and food, arsenic in foods) and explanation of the interaction between the main outputs of opinions with the management activities to be undertaken; • Single case risk assessment / management - "case-by-case" approach of risk assessment and risk management concerning contaminants; • Reminders on risk management measures taken at EU level to minimise the presence of contaminants in food and feed; • Practical examples showing the link of MLs in food and feed, e.g. aflatoxins B1 – M1. • Practical examples showing the role of the main elements (occurrence data, consumption data, body weights) on exposure assessment.

Key concepts, information and messages for this module
The risk analysis framework includes risk assessment, risk management and risk communication. In order to perform risk assessment, the Tolerable Daily Intake (TDI) should be established. This can be done by using NOAEL and Benchmark dose approaches. Derivation of the health-based guidance value (HBGV) for human and animals differs because of the absence of safety factor for animal. In the peculiar case of carcinogenic compounds, they can only be present at concentrations As Low As Reasonably Achievable (ALARA). It is thus important to determine the Margin of Exposure (MoE). When there is insufficient toxicological record, it is impossible to determine a TDI. New approaches are needed to characterise the risk without characterising the danger. In conclusion, the new challenges in risk assessment of food contaminants concern (i) the analysis of low dose effects, especially in non-monotonic effect curves and (ii) toxicity of mixtures of different food contaminants.

Module 1.4: Open discussion: from risk assessment to risk management

Tutor(s): Isabelle Oswald
Duration: 30 min
Format: Open discussion

Module Description
Round table discussion on: • overall risk assessment process of contaminants in the agri-food chain and its influence on risk management decisions • principles for regulating contaminants in feed and food (e.g. ALARA, precautionary principle)

Key concepts, information and messages for this module
The discussion will open with the following: • Difference in risk management actions between a genotoxic/carcinogen and a non-genotoxic/carcinogen substance • How to deal with substances for which health-based guidance values (HBGVs) exist but do not have a legal maximum limit? • Prohibition of dilution to reduce the overall concentration of the contaminant

Reference documents – Topic 1

The list of refence documents for this topic has been prepared based on the following criteria:

- Description of the main principles regulating risk assessment cycle to be adopted in the control of contaminants along the agri-food chain;
- Description of the main differences among the various toxicological parameters.

The final selection is:

- Regulation EC/178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and its amendments
- Opinion of the Scientific Committee on a request from EFSA related to A Harmonised Approach for Risk Assessment of Substances which are both Genotoxic and Carcinogenic. The EFSA Journal (2005) 282, 1-31.
- Diane Benford, P. Michael Bolger, Philip Carthew, Myriam Coulet, Michael DiNovi, Jean-Charles Leblanc, Andrew G. Renwick, Woodrow Setzer, Josef Schlatter, Benjamin Smith, Wout Slob, Gary Williams, Tanja Wildemann. Application of the Margin of Exposure (MOE) approach to substances in food that are genotoxic and carcinogenic. Food and Chemical Toxicology 48 (2010) S2–S24.
- EFSA and WHO - Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree, 2016. Available at https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-1006
- EFSA Scientific Committee - Simon J. More, Vasileios Bampidis, Diane Benford, Jos Boesten, Claude Bragard, Thorhallur I, Halldorsson, Antonio F Hernández-Jerez, Susanne Hougaard Bennekou, Kostas P, Koutsoumanis, Hanspeter Naegeli, Søren S Nielsen, Josef R Schlatter, Dieter Schrenk, Vittorio Silano, Dominique Turck, Maged Younes, Ursula Gundert-Remy, George E N Kass, Juliane Kleiner, Anna Maria Rossi, Rositsa Serafimova, Linda Reilly and Heather M Wallace. Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment – Available at https://www.efsa.europa.eu/sites/default/files/consultation/consultation/181112-d.pdf

TOPIC 2: Risk management measures for contaminants in food and feed

Specific objectives of Topic 2:

At the end of Topic 2, participants will be able to:

- identify and use existing risk management measures with regards to contaminants / undesirable substances in the control activity all along the agri-food chain
- employ various tools in the risk management of contaminants / undesirable substances (e.g. COPs, MLs and their combinations with COPs, dietary advice)

Module 2.1: Control measures for contaminants in feed and food: part 1, food contaminants

Tutor(s): Klara Jirzik / Annette Rexroth
Duration: 45 min
Format: Presentation

Module Description
Extensive overview of EU risk management measures (regulations, COPs, guidance) covering the agricultural, environmental and industrial contaminants in food such as: • Maximum levels of contaminants in food • Prevention/reduction of contaminants in food (CoPs, toolboxes, FBOs' self-controls systems) • Indicative, benchmark and action levels • Commission Recommendations on monitoring of contaminants (e.g. acrylamide, metals, ergot alkaloids etc.) • Collection of occurrence data and its communication to EFSA; • Dietary consumption advice • Increased controls of imported food from third countries

Key concepts, information and messages for this module
According to Art. 17 of Reg. (EC) 178/2002 Food Business Operators (FBOs) shall ensure that foods comply with the requirements of food law at all stages of the food chain. General requirements and general principles related to food safety are established in the basic European food Regulation (EC) No. 178/2002 (General Food Law, GFL). Such basic food safety requirements are also relevant for contaminants and include the following: ○ Precautionary principle (Art. 7 of GFL) ○ Public information (Art. 10 of GFL) ○ Withdrawal/recall of unsafe food from the market/consumer: According to Art. 14 of GFL: Food which is unsafe and poses a risk to human health (for example due to high levels of contaminants), cannot be placed on the market. ○ Rapid alert system and crisis management (Art. 50 - 57 of GFL) ○ Art. 53 of GFL: safeguard measures with regards to food originating in the EU or imported from a third country: where such food is likely to constitute a serious risk to human health the Commission may adopt measures such as suspension of the placing on the market or use of the food in question or laying down special conditions for import of the food concerned). In addition, different risk management instruments are available which are specifically applied to minimize the levels of contaminants in food as much as possible. The most important risk management or food safety measures for contaminants are presented:

- **Maximum levels** (MLs) established in Regulation (EC) No. 1881/2006: MLs, as established by Reg. (EC) 1881/2006, are an efficient tool to avoid/reduce exposure to high levels of contaminants. In case a ML is exceeded, the food shall not be placed on the market. MLs are set on the basics of the ALARA-principle (see below) and therefore a good knowledge of the presence/occurrence of a contaminant in the food is necessary for deriving a ML.
- However, setting MLs is not always feasible or may not provide a sufficient level of health protection. Extensive sampling and compliance testing of every lot of product is not possible. Moreover, ML-based measures focus more on control of final products rather than tackling contamination at source. Furthermore, the establishment of MLs may not be possible or in case of insufficient knowledge of the risk profile of a contaminant and/or its presence/occurrence in the food. So, there is a need for preventive Measures in addition or instead of MLs.
- **The preventive approach** is based on minimisation strategies such as good agricultural/production practices, HACCP/self-control systems of FBOs, **C**ode **o**f **P**ractices (CoPs) or toolboxes. CoPs or toolboxes are often elaborated in close cooperation of official authorities and FBOs and contain specific tools to prevent or reduce contamination all along the food chain. The legal basis for the mitigation or preventive approach is established in Art. 2 of Council Reg. (EEC) 315/93 laying down Community procedures for contaminants in food: to ensure a high level of consumers health protection, contaminant levels shall be kept **a**s **l**ow **a**s can **r**easonably be **a**chieved by following good practices. This principle is also referred to as **ALARA-principle**. It may be more effective in avoiding, reducing and controlling food contamination at source/all along the feed/food chain. Preventive/minimisation measures are often used in combination with indicative (sometime also called benchmark levels), action levels or target levels. These levels are “performance indicators” to be used to verify the effectiveness of mitigation measures and thereby assist the FBO in the implementation of their minimisation strategy. The principles and objectives of such “performance indicators” are always the same: they are - in contrast to MLs - non-legally binding levels and therefore their exceedance does not necessarily require the withdrawal of the food from the market. The exceedance of an indicative, action or target level is an indication that contaminants levels are higher than the usual (unavoidable) level and that action needs to be taken in order to reduce contamination below the indicative, action or target levels. Such an action is to be taken by Official Controls Authorities and/or the responsible Food Business Operator. It is thus possible to elucidate the source of contamination and to take measures to reduce or eliminate it. Therefore, indicative, action or target levels serve as an early warning tool and allow a proactive approach in risk management.
  Another important risk management tool is **monitoring and collection of chemical contaminants data**. The aim of monitoring is to get a representative data basis for the presence of contaminants in food. Representative occurrence data is the basis for accurate exposure/risk assessment and essential in view of the establishment of future risk management strategies (e.g. for deriving MLs, see above). Therefore, Member States should perform monitoring as a very important first step in risk management. EU-monitoring recommendations often provide the legal framework for unionwide monitoring exercises in relation to contaminants are often so-called EU-monitoring recommendations.
- Further risk management measures for control measures include **dietary consumption advice**, prohibitions/restrictions on the placing of food on the market and **special conditions/restrictions for import** of food.

This presentation provides an overview of the most important control measures to be applied by Competent control Authorities (CAs) in the area of agricultural contaminants (e.g. mycotoxins, ergot alkaloids, inherent plant toxins), environmental contaminants (metals, dioxins and PCB) and process contaminants (e.g. Acrylamide (AA), PAH). For each type of

contamination examples of the practical implementation of suitable risk management tools are given, including the following:

Authorities are responsible for control of compliance with MLs and need to take measures to ensure the implementation of mitigation practices. According to the new Reg. (EU) 2017/2158, Member States Authorities shall regularly perform official controls to verify that the FBOs comply with the mitigation provisions for Acrylamide laid down in that regulation and that the AA-levels in foods are below the benchmark levels. In case the benchmark level is exceeded the FBO shall review and adjust processes/controls to achieve levels of AA below the benchmark (ALARA). Details of mitigation measures taken to reduce the levels of acrylamide below the benchmark level shall be made available to competent control authorities upon request.

Recently, the Comm recommendation for monitoring AA-levels in certain foods has been adopted by the EU-Commission. The objective of this monitoring recommendation is to collect data on AA-occurrence levels in certain other food groups which so far have not been in the focus of attention (e.g. vegetable crisps, roasted nuts, cocoa products, etc.) and for which no benchmark levels have been established so far. On the basis of new AA-monitoring further data health protecting measures (such as further benchmark levels and/or MLs) may be established at European level.

Occurrence data on contamination levels (e.g. on AA, metals, dioxins, mycotoxins etc.) should regularly be collected and communicated to EFSA for a compilation into the database. Data transmission to EFSA is to be performed in line with Standard Sample Description (SSD); food categories need to be accurately defined according to the FoodEx catalogue of the SSD to allow a unique/unambiguous description of the sample. This is necessary to enable EFSA to carry out a reliable risk assessment (which is the basis for deriving risk management measures).

A combination of different risk management tools is often applied for contaminants in order to achieve the highest level of health protection: for example, in case of dioxines and PCB, MLs are applied in combination with action levels. Action levels, established by Recommendation 2013/711/EU, stimulate a proactive approach and are used as a tool by CAs and FBOs to highlight those cases where it is appropriate to identify a source of contamination for dioxins/PCBs. Respectively, to take the necessary measures in order to reduce or eliminate it. Action levels are set at a lower level as compared to MLs. In case of an exceedance of an action level for dioxines/PCBs no withdrawal is needed (as would be the case for an exceedance of a ML). But it is an indication that there might be a problem of higher contamination. Therefore, it requires action and/or an investigation to be taken by FBO in cooperation with CAs.

Also, for risk management of toxic metals in food (e.g. lead, Arsenic) MLs as well as the preventive approach (e.g. Code of mitigation practices) are applied. In case of ergot alkaloids (a group mycotoxins) we have a combination of the following different approaches:
- MLs for ergot sclerotia in unprocessed cereals
- withdrawal from the market in case of unsafe levels of ergot alkaloids in food according to Art. 14 of GFL
- recommendations for action to minimize ergot alkaloids in cereals as well as
- further monitoring of ergot alkaloids levels in cereals in view of establishment of further health protecting measures in the near future (this topic will also be discussed more in detail in a specific case study in 2.2).

Dietary consumption advice is an important risk management instrument, particularly in cases where MLs and other preventive measures do not provide sufficient health protection. Certain population groups (e.g. pregnant or breastfeeding women, infants/young children) are

particularly sensitive to adverse effects of contaminants and hence should follow specific consumption advice.

Module 2.2: Open discussion on controls measures in feed and food: food contaminants

Tutor(s): Klara Jirzik / Annette Rexroth
Duration: 60 min
Format: Open discussion based on specific case studies

Module Description
Open discussion about specific case studies (also showing the application of HACCP principles), such as: • Dioxins and non-dioxin like PCBs in fish and dioxins in fish from the Baltic region; • Heavy metals in cereal-based food products; • Mycotoxins in food; • Industrial contaminants.

Key concepts, information and messages for this module
Case study 1 **Ergot alkaloids in cereals and cereal derived foods (instead of Dioxins and non-dioxin like PCBs in fish and dioxins in fish from the Baltic region):** In 2012 EFSA adopted an opinion on ergot alkaloids in food and feed and established a group acute reference dose. Based on this scientific opinion, the EU-Commission decided to establish appropriate measures for protection of public health. This case study demonstrates how different risk management tools may be combined in order to reduce contamination as much as possible. The example on ergot alkaloids can be used as a "practical implementation" of the risk managements "facts" presented in 2.1. It will cover the following aspects of risk management: ✓ Max. levels (so far MLs have only been established for ergot sclerotia in cereals); ✓ Measures in accordance with Article 14(8) of Reg. (EC) No 178/2002 as regards restrictions on the placing on the market or withdrawal from the market, where the food is found unsafe because of the level of ergot alkaloids despite its compliance with the maximum level on ergot sclerotia; ✓ Need for more data: the presence of ergot sclerotia does not fully correlate with the content of ergot alkaloids. Therefore, it is important to gather data on the presence of ergot alkaloids in cereals and cereal products in order to establish the relationship between the presence of ergot alkaloids and the presence of ergot sclerotia; ✓ More data on ergot alkaloids in cereals and cereal-based food are necessary in order to be able to derive specific risk management tools for ergot alkaloids (in addition to the existing MLs for ergot sclerotia); ✓ Legal framework for monitoring exercise in ergot alkaloids; ✓ Art. 9 of Reg. 1881/2006 according to which Member States and professional stakeholder organisations are strongly recommended to monitor the presence of ergot alkaloids in cereals and cereal products; ✓ Recommendation 2012/154/EU on the monitoring of the presence of ergot alkaloids in feed and food;

- ✓ MLs are currently under discussion at European expert level for ergot alkaloids;
- ✓ Strategies for prevention of reduction of the presence of ergot alkaloids in food: e.g. CoP established by Codex Alimentarius in 2017.

Case study 2
Dioxins in eggs from free range chicken:
Commission Regulation (EU) No. 1881/2006 sets MLs for dioxins in eggs. These eggs have a higher risk of being contaminated with increased levels of dioxins than barn or cage eggs. Ingestion of soil particles from environmentally contaminated areas may contribute to elevated dioxin levels in free-range chicken eggs. Furthermore, there are many other possible contamination sources as feed, waste, water etc. As many consumers take into account animal welfare when choosing their food, eggs from free-range chicken are becoming increasingly important in the diet.

In the present case study participants should discuss which measures could be taken to prevent non-compliant eggs from being placed on the market. Possible contamination sources and carry-over effects should be taken into account.

Case study 3
Acrylamide mitigation in foods for babies and infants:
Participants should discuss possible follow-up measures to be taken by Competent Authorities in case of the exceedance of the benchmark value for Acrylamide (AA) in baby foods. In doing so, they may consider relevant FDE pamphlets for specific mitigation of AA in baby foods. Participants may also think about drafting a process flow-chart mentioning the major influences on Acrylamide formation in baby biscuits. In addition, Reg. 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the levels of Acrylamide in food, needs to be taken into account. Reg. 2017/2158 also sets specific benchmark levels for baby foods.

When the benchmark levels are exceeded, FBOs shall review the mitigation measures applied and adjust processes and controls with the aim to achieve levels of acrylamide as low as reasonably achievable below the benchmark levels set out in Annex IV of the Regulation. As outlined in recital 14 of the Regulation (EU) 2017/2158, Member States Authorities' must ensure compliance with this Regulation and to perform therefore regularly official controls.
Approaches and strategies for implementation of such official controls – is it part of the previous sentence or it's not finished?

Module 2.3: Control measures for contaminants in feed and food: part 2, undesirable substances in feed

Tutor(s): Marjana Mohorko / Sabine Kruse
Duration: 45 min
Format: Presentation

Module Description
Extensive overview of EU risk management measures (regulations, COPs, guidance, etc.) on the undesirable substances in feed (inorganic contaminants and nitrogenous compounds, mycotoxins, plant toxins, organochlorine compounds, including dioxins and PCBs, harmful botanical impurities, cross-contamination of feed additives) such as for e.g.: • Use of action thresholds for dioxins and PCBs (annex II, Dir 2002/32/EC) as a tool to reduce / eliminate contamination; • Guideline levels for certain mycotoxins in feed;

- Development of COPs for the prevention and reduction of undesirable substances in feed;
- Collection of occurrence data through recommendations on monitoring (e.g. dioxins and PCBs, ergot alkaloids).

Key concepts, information and messages for this module
Feed business operators are responsible to ensure feed safety. If the feed is not safe, it should not be placed on the market or used for feeding animals. In addition to the General Food Law (GFL), special requirements are included in the Reg. (EC) 183/2005 on feed hygiene. Feed business operators at the level of primary production of feed shall follow the good agricultural practices to avoid any contamination of feed, including pasture and drinking water for animals. Other feed business operators shall put in place, implement and maintain procedures based on HACCP. The legislation does not describe in detail how feed business operators should implement HACCP. However, the HACCP principles guarantee safe feed in combination with good hygiene practices. HACCP is a tool for monitoring, control and management of undesirable substances in feed. The presentation goes through the points which need to be taken into account by official control of feed business operators. Feed exceeding ML of undesirable substances may not be diluted or mixed, but the content of undesirable substances may be reduced by decontamination (physical, chemical or biological processes) operated by an authorised feed business operator. The Reg. (EU) 2015/786 establishes requirements for decontamination processes. The management strategy for the control of a specific undesirable substance depends on the sources, the toxicology, the transfer and other factors. Explanation of EU strategies are also provided in details based on the examples of mycotoxin and dioxins/PCBs in feed. The competent authorities in the Member States are responsible for enforcement of the provisions. Examples of implementation of the official feed control in Germany and in Slovenia from the point of view of undesirable substances in feed are provided.

Module 2.4: Open discussion on control measures in feed and food: undesirable substances in feed

Tutor(s): Marjana Mohorko / Sabine Kruse
Duration: 30 min
Format: Open discussion based on specific case studies

Module Description
Open discussion about specific case studies such as: • Dioxin and non-dioxin like PCBs in fishmeal and fish oil used as feed • Ambrosia contamination in feed • Mycotoxins in feed • other current cases. Discussion of different management strategies in the feed sector

Key concepts, information and messages for this module
The objective of the management strategies in the feed sector is not only the human health, but also animal health and the protection of the environment. In addition, the demand of the different animal species must be taken into account. Based on some examples the implementation of legal regulations will be discussed. The following aspects of management strategies will be discussed: – The characteristic of the relevant undesirable substance. – The available tools for prevention, monitoring, control and management of undesirable substances. – The measures for reduction of the content of undesirable substances in feed. – The responsibility of feed business operators and the competent authorities. Feed business operators are responsible for the safety of the feed which they produce, transport, store or sell. The authorities shall monitor and verify that the feed business operators fulfil the requirements of the feed law. The official feed control should be focused on the verification of the HACCP in the establishments by on the spot control and on verification of the effectiveness of the self-control systems by taking samples.

Module 2.5: Control measures for contaminants in feed and food: focus on recent developments and outlook

Tutor(s): Klara Jirzik / Annette Rexroth
Duration: 45 min
Format: Presentation

Module Description
Presentation of the recent developments and outlook in the legal provisions for some of the most concerning contaminants occurring in foods and feeds will be given with a focus on: • Mycotoxins - MLs for ergot sclerotia, citrinin; • Plant Toxins - opium alkaloids in poppy seeds, erucic acid in oils and fats, tropane alkaloids; tetrahydrocannabinol; pyrrolizidine alkaloids (PA); • Industrial contaminants - Ethyl carbamate - PAH, MCPD esters and glycidylesters ; • Heavy metals - Pb, Cd, As. Review of MLs for Hg. Progresses made with regards to Cr. Commission recommendations on monitoring (e.g. Cadmium); • Other environmental contaminants: perchlorate; • Dioxins and PCBs – Reg (EU) 2017/644; Dir 2002/32/EC; • Progresses with regards to other Persistent Organic Pollutants: PFAS, Brominated Flame Retardants; • Mineral oil - 2012 EFSA Scientific Opinion on mineral hydrocarbons in food: important pathways of mineral oil entering in the food chain; • Undesirable substances in feed.

Key concepts, information and messages for this module
The presentation provides an overview on the recent developments in the legal provisions for agricultural, environmental and process contaminants. Important note: data collection and monitoring activities are very important tools for risk management. Risk management is not only the control of compliance with regulatory levels (such as MLs) as already given in food legislation. Another important issue is to address new or emerging risks related to contaminants for which no MLs have been established yet. A reliable database is a prerequisite for elaboration of further minimization and risk management strategies (e.g. MLs). Therefore, Member States should perform monitoring as

a very important first step in risk management. Member States should also consider this when setting up their MANCPs.

Over recent years risk managers increasingly encounter emerging risks related to the presence of inherent plant toxins in foods, including tropane alkaloids, pyrrolizidine alkaloids, opium alkaloids and tetrahydrocannabinol (THC). Inherent plant toxins may occur as secondary plant substances in invasive, foreign plant species, which grow on the same cultivation area as crop plants. Therefore, agricultural crop foods may become contaminated, for example, due to weed contamination. As inherent plant toxins show tox. properties, they are of concern for food safety and hence risk managers.

The presence of psychoactive THC in food may be of potential health concern; more data are needed to carry out a reliable risk assessment. Hence, as a first step for risk management, Member States should monitor the presence of Δ9-THC, its precursors and other cannabinoids in food of animal origin (possible carry over) and hemp-derived foods, as indicated in Comm. Rec. (EU) 2016/2115.

In case of tropane and pyrrolizidine alkaloids, current measures also focus on data collection in various foods in order to enable EFSA to carry out a more accurate exposure/ risk assessment and to possibly establish further risk management at EU-level in the future. Work on mitigation strategies to prevent and reduce PA- and TA-contamination in Food (e.g. in tea) is done in parallel. MLs for (-)-hyoscyamine and (-)-scopolamine in cereal-based baby foods have already been established in Reg. 1881/2006. MLs for tropane alkaloids in other food groups (e.g. cereal derived foods and herbal infusions) are under discussion. Furthermore, MLs for PA in different foods (such as tea, herbs and spices) are currently sentence to be finished.

All foods containing refined oils (e.g. infant formula) can potentially be contaminated with 2- and 3-MCPD/glycidyl fatty acid esters. Glycidyl fatty acids are possibly carcinogenic to humans (category 2B), so gathering more occurrence data in view of elaboration of further risk management measures is paramount. Current monitoring exercises carried out pursuant to Comm. Rec. (EU) 2014/661 focus on data collection for various foods including baby foods. Based on the monitoring data obtained in application of Recommendation (EU) 2014/661/EU, the EU-Comm recently established MLs for Glycidylesters in vegetable oils and foods destined for infants and young children. MLs for 3-MCPD-Esters in oils for human consumption as well as baby foods are also expected in the near future.

EFSA adopted a scientific opinion on the risks for public health related to the presence of furans and methylfurans in food. EFSA concluded that the current exposure to furan indicates health concern. Also, methylfurans may add significantly to the overall exposure and therefore, increase the health concern. It is acknowledged that there are insufficient data available on the presence of methylfurans in food. Furthermore, recent information has become available on the presence of another alkylfuran, i.e. 2-pentylfuran in foods for infant and young children. It is therefore appropriate to recommend the monitoring of furan and alkylfurans in food.

On the basis of recent risk assessments, EFSA concluded that dietary exposure to lead, cadmium and inorganic arsenic needs to be reduced. Therefore, new Maximum Levels have been established for lead and cadmium in foods for infants and young children by recent amendments of Reg. (EC) 1881/2006. These also include a new ML for iAs in rice specifically destined for baby food production. Moreover, in case of Nickel which, as a result of its presence in food, may cause chronic and acute (allergic) effects, Comm. Rec. (EU) 2016/1111 is in place. Better knowledge on the nickel content in main contributors is required in view of possible future risk management measures.

Seaweed and halophytes form an increasingly important contribution to the consumption patterns of certain EU consumers. Therefore, it is necessary to assess whether the contribution of arsenic, cadmium, lead and mercury from seaweed and halophytes to the total exposure of these substances, would necessitate the establishment of MLs for arsenic, cadmium and lead for these commodities. Occurrence data for arsenic, cadmium, lead and mercury in different seaweed species, halophytes and products based on seaweed should be gathered to support a dietary exposure assessment. This is why the published recommendation (EU) 2018/464 of 19 March 2018 on the monitoring of metals in seaweed, halophytes and products based on seaweed.

Mineral Oil Hydrocarbons (MOH) are a complex mixture of Mineral Oil Saturated Hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH).

MOH may enter the food chain through various pathways such as environmental contamination, lubricants for machinery used during harvesting and food production and food contact materials.

Some MOAH may be mutagenic and carcinogenic and thus of potential health concern. Therefore, Comm. Rec. (EU) 2017/84 has been established in order to monitor MOH in different foods and Food Contact Materials (FCM) used for those foods.

In case of detection of MOH in Food, competent authorities should perform further investigations covering the systems of FBO that could affect contamination, e.g. production and processing, HACCP-methods etc. in order to elucidate possible sources. In case of detection of MOH in FCM, authorities should collect data on production and processing methods of FCM, type and composition of the packaging material, presence of functional barrier, etc. As this is a complex process, the active involvement of different stakeholders in reducing the contamination sources for MOH needs to be highlighted.

Module 2.6: Case study on control measures and prevention of contamination: links between feed and food

Tutor(s):	Klara Jirzik / Annette Rexroth, Marjana Mohorko / Sabine Kruse and Training Coordinator
Duration:	60 min
Format:	Practical activity (group work + debriefing)

Module Description

Provide a matrix with the different type of productions that can be affected by contaminants/undesirable substances (feed production; food production: both feed and food production).
Appoint to every group a specific substance (a good example applicable on both the type of production).
Every group should:

- identify in which type of production the substance can occur;
- detail the types of controls they shall make (including on mitigation measures and monitoring);
- plan the prevention measures to avoid the occurrence of the substance;
- describe how to manage a situation when maximum/action/guidance /indicative level is exceeded.

Every group will then present the outcomes of the discussion and with the help of the TC some conclusions will be taken.

Key concepts, information and messages for this module
Discussion in 4 groups around: Cadmium Aflatoxins Dioxins/PCBs Rye ergot

Reference documents – Topic 2

The list of refence documents for this topic has been prepared based on the following criteria:

- Description of the main issues related to the management measures to be adopted in a practical way for solving possible harmful and/or emergency situations.
- Non-mandatory legislative provisions related to the actions recommended for mitigating a risk derived from the presence of contaminants in food and feeds products.

The final selection is:

- Council Reg. (EEC) 315/93 of 8 February 1993 laying down Community procedures for contaminants in food and its amendments
- DIRECTIVE 2002/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 May 2002 on undesirable substances in animal feed and its amendments
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs and its amendments.
- Reg. (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Reg. (EC) 999/2001, (EC) 396/2005, (EC) 1069/2009, (EC) 1107/2009, (EU) 1151/2012, (EU) 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Reg. (EC) 1/2005 and (EC) 1099/2009 and Council Dir. 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Reg. (EC) 854/2004 and (EC) 882/2004 of the European Parliament and of the Council, Council Dir. 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/ EC and Council Dec. 92/438/EEC (Official Controls Regulation)
- Reg. (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council
- Commission Rec. 2010/161/EU of 17 March 2010 on the monitoring of perfluoroalkylated substances in food
- Commission Rec. 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products
- Commission Rec. 2014/118/EU of 3 March 2014 on the monitoring of traces of brominated flame retardants in food Text with EEA relevance
- Commission Rec. 2014/661/EU of 10 September 2014 on the monitoring of the presence of 2 and 3-monochloropropane-1,2-diol (2 and 3-MCPD), 2- and 3-MCPD fatty acid esters and glycidyl fatty acid esters in food
- Commission Rec. (EU) 2015/682 of 29 April 2015 on the monitoring of the presence of perchlorate in food
- Commission Rec. (EU) 2015/1381 of 10 August 2015 on the monitoring of arsenic in food

- Commission Rec. 2016/2115 of 01/12/2016 on the monitoring of the presence of Δ9-tetrahydrocannabinol, its precursors and other cannabinoids in food
- Commission Rec. (EU) 2016/1110 of 28 June 2016 on the monitoring of the presence of nickel in feed
- Commission Rec. (EU) 2016/1111 of 6 July 2016 on the monitoring of nickel in food
- Commission Rec. (EU) 2018/464 of 19 March 2018 on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed
- Commission Rec. 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products
- Commission Rec. 2003/598/EC of 11 August 2003 on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages
- Commission Rec. 2014/662/EU of 10 September 2014 on good practices to prevent and to reduce the presence of opium alkaloids in poppy seeds and poppy seed products
- Commission Rec. 2012/154/EU of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food
- Commission Rec. (EU) 2015/976 of 19 June 2015 on the monitoring of the presence of tropane alkaloids in food
- Commission Rec. 2007/196/EC of 28 March 2007 on the monitoring of the presence of furan in foodstuffs
- Commission Rec. (EU) 2016/22 of 7 January 2016 on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits, repealing Rec. 2010/133/EU
- Compilation of agreed monitoring recommendations as regards the presence of mycotoxins and plant toxins in food. Available at https://ec.europa.eu/food/sites/food/files/safety/docs/cs_monitoring_recommendations_en.pdf
- Commission Rec. 2014/193/EU of 4 April 2014 on the reduction of the presence of cadmium in foodstuffs
- Commission Rec. (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food
- GOOD PRACTICES FOR THE FEED INDUSTRY Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding, FAO and IFIF 2010. Available at http://www.fao.org/3/i1379e/i1379e00.htmPrevention and Reduction of Food and Feed Contamination, Codex Alimentarius 2012. Available at http://www.fao.org/3/i2556e/i2556e.pdf
- Commission Rec. (2013/711/EU) of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in feed and food

TOPIC 3: Implementation of Official Controls: planning, procedures and controls on imports

Specific objectives of Topic 3:

At the end of Topic 3, participants will be able to:

- plan official controls on contaminants and examine their completeness from field till fork
- use a harmonised approach in the development of particular control procedures
- describe existing good practices on planning and implementation of official controls
- describe the official controls on contaminants in food / feed at an import level
- prepare RASFF notifications and implement follow-up activities following a RASFF notification

Module 3.1: Current and new OCR

Tutor(s): Akos Jozwiak
Duration: 30 min
Format: Presentation

Module Description
Reminders on general legal provisions applicable to the control of contaminants with focus on highlights of recent SANTE-F audits and highlighting of the main changes between Regulation (EC) 882/2004 and Regulation (EU) 2017/625: • Competent Authorities: demarcation of responsibilities for official controls on contaminants in food and feed. Communication, co-ordination and co-operation among them; • Laboratories: designation by CAs, compliance with ISO 17025 / customer requirements. Communication with accreditation body; • extended scope and integrated approach; • changes with regards to official control fees; • impact on official controls at EU borders; • integrated information management system.

Key concepts, information and messages for this module
The organisation of official controls is regulated by Reg. (EC) 882/2004 and the 'new' Reg. (EU) 625/2017. The new regulation brings – among others – new approach by defining 'official controls' and 'other official activities', by introducing chain approach and by tackling emerging issues and laboratory accreditation rules in a more flexible way. There are new provisions on areas important for control of chemical contaminants, such as on control fees, on possible actions, on border control activities and an integrated information management system (IMSOC) is to be introduced. IMSOC is supposed to be a single IT framework, connecting all current official control reporting services. The European Commission's DG-SANTE Directorate F (Health and food audits and analysis) is currently preparing a reporting template for aggregate data on MS official control activities. From the point of view of planning of official controls the articles on the Multi-annual National Control Plan (MANCP) are important. The aim of the MANCP is to be a bridge between high level strategies and (annual) operational control plans and via this to ensure that official controls are performed in a risk-based and efficient way. The MANCP should follow the PDCA-cycle (plan – do – check – act), and it is important to emphasise that PDCA-cycles exist at multiple levels: there is a PDCA for the planning (drafting) of the MANCP itself, for the (annual) implementations, etc.

During the MANCP planning process the high level (strategic) objectives should be broken down into middle and then to lower level (operational) objectives, using SMART principles for setting the objectives (specific – measurable – attainable – relevant – time-bound). It is important to note that not all the principles of SMART are equally crucial at all levels of objectives. A risk-based approach should be used in breaking down the objectives, thus the 'risk based' concept will gain a meaning: explaining the reason for choosing objectives.

The most important take-home message is that control plans stem from strategic objectives, thus having a direct contact with long term risk mitigation goals.

Module 3.2: Setting up control programmes on contaminants in feed and food

Tutor(s): Akos Jozwiak
Duration: 30 min
Format: Presentation

Module Description
• Implementation of risk based approaches for the planning of official controls. Risk categorisation system. • Sampling program: establishment of levels and frequency, including integration of monitoring recommendations. Examples of good practices (e.g. sampling capacity previewed in case of suspicion). • Inspection program (e.g. good practices for the risk categorisation system, verification of general hygiene provisions for FNAO).

Key concepts, information and messages for this module
During drafting annual national control plans the 'risk cascade' concept should be kept in mind: there are multiple, cascading levels of risks (inherent product risk – legislative risk – compliance risk – official control risk – audit risk – residual consumer risk). When it comes to drafting the control plans, a systematic, process-based approach could be of help. In this context, we divide this process into 3 steps: 1. Input: it is divided into four broad categories: – entities for categorisation – features of those entities (among many features, Total Diet Studies could be used) – control parameters – criteria (or rules) for categorising entities and assigning control parameters for the categories 2. Process: several processes may be needed, for example: at national, regional and local level 3. Output: it is essentially a mapping between entities and a (set of) control parameter(s) or in other words: (1) targeting of controls and (2) applying the most appropriate methods/frequency to the target groups. An important feature of this planning methodology is that it helps to be systematic and transparent, thus providing objective evidence in terms of soundness of the planning and priority setting process. There is no possibility of control over all the legal provisions and the process of careful prioritisation helps in selecting the most important things. When planning sampling or inspection plans, it is essential to be aware of the purpose of those plans, since different sampling strategies (objective, selective, suspicion) should be used depending on the main aim and purpose of control. The results of different sampling

strategies are not statistically comparable, as also emphasised by the latest Commission report on the MANCP annual reports. In practice, a balance between objective and selective sampling programs should be kept.

Module 3.3: Case study on NCP for contaminants

Tutor(s): Akos Jozwiak
Duration: 45 min
Format: Practical activity (group work + debriefing)

Module Description
Participants shall prioritise relevant contaminants as part of the NCP on contaminants in feed and food. Each result will be presented and discussed.

Key concepts, information and messages for this module
Participants are divided into groups for a role-play, where they have to act the roles of scientific risk assessor, laboratory expert, central level food/feed safety risk manager or high -level decision maker, local level food/feed safety risk manager and industry representative. The task of the discussion groups is to set rules (algorithm) for ranking different hazard-matrix pairs in relation to mycotoxins: to set weights for different features and to assign values to the given hazard-matrix pairs. The group should try to come to an agreement on weights and values. The rapporteurs report back the weights of features, the rank of the given hazard-matrix pairs and the problematic issues experienced during the group discussion. The main purpose of the exercise is to show how different priorities of the participants (i.e. different viewpoints, objectives, perceptions of the decision makers) would change the outcome of the ranking process, leading to different sampling plans and reflecting the priorities of the planning group. Despite the different outcomes, the systematic and documented planning procedure gives objective reasoning for different choices.

Module 3.4: Procedures for the performance of control activities

Tutor(s): Akos Jozwiak
Duration: 30 min
Format: Presentation

Module Description
Documented procedures and instructions for the implementation of inspection and sampling program, such as: • scope and depth of the official controls; • sampling instructions (SOP, EU Regulation, and International Norms); • reporting of control activities; • actions in case of non-compliant results and financial sanctions; • verification of official controls' effectiveness. Exchange on good practices.

Key concepts, information and messages for this module
The most important control principles are the assurance of the quality, consistency and effectiveness. Official controls should be thorough and effective, especially in light that those always pose a burden for FBOs. The competent authorities act in the interest of operators and of the general public, therefore, accountability and providing access to information is a key issue. Written procedures, reporting and documentation activities play key role in assuring these basic principles. A solid reporting and documentation system provide (the only) objective evidence and allow for information collection and analysis for the continuous development of the official control activities. The reporting tasks related to the control of chemical contaminants need a common ground for data collection and analysis. This is ensured by the Standard Sample Description (SSD) and as a part of it the FoodEx systems of EFSA. The SSD supports the data collection and transmission of the samples data and the results of analytical measurement of several data collections domains. It is designed for data storage (relational database) and analysis. The FoodEx system provides a multiple-hierarchical, faceted classification of products as part of the SSD system. An usual MS problem is that Risk Managers collect the samples (and the data) in a different format, with a different aim, compared to risk assessment needs. The multi-hierarchical, faceted approach of the FoodEx system allows for development of (national) data collection and reporting systems, incorporation of other factors like risk management viewpoints. More standardised data reporting activities are expected for more data domains. Reporting of official control activities other than samplings is not yet harmonised, however, the trend is clear: the IMSOC and a common template for the MANCP annual report are huge steps towards common data collection systems for ensuring continuous development. To close the loop of the PDCA cycle, we have to ensure the measurement and verification of the effectiveness of official controls. Effectiveness of official controls could only be explored in the context of the objectives. For that, an indicator (and a monitoring) system has to be in place, which is linked to the strategic and operational objectives, and measures output, outcome and impact indicators as well.

Module 3.5: Official controls on imported food and feed and RASFF notification system

Tutor(s): Francesco Montanari / Carlo Donati
Duration: 45 min
Format: Presentation

Module Description
• Risks associated with the type of food/feed and adequate targeting for official sampling and analysis; • Practical situations that can occur depending on the different points of entry and the existing facilities: DPEs and DPIs; • Documentary checks; Physical checks. Selection of consignments to be tested. Sampling in case of suspicion; • Management of non-compliances for imported goods and use of RASFF.

Key concepts, information and messages for this module
There are various specific risk management tools provided by EU import control legislation of relevance to contaminants and in particularly to feed and food of non-animal origin. The current applicable measures are: • Reinforced border control system - Reg. (EC) 669/2009 • Emergency measures on Aflatoxins - Reg. (EU) 884/2014 • Emergency measures on guar gum from India - Reg. (EU) 2015/175 • Approval of pre-export checks for USA and Canada - Reg. (EU) 2015/949 These different systems entail diverse provisions depending on the risk being ranked ´medium´ or ´high´; or controls can be relaxed if pre-export checks accepted. Reinforced border controls require all checks (documentary, identity and physical) being carried out at the designated point of entries (DPEs) and the pre-notification of the arrival of the relevant consignment through a common entry document (CED). There are no additional import conditions, simply a coordinated approach that MS authorities must follow at the EU borders. Conversely, emergency measures set out additional import guarantees, such as health certificates and analytical reports that must arrive with the consignment that is pre-notified through the CED. The most important emergency measure currently in place concerns aflatoxin contamination; it establishes a system where relevant consignments from listed non-EU countries must arrive to the EU through a DPE (located at the border), where at least documentary checks are carried out. The measure foresees that identity and physical checks may be carried out at another control point, known as designated point of import (DPI) that may be located at the EU border or inland. Approval of pre-export checks is granted by the EU provided that certain conditions are met, including the favorable outcome of an audit performed by the European Commission services audit on the official control system of the exporting country. They are currently in place for certain products of non-animal origin from the USA and Canada and subject to strict conditions (i.e. health certificate and analytical report must also accompany the consignment). However, only a minimal (<1%) control frequency at EU borders is maintained. To note that is in the pipeline an implementing Regulation on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) 178/2002 of the European Parliament and of the Council. The new Regulation will repeal Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) No 2015/175, (EU) No 2017/186 and (EU) 2018/1660. It shall apply from 14 December 2019. Details of the new draft Regulation can be found on: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-3883724_en

Module 3.6: Simulation of a RASFF notification preparation

Tutor(s): Francesco Montanari / Carlo Donati
Duration: 45 min
Format: Working group and debriefing

Module Description

The participants shall: • prepare a RASFF notification on the basis of a real case of contamination of feed/food; • prepare follow up activities, based on a real recent RASFF notification.

Key concepts, information and messages for this module
General objective of the exercise is to identify: • legal requirements that apply to each situation; • whether or not a RASFF notification is needed and, if so, which type of notification; • the enforcement actions that competent authorities may take.

Reference documents – Topic 3:

The list of refence documents for this topic has been prepared based on the following criteria:

- Regulations on general rules of official controls currently in place and entering into force in the near future
- Selection of implementing regulations important for the understanding of the course
- Other guidelines important from a practical implementation aspect

The final selection is:

- Reg. (EC) No 882/2004 of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
- Reg. (EU) 2017/625 of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC
- Reg. (EU) 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed
- Commission Dec. 2008/654/EC of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Reg. (EC) 882/2004 of the European Parliament and of the Council
- Reg. (EC) 669/2009 of 24 July 2009 implementing Reg. (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Dec. 2006/504/EC and its amendments
- Commission Implementing Reg. (EU) 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Reg. (EC) 1152/2009 and its amendments
- Commission Rec. 2014/661/EU of 10 September 2014 on the monitoring of the presence of 2 and 3-monochloropropane-1,2-diol (2 and 3-MCPD), 2- and 3-MCPD fatty acid esters and glycidyl fatty acid esters in food
- Commission Rec. (EU) 2015/682 of 29 April 2015 on the monitoring of the presence of perchlorate in food

- Commission Rec. (EU) 2016/1110 of 28 June 2016 on the monitoring of the presence of nickel in feed
- Commission Rec. (EU) 2016/1111 of 6 July 2016 on the monitoring of nickel in food
- Commission Rec. (EU) 2018/464 of 19 March 2018 on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed
- Commission Rec. 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products
- Commission Rec. 2003/598/EC of 11 August 2003 on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages
- Commission Rec. 2014/662/EU of 10 September 2014 on good practices to prevent and to reduce the presence of opium alkaloids in poppy seeds and poppy seed products
- Commission Rec. 2012/154/EU of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food
- Commission Rec. (EU) 2015/976 of 19 June 2015 on the monitoring of the presence of tropane alkaloids in food
- Commission Rec. 2007/196/EC of 28 March 2007 on the monitoring of the presence of furan in foodstuffs
- Commission Rec. (EU) 2016/22 of 7 January 2016 on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits, repealing Rec. 2010/133/EU
- Commission Rec. 2014/118/EU of 3 March 2014 on the monitoring of traces of brominated flame retardants in food Text with EEA relevance
- Commission Rec. (EU) 2015/1381 of 10 August 2015 on the monitoring of arsenic in food
- Commission Rec. 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products
- Commission Rec. 2016/2115 of 01/12/2016 on the monitoring of the presence of Δ9-tetrahydrocannabinol, its precursors and other cannabinoids in food
- Commission Rec. (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food
- Commission Rec. 2013/647/EU of 8 November 2013 on investigations into the levels of acrylamide in food
- Commission Rec. 2010/307/EU of 2 June 2010 on the monitoring of acrylamide levels in food
- Commission Rec. 2010/161/EU of 17 March 2010 on the monitoring of perfluoroalkylated substances in food
- Commission Implementing Reg. (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins
- Commission Implementing Reg. (EU) 2015/949 of 19 June 2015 approving the pre-export checks carried out on certain food by certain third countries as regard the presence of certain mycotoxins
- Questions & Answers Paper on the provisions of Reg. (EC) 669/2009 as regards the increased level of official controls on imports of certain feed and food of non-animal origin, March 2015.
- COMMISSION STAFF WORKING DOCUMENT on the enforcement by national customs authorities of Reg. (EC) 669/2009 of 24 July 2009 implementing Reg. (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Dec. 2006/504/EC and its amendments
- Risk evaluation of chemical contaminants in food in the context of RASFF notifications - Rapid Assessment of Contaminant Exposure tool (RACE) - 15 May 2019: available at https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2019.EN-1625

TOPIC 4: Implementation of official controls: on-site control activities

Specific objectives of Topic 4:

At the end of Topic 4, participants will be able to:

- control a food or feed operator and appraise the efficient implementation of prevention measures and self-monitoring
- apply harmonised control approaches
- describe best practices and make use of existing tools to tackle current issues in the implementation of control activities

Module 4.1: Official controls along the feed chain on undesirable substances

Tutor(s): Luca Nicolandi
Duration: 30 min
Format: Presentation

Module Description
Implementation of official controls, such as: • verification of compliance with MLs for undesirable substances • verification of feed business operators' sampling programs for the monitoring of undesirable substances • verification of procedures aimed to minimise cross-contamination of feed additives • documentary assessment, including testing results Practical examples of HACCP audits at feed business operators as regard undesirable substances. Specific issues.

Key concepts, information and messages for this module
All Member States must enforce official controls in feed and food sector and verify that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution. Official controls must therefore affect the whole food chain, especially in the case of contaminants. In fact, many are the examples where an environmental contamination can be traced back to the chain by bringing discussion of consumer health. Official controls must be carried out within the framework of a risk-based program taking in account EFSA opinions and new hazards highlighted by RASFF. Official controls must also take in account the use of products that may influence integrity and wholesomeness of food as underlined in Regulation (EU) 2017/625. It is important to use correctly the tools offered by the regulations, particularly inspection and audit, but without forgetting the importance of proper risk categorization of companies. Sampling and inspection plans must be made in such a way as to ensure a proper distribution of activities throughout all the year as well as a proper distribution on the territory. For this reason, it is important not only to have staff and equipment, but also training, skills and a coordinated and uniform approach, through the preparation and use of appropriate operating instructions.

The organisation of the sampling plans at local level is based on the content of the MANCP. MANCP is based on previous business activity data. Consequently, a non-compliance to a given contaminant may result in an increase in the sample for the following year. On the other hand, in the case of coccidiostats in feed, where carry-over is very difficult to be kept under control, FBOs often decide to suspend or eliminate the production of certain products, outsourcing their production. It may happen that at local level there are samplings that cannot be performed because the matrices are no longer available. In these cases, it is crucial to exchange information between the local and the central level during the preparation of the MANCP in order to be able to redistribute these samples at national level.

Module 4.2: Simulation of an official control on undesirable substances in feed

Tutor(s): Luca Nicolandi
Duration: 45 min
Format: Practical activity (group work + debriefing)

Module Description
Participants will be divided in groups and shall simulate an official control of a feed business operator. They have to verify how the feed business operator should avoid the presence of undesirable substances and guarantee compliance with EU legislation. Following examples can be considered as subject of simulation: • Free ranging animals (Dioxin/polychlorinated biphenyl (PCB)contamination) • Feed mills (carry over of authorized feed additives) • Feed material producers (e.g. mycotoxins in by products from grain) After the simulation, every group will share their findings and agree on a common control approach.

Key concepts, information and messages for this module
In order to facilitate the correct use of the official control instruments by addressing the choice of one tool rather than another participants are divided in 4 group and work on two official control simulations: 1. Dioxin/PCB on grass coming from a contaminated area 2. Tetrahydrocannabinol (THC) in feeding stuffs for dairy cows For each simulation is provided a description of the operating context, the reasons behind the official control and the hazard description. For each simulation each working group must identify: • which official control tool to use, • what activity to carry out, • possible preventive measures. The dioxin simulation highlights the importance of environmental monitoring of contaminants that may unintentionally enter in the agri-food chain and become a serious risk to the consumer. For this reason, EU laws foresee an action level beyond which competent authorities start investigations to identify the contamination source. Environmental contaminants aren't directly related to the contamination place; in fact, fodder in an area can feed animals of other areas that will produce foods destined for people other than those in the contaminated area. More specifically, with regards to dairy animals, a first distinction must be made between animals kept in a farm and grazing animals (with higher risk of exposure). In the case of cattle breeding, the problem is that hay or grass used for animal feed is not necessarily coming

from the same area where animals are bred. It is therefore necessary to map both farms and fields and it could happen that hay or grass from the contaminated area are used to feed animals in farms even many kilometers away. The result is the need to define a larger-scale risk map.

The THC simulation highlights the importance of proper animal nutrition management in farms where hemp seed are used for increasing the protein content for lactating cows ration without taking in consideration the possibility to transfer a THC rate from feed to food of animal origin. The higher risk is connected with milk used for the production of "fresh pasteurized milk" underling the importance of the "from farm to fork principle" and the importance of respecting HACCP procedures.

Module 4.3: Official controls on contaminants in food

Tutor(s): Luca Nicolandi
Duration: 30 min
Format: Presentation

Module Description
Implementation of official controls, such as: • verification of MLs according to the sampling programs (e.g. practical examples on sampling levels, points of sampling along the food supply chain and instructions for sampling taken under suspicion) • on the spot official controls and practical examples on assessment of Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), Good Farming Practices (GFP) and Hazard Analysis and Critical Control Points (HACCP) • documentary assessment of raw materials and testing results against the requirements of Reg. (EC) 1881/2006 • verification of compliance with food contaminants' requirements and with general hygiene requirements for primary production for the food of non-animal origin (FNAO) Practical examples of HACCP audits' of food business operators as regards contaminants (e.g. food of animal origin – PAH, heavy metals, dioxins in fish production; dioxins, PCBs in egg production; mycotoxins in milk and food of non-animal origin). Specific issues (e.g. non-compliance at retail stage).

Key concepts, information and messages for this module
Official controls on contaminants should be carried out in both small businesses and large plants. In small businesses, although the type of authorization is related not to the size of the company or to its productive capacity but to the food or feed it produces, the official control must take into account the small size of the company and the reduced staff involved in feed and food safety. This concerns above all the correct implementation of HACCP and it makes even more important to know how to properly assess a plan by competent authorities. The ability to evaluate HACCP plans is crucial and must take into account mostly the correct identification of hazards and related risks and flexibility aspects mainly linked to the use of good practice guides or sector HACCP guides. These guidelines, starting from pre-determined CCP, describe how to control hazards with practical and simple description and very often reduce FBOs administrative burden foreseeing to avoid record if everything is compliant. Reg. (EU) 2019/627 defines clearly that where a food business operator uses

procedures set out in guides to the application of HACCP-based principles, OC shall cover the correct use of those guides

Three HACCP assessment examples are presented in order to clarify how a different approach is needed on a case-by-case basis:

a) a feed mill producing feeding stuffs for each category of livestock, from pigs to dairy cows, from rabbits to horses;
b) a dairy industry using milk coming from large size farms after a rainy and hot summer;
c) a feed mill producing flour (corn and grain).

The verification is completed with the sampling plan assessment as a tool for assessing the effectiveness of HACCP through samples sent to accredited laboratories.

The definition of sampling frequencies and sampling matrices is much clearer for the microbiological aspects than chemical aspects within Community legislation. In any case, only trends can be defined rather than precise indications on the frequencies of sampling to be carried out both for the food and feed sectors.

Module 4.4: Simulation of an official control on contaminants in food

Tutor(s): Luca Nicolandi
Duration: 45 min
Format: Practical activity (group work + debriefing)

Module Description
Participants shall simulate an official control of a food business operator. They have to verify how the food business operator should avoid the presence of contaminants and guarantee compliance with EU legislation. The simulation will consider agricultural / environmental and/or industrial contaminants. After the simulation, every group will share their findings and agree on a common control approach.

Key concepts, information and messages for this module
In order to facilitate the correct use of the official control instruments by addressing the choice of one tool rather than another participants are divided in 4 group and work on two official control simulations: 1. lead contamination in slaughtered pigs, 2. aflatoxin M_1 contamination in milk used for producing fresh cheese. For each simulation is provided a description of the operating context, the reasons behind the official control and the hazard description. For each simulation each working group must identify: • which official control tool to use, • what activity to carry out, • possible preventive measures. The simulation of lead contamination still reveals the close relationship between feed and food controls. Having identified the presence of lead over ML in pig meat has allowed the competent authorities to detect structural deficiencies in pig breeding and to improve the efficacy of the controls in pig meat chain.

The specific case of aflatoxin M_1 is a useful example of how to control food, such as milk, giving the possibility to have information on the quality of the feed used to produce it and to take steps to solve the problem.

The difficulty in managing aflatoxin limits, which are significantly lower in the EU than the standards defined by Codex Alimentarius, can be overcome by a constant and accurate monitoring of the level of this contaminant in milk and by defining an action level lower than the legal limits for the next feed inspection in the farms which have exceeded the level. EU legislation does not formally define aflatoxin limits in cheese but since aflatoxin has a strong affinity for casein, scientific studies have shown that in the cheese production there is a concentration of aflatoxin in cheese. It is also possible to define a conversion coefficient which allows us to state that a given aflatoxin value in a cheese corresponds to a certain aflatoxin value in the milk used to produce this cheese. It is thus possible to know whether the milk used meets the legal limits and therefore whether the cheese can be put on the market or not.

Module 4.5: Open discussion on the controls all along the food chain

Tutor(s): Luca Nicolandi + TC
Duration: 45 min
Format: Open discussion

Module Description
Open discussion with participants on: • the importance of official controls all along the agri-food chain on contaminants; • existing issues and how they should be tackled (based on SANTE-F reports); • exchange of best practices and common encountered issues in the implementation of official controls in the participants' countries.

Key concepts, information and messages for this module
It is increasingly evident that contaminations of foodstuffs for food producing animals are causing risks to consumers. For this reason, the organisation of official controls is a crucial moment in the system of controls, especially at a time of economic resources shortage. The analysis of the recommendations, contained in the DG-SANTE F reports, on audits to monitor MS contaminant control plans, highlights how it is still necessary to work to develop official control plans that are able to guarantee the homogeneous distribution of activities across the country and during the year. Trainings that overcome the barriers of professional specialisation and involve competent authorities from different countries are, for these reasons, irreplaceable. The goal is to tell each one their own reality and to use the solution that best solves everyday problems. In order to stimulate the discussion, the example of the management of uncertainty of measurement of aflatoxin non-compliance in milk samples is presented.

Reference documents – Topic 4:

The list of reference documents for this topic has been prepared based on the following criteria:

- Selection of implementing regulations important for the understanding of the course
- Other guidelines important from a practical implementation aspect

- EU Regulations on official control activities
- Commission's recommendations, notice and guidance documents that clarify and deepen the contents of the EU regulations
- EFSA opinions and scientific papers on specific issues

The final selection is:

- Reg. (EC) 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs and its amendments
- Reg. (EC) 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin and its amendments
- Reg. (EC) 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene and its amendments
- Reg. (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products
- Commission Regulation (EC) 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs and its amendments
- Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed
- Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625
- Guidance Document. Key questions related to import requirements and the new rules on food hygiene and official food controls. Available at https://ec.europa.eu/food/sites/food/files/safety/docs/ia_ic_guidance_import-requirements.pdf
- Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2016/C 278/01)
- Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ9-tetrahydrocannabinol, its precursors and other cannabinoids in food
- Nicolandi L., Barzanti P., Enrico D., Gherardi P., Osella M.C., Marino C., Ru G. "Food safety and Small Developed Businesses: survey in piedmont dairy operators" VI° Veterinary Epidemilogy National Workshop Orvieto (TR), 1-2 dicember 2011
- Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin EFSA Journal 2015;13(6):4141

TOPIC 5: Implementation of official controls: sampling, analysis and interpretation of results

Specific objectives of Topic 5:

At the end of Topic 5, participants will be able to:

- develop sampling procedures for the control of different contaminants
- verify whether analysis method and reporting of results comply with EU requirements
- interpret the analytical results and develop follow-up actions

Module 5.1: Implementation of sampling procedures

Tutor(s): Carlo Brera
Duration: 45 min
Format: Presentation

Module Description
• In-depth analysis of guidelines on sampling and analysis of different contaminants; • Sampling procedures for control of compliance with EU legislation on aflatoxins; • Representative sampling selection – matrix; • Sample acceptance criteria; • Practical examples of sampling procedures; • Differences between sampling performed by the operators and sampling performed by the CA.

Key concepts, information and messages for this module
Whenever the quantitative evaluation of an analyte in a food and/or feed lot has to be performed, the sampling step is very relevant. The most critical situation occurs when the analyte is heterogeneously distributed in the lot, especially at low concentration levels, since sampling uncertainty is on average much higher than the one associated to sample preparation and the analytical step. As a consequence wrong sampling procedures can lead to invalidation of the overall analytical testing. In addition, the economic and legal implications and consequences of such a failure could greatly exceed the cost associated to the performance of an accurate sampling. Furthermore, in terms of traceability, when the analyte has by law to be analytically traced, a low reliability of sampling in any step of the production and distribution chain could cause the failure of the entire traceability system. Key words for interpreting the real role and impact of proper implementation of sampling plans are “representativity” and “feasibility”. Since it is not possible to analyse the whole lot, its compliance is insured taking a sample respecting all the procedures to handle a representative sample. Therefore, “representativeness” means that all the information that is searched for in the sample must be the same of the entire lot. In statistics, this condition relates to the principle of inference. Therefore, the acceptance of a sample to be analysed in the laboratory has to be fully related to the evaluation of the procedures followed by the operator and duly reported in the sampling report.

The correct interpretation of the existing Legislation is fundamental. The consultation of Guidance documents for implementing the Legislation in the right way is highly encouraged. Another crucial point refers to the full understanding of the possible differences among different sampling procedures that have to be implemented at various level of control along the agri-food chain.

It's important to note that FBOs are not requested to follow the implementation of their own-check activities strictly following the rules as described in the existing Legislation, but they can adopt own procedures that will be subject to the judgment of appropriateness during audit visits performed by the official inspectors. However, key messages for the FBOs are to operate in such a way to demonstrate the full evidence of having applied representative sampling plans with the aim to assure the safety of the food or feed produced.

Vice versa, from the OC side, the rules as described in the Legislation must be followed and correctly applied in order to guarantee the reliability of the control activity.

When sampling is performed, the basic steps to be carried out during an official control activity are as follows:

1. Identification of how many lots compose a consignment or, in general, which is the lot or sublot to be checked for the presence of contaminants;
2. Calculation of the (sub)lot size from which the number of incremental samples derives;
3. Collection of the correct number of incremental samples from different points throughout the lot;
4. Formation of aggregate sample by gathering all the incremental samples, collected in step 3;
5. Homogenisation of the aggregate sample;
6. Official labelling of the aggregate sample;
7. Transmission of the samples to an official laboratory.

All these activities are generally performed by official inspectors. Once an aggregate sample reaches the laboratory, official aliquots must be performed by the laboratory personnel, according to the existing legislative provisions at EU level. The official aliquots correspond to the so-called "enforcement" (first analysis), "reference" (counter analysis) and "defence" samples (available for analysis by the owner of the commodity). After the implementation of these activities, the compliance of the (sub) lot is released either by the reference laboratory or by the Competent Authority or after a court decision, depending on the national rules.

Module 5.2: Case study on sampling procedures for the control of contaminants

Tutor(s): Carlo Brera
Duration: 60 min
Format: Practical activity (group work + debriefing)

Module Description
The participants will develop sampling procedures for: • the correct calculation of the number of the incremental samples • ensuring the representativeness of the aggregate samples • correct determination of laboratory samples

Key concepts, information and messages for this module
Exercises on how to face different cases of sampling procedures to be performed at different sampling sites such as harbors or warehouse etc. must provide participants the most reliable information to understand the key role of sampling in the “analytical chain”. Important points to consider are: - Lot size - Sampling site - Sampling approach (manual vs automatic and static vs dynamic) - Calculation of Incremental samples - Formation of aggregate/laboratory samples - Sending of aggregate/laboratory samples to official laboratory - Formation of official test aliquots

Module 5.3: Analysis and interpretation of results

Tutor(s): Carlo Brera
Duration: 45 min
Format: Presentation

Module Description
• In-depth insight on EU requirements governing the methods of analysis. • Relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation. • How to assess, handle and calculate: – Method Performance characteristics – Compliance criteria – Negative results – Recovery factors – TEFs and TEQs g – Processing factors – Measurement uncertainty, dry matter/fresh matter (feed: 88% dry matter; food: fresh matter) – Intended use – How to express the results in a certificate (significant figures) • Reporting of results and their interpretation.

Key concepts, information and messages for this module
Laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria based performance standards and use methods of analysis that have as much as possible been validated. The legislative frame that represents the technical basis for validating analytical methods is the ISO norm 17025:2017. By definition, validation means the full evidence that a particular requirement for a specific intended use is fulfilled. Validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol. Validation includes: • Specification of the method (scope, principle of the method, field of application, range of contamination)

- Determination of the performance characteristics of the methods such as precision (R, trueness, LOD/LOQ, uncertainty)
- Verification that the requirements can be fulfilled by using the method
- Validation report.

Method Validation is requested by Accreditation Bodies that operate according to Reg. (EC) 765/2008 and it plays a fundamental role for guaranteeing reliability of results and assuring better agreement between analysts/laboratories/ countries.

Validation is necessary when a new method is developed for a particular topic or an established method is revised to incorporate improvements or is extended to a new topic. Other cases that require the full validation of the analytical methods occur when quality control indicates that an established method is changing performance characteristics or when a laboratory intends to use an established method used in a different laboratory, or with different analysts or different instrumentation and lastly when it is necessary to demonstrate the equivalence between two methods, e.g. a new and a standard method.

Methods of analysis should be characterised by the following criteria:
(a) accuracy;
(b) applicability (matrix and concentration range);
(c) limit of detection;
(d) limit of determination;
(e) precision;
(f) repeatability;
(g) reproducibility;
(h) recovery;
(i) selectivity;
(j) sensitivity;
(k) linearity;
(l) measurement uncertainty.

As regards the interpretation and expression of results, attention must be paid to the following issues:

- relationship between fresh and dry matter of a food or feed product;
- relationship between the edible and not edible part;
- the intended use of the product, e.g. for direct human consumption or subject to further processing;
- the presence in a food/feed product of one or more than one ingredient contributing to the presence of a certain contaminant;
- the expression of the proper measurement unit of the analytical result that must be reported as set in the Regulation of reference, in terms of significative figures;
- the correct handling of values below the Limit of Quantification, that, depending on the case, must be reported either according to a lower bound approach (i.e. mycotoxins) either to an upper bound approach (i.e. dioxins);
- the correct use of the recovery factors;
- the correct use of the measurement uncertainty to be calculated either following metrological approaches either following Horwitz equation.

Module 5.4: Practical activity on interpretation of results and follow-up activities

Tutor(s): Carlo Brera
Duration: 60 min

Format: Practical activity (group work + debriefing)

Module Description
On the basis of analysis results, the participants shall: • check if the results are reported in a consistent manner allowing their equal interpretation; • carry out the interpretation of results and propose follow-up actions.

Key concepts, information and messages for this module
Exercises on how to calculate the amount of test aliquot to be considered in the reporting of results and what most proper approach should be followed when single and multi-ingredient compose a food product are given to participants in order to understand the right way to proceed during the performance of the analysis of a test aliquot.

Module 5.5: EURLs/NRLs

Tutor(s): Carlo Brera
Duration: 30 min
Format: Presentation

Module Description
• Reminders on EURLs and NRLs functions. Methods and laboratory accreditation; • Roles of NRLs in the control of contaminants, beyond analyses: contribution to design of sampling programmes, establishment of sampling methods, sample size and acceptance criteria.

Key concepts, information and messages for this module
Measurements are the key tool for guaranteeing food safety along the agri-food chain, monitoring not only products that are purchased within national borders, but also performing import/export control at EU borders. In order to keep the costs of monitoring affordable, duplication and multiplication of analytical work should be avoided. Therefore, the need of a Reference Organisation deputed to harmonise the principles, diagnostic tools, operating procedures, is a must for targeting the CAs' mission. An additional target is the facilitation of trade issues, contributing to the resolution of disputes when disagreements occur. The main activities that EURLs/NRLs must undertake are described in Reg. (EU) 2017/625 art 94 for EURL and art.101 for NRL and are the following: **EURLs** a. Providing NRL with details and guidance on the methods (including reference methods); b. Providing reference materials; c. Organizing regular inter-laboratory comparative testing or PTs and ensuring appropriate follow-up, also informing the Commission and the MS of the results and follow-up to the inter-laboratory comparative testing or PTs; d. Coordinating practical arrangements to apply new methods, and informing NRL of advances in this field; e. Conducting training courses for staff from NRL (and from other official laboratories), as well as of experts from third countries; f. providing scientific and technical assistance to the Commission.

NRLs

a. Collaborate with the EURL, and participate in training courses and in inter-laboratory comparative tests;
b. Coordinate the activities of OL designated with a view of harmonising and improving methods;
c. Organise inter-laboratory comparative testing or proficiency tests between OL, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;
d. Ensure the dissemination to the CA and OL of information that the EURL supplies;
e. Provide scientific and technical assistance to the CA for the implementation of MANCPs and the of coordinated control plans;
f. Validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;
g. Conduct training courses for the staff of OL.

OLs

Competent Authorities may only designate as official laboratories those that operate and are assessed and accredited in accordance with the following European standards:

- EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
- EN 45002 on 'General criteria for the assessment of testing laboratories';
- EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.

From the application of the above mentioned EU standards any OL can ask for the accreditation of single or multiple trials under fixed or flexible scope.

By definition, Accreditation is the formal recognition of the competence of:

- testing and calibration laboratories
- inspection bodies
- certification bodies

It is released by Accreditation Bodies operating in accordance with Reg. (EC) 765/2008 and issuing an Accreditation Decree/ Accreditation Certificate.

Reference documents – Topic 5:

The list of refence documents for this topic has been prepared based on the following criteria:

- Update of the mandatory provisions related to sampling procedure implementation
- Update of non-mandatory documents related to sampling procedure implementation

The final selection is:

- Reg. (EC) 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs and its amendments
- Reg. (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Reg. (EU) 589/2014
- Guidance document for CA for the control of compliance with EU legislation on aflatoxins. November 2010. Available at

https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_sampling_analysis-guidance-2010_en.pdf

- Guidance document for the implementation of Commission Reg. (EU) 691/2013 of 19 July 2013 amending Reg. (EC) 152/2009 as regards methods of sampling and analysis. Standing Committee on the food chain and animal health section animal nutrition at its meeting on 16-17 June 2014. Available at https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed-guidance_documents_691_2013_en.pdf
- Guidance document for the implementation of Commission Reg. (EU) 519/2014 of 16 May 2014 amending Reg. (EC) 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in food. Available at https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_sampling_guidance-sampling-final_en.pdf
- ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories
- Reg. (EC) 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Reg. (EEC) 339/93
- Reg. (EC) 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs
- Reg. (EC) 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs and its amendments
- Reg. (EC) 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed and its amendments
- Reg. (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
- Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation. Available at https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_sampling_analysis-report_2004_en.pdf

TOPIC 6: Integration activity

Specific objectives of Topic 6:

At the end of Topic 6, participants will be able to:

- analyse an incident of contamination and develop follow-up actions
- assess the performance of a control system on contaminants and propose actions for its improvement

Module 6.1: Integration activity: contaminants from feed to food

Tutor(s): Carlo Brera
Duration: 75 min
Format: Practical activity (group work + debriefing)

Module Description
On Day 1, the group is divided in groups of 5/6 people each depending on the number of participants. Every group receives a scenario with the results of sample analysis which demonstrates real danger for public health. Every group should: • identify where the substance may have occurred (list to prepare); • analyse the reasons which may have caused the occurrence of the substance and propose follow-up actions; • analyse the existing control system and identify the measures that should have been taken to minimise / avoid the incident; • propose actions that would improve the actual control system on contaminants. At the end, there will be 30 minutes dedicated to every group presentation.

Key concepts, information and messages for this module
The recap activity will deal with one scenario relating to one of the most challenging food and feed chain. In this context, real case studies concerned by the presence of contaminants from field to fork will be duly selected and chosen for fitting the main aim of the module. Participants will be asked to tackle an emergency situation or an alert notification with the aim to find out remedies and corrective strategies for normalizing the situation. Doing this, Good Agricultural Practices, Good Storage Practices, Good Industrial Practices, Risk assessment and Risk management principles will have to be duly considered considering their role in the various steps along the agri-food chain.