BETTER TRAINING FOR SAFER FOOD

MODULES DESCRIPTION and SYLLABUS
Version: 17 July 2019

Organisation and implementation of training activities on

Animal Nutrition

under the "Better Training for Safer Food" initiative

Course 2 – EU Feed Hygiene Rules and HACCP Auditing

Contract 2016 96 04 – Phase 2

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List of abbreviations

FHR	Feed Hygiene Regulation
ABP	Animal by-products
BCP	Border Control Post
BSE	Bovine spongiform encephalopathy
CA	Competent Authority
CCP	Critical control point
DCP	Dicalcium phosphate
CN HACCP	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)
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
EU	European Union
FAMI-QS	Quality and Safety System for Specialty Feed Ingredients and their Mixtures
FBO	Food business operator
FeBO	Feed business operator
FEFAC	European Feed Manufacturers' Federation
FF	Former food
HACCP:	Hazard analysis and critical control points
ISO:	International Organization for Standardization
MANCP	Multi Annual National Control Plan
MS	Member State
NCA	National Competent Authority
PAO	Products of animal origin

PAP	Processed animal protein
PCR	Polymerase chain reaction
PCS	Private Certification Schemes
QCP	Quality Control Plan
RASFF	Rapid Alert System for Food and Feed
SRM	Specified risk material
TC	Third Country
TCP	Tricalcium phosphate
TSE	Transmissible spongiform encephalopathy
VMP	Veterinary medicinal product

Topic 1: Legal framework

Specific objectives of Topic 1:

The objective of this topic is to present the current EU legislation applicable to the animal feed domaine. The scope of the most important legal acts in the field of animal feed in the EU is explained. Special emphasis is put on General Food Law and Feed Hygiene Regulation principles. It is expected to raise the participants' awareness on the feed hygiene rules through detailed description of the legislative requirements laid down by Regulation (EC) No. 183/2005, exposing real life cases to highlight the application of legal dispositions with practical examples. The case studies are targeted to invite participants to work together and use the knowledge they were introduced to place in practice what is required from specific feed business operators.

Module 1.1 Feed law – general overview

Tutor(s): Marot Hibbey
Duration: 75 minutes
Format: Theoretical presentation + case study in working groups
Aids if any: Infographic

Module Description
• Quick intro on the EU Feed Law framework - infographic overview - The scope of the most important EU regulations in the field of animal feeding is presented, highlighting the interaction of the feed hygiene regulation into the scope of the remaining relevant applicable legislation. • Syntheses of the main requirements linked to Food Safety (General Food Law and traceability – withdrawal of products, FeBO's obligations). • Categories and characteristics of different types of feed: distinctions and borderline products. • Feed hygiene requirements (Regulation (EC) No. 183/2005 and amendments): scope, general and specific obligations, requirement at each step of the feed chain, guide to good practices, imports. Overview of the specific provisions for implementing feed hygiene at primary production level. • Overview of the specific provisions as regards to activities, other than primary production. • EU / National Guides and recommendations.
Group discussion: Application and compliance of Feed Law rules
Case studies on feed hygiene rules according to the developed activities: Presentation of 6 case studies where the application of Regulation (EC) No 183/2005 is not easy

Key concepts, information and messages for this module

Regulation 178/2002 EC (General Food Law)
The main principles of the White Paper on Food Safety were implemented by Regulation (EC) No. 178/2002. The aim of the General Food Law Regulation is to provide a framework to ensure a coherent approach in the development of food legislation. It also foresees the frame for those areas not covered by specific harmonised rules. It lays down definitions, principles and obligations

covering all stages of food/feed production, processing and placing on the market. This integrated "farm-to-fork" approach is now considered a general principle for the EU food safety policy to protect consumers' health and interest, including fair practices in food/feed trade. Meanwhile, it harmonizes general principles and requirements in order to ensure the free movement of food and feed within the EU.
Regulation (EC) No. 178/2002 shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food/feed for private domestic consumption.

Regulation (EC) No. 178/2002 lays down different procedures in matters of food/feed safety. In particular, it provides for:

- the establishment of EFSA;
- the creation of the Rapid Alert System for Food and Feed (RASFF);
- the adoption of emergency procedures;
- crisis management; Modus Operandi between MS and Commission.

The Regulation establishes the basic principle that the main responsibility for ensuring compliance with food law, and the safety of the food and feed, rests with the food and feed business operators.

Articles in Feed Law which are of importance for the understanding and future development of feed legislation are:

Article 3: definitions of feed, feed business, and feed business operator, placing on the market, risk analysis, hazard, traceability,

Article 6: Food law shall be based on risk analysis, which is further explained:

- risk assessment: scientific evidences undertaken in an independent, objective and transparent manner
- risk management: regulation and control according to the results of risk assessment
- risk communication: clear communication on existing and emerging risks

Article 7: Precautionary principle - the use of scientific advice underpins Food Safety policy, however the precautionary principle may be used where appropriate.

Article 8: Protection of consumers' interests in a way to prevent fraudulent or deceptive practices, the adulteration of food; and any other practices which may mislead the consumer.

Article 9: Transparency.

Article 11 and 12: Imported and exported feed shall comply with the relevant requirements of food law or conditions recognised by the EU to be at least equivalent thereto.

Article 15: Feed safety requirements - feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

Article 18: Traceability - the ability to trace products through the whole food chain is the key issue of the Food Law. Feed business operators including importers shall be able to identify the immediate

supplier of the product in question and the immediate subsequent recipient, with the exemption of retailers to final consumers (one step back-one step forward). Traceability of feed is further regulated in Feed Hygiene Regulation.

Article 20: Responsibilities of feed business operators (FeBOs) – they have the main responsibility on the safety of feed, for withdrawal or recall of the product suspicious to be unsafe, immediately inform the competent authorities if it considers or has reason to believe that a feed which has been placed on the market may be injurious to human health.

Product categorisation: Legislation defines different types of feed and other products, and feed can be placed on the market only under one of the established feed categories. As the legal provisions on how to place a product on the market basicly differ depending on which category the product belongs to, it is essential to properly classify the product. For that purpose the following categories are presented together with their definitions and the main caracteristics they shall meet: feed materials, feed additives, pre-mixtures of feed additives, compound feed, complementary feed, complete feed, dietetic feed, medicated feed, as well as non-feed products, such as biocides, technical products, forbidden substances and veterinary medicinal products, including medicated premixes. A decision tree is provided for an easier classification. Another decision tree helps to distinguish between products which contain one or more feed materials and one or more feed additives.

Borderline issues: Every categorisation creates questions that are susceptible to different approaches. Guidelines are provided in line with Recommendation (EC) 2011/25 which helps product categorisation for competent authority staff, as well as for operators. It is highlighted that decisions cannot be made based on only one principle; all of them shall be taken into consideration on a case-by-case basis. An evaluation is to be made, and the decisions remain in some cases still arbitrary. Decisions taken previously shall also be taken into consideration.

Regulation (EC) No. 183/2005 laid down the requirements for feed hygiene. Feed Hygiene Regulation (FHR) introduces the following main elements:

- compulsory registration of all feed business operators;
- approval of feed business establishments carrying out operations involving the more sensitive/risky substances;
- general and specific obligations for feed business operators to ensure harmonised hygiene requirements;
- application of good hygiene practice;
- introduction of the HACCP principles for FeBOs other than at primary production level;
- encouragement of the development of the EU and national guides to good practice in feed production.

Regulation (EC) No. 183/2005 applies to activities of feed business operators at all stages of the chain, from and including primary production of feed, up to and including the placing of feed into the market, feeding of food-producing animals and imports and exports of feed from and to third countries.

Regulation (EC) No. 183/2005 shall not apply to private domestic production of feed for food-producing animals kept for private domestic consumption and for animals not kept for food production. Regulation shall not apply to feeding of food-producing animals kept for private domestic

consumption or for the activities referred to in Article 1(2)(c) of Regulation (EC) No. 852/2004/EC. Feeding of animals not kept for food production and direct supply of small quantities of primary production of feed at local level by the producer to local farms for use on those farms is also excluded from the scope of the Regulation.

Small quantities: As small quantities of primary production of feed at local level by the producer to local farms for use on those farms could be excluded from the scope of regulation, MSs are requested to define "small quantities" and "local level". MSs use slightly different approaches when defining small quantities. For example, in Slovenia "small quantities" of feed made from primary products of plant origin are all quantities that a business operator delivers directly to farms as final consumers in a local area, where local area means the whole area of the Republic of Slovenia. A table is shown to the participants with examples currently available of MSs' concepts as regards the limits adopted at national level for primary production. This information will also be considered under the coming Commision Guidance Document on the implementation of certain provisions of Regulation (EC) No 183/2005 laying down requirements for feed hygiene

Primary Production of Feed is defined in Article 3(f) of Regulation (EC) No. 183/2005:

(f) 'primary production of feed' means the production of agricultural products, including in particular growing, harvesting, milking, rearing of animals (prior to their slaughter) or fishing, resulting exclusively in products which do not undergo any other operation following their harvest, collection or capture, apart from simple physical treatment"

Primary producers - farmers shall satisfy:

- general rules (Art. 4) - relevant hygiene requirements laid down in Regulation (EC) No. 183/2005, to avoid the risk for contamination of feed, animals and animal products, keeping it as low as reasonably achievable;
- specific obligations (Art. 5) – complying with the provisions in Annex I, and Annex III when feeding food-producing animals.

The same rules (Annex I) as for primary production of feed apply also to:

- transport, storage and handling of primary products at the place of production;
- transport operations to deliver primary products from the place of production to an establishment;
- mixing of feed for the exclusive requirements of their own holding without using additives or premixtures of additives, except for silage additives.

Obligations of FeBOs above primary production level: short reference is made on general hygiene prerequisites for facilities, equipment, production, quality control, accuracy tests, personnel, and the system of complaints and recalls.

Borderline between Annex I and Annex II farms: The borderline between primary producers and other feed businesses is defined in Article 5 (1) and Article 5 (2) of Regulation where primary producers shall comply with the provisions in Annex I and all other feed business operators, including mixing of feed for the exclusive requirements of their own holding when using additives or premixtures of additives with the exception of silage additives, shall comply with the provisions in Annex II.

In case of compound feed production, two elements are to be complied in order to remain within the

scope of Annex I:

- production exclusively for the needs of own farm, AND
- production without additives or premixtures (except silage additives).

If any of the two fails, then the activity belongs to Annex II. For example, a FeBO producing compound fees for marketing will be above primay production level, and as a consequence, will be an Annex II FeBO, even if it does not use additives or premixures of additives with the exception of silage additives.

To define the borderline between holdings as referred to in Annex I, and holdings of Annex II, the borderline between premixtures and complementary feedingstuffs shall be defined. Clear borderline was established with the adoption of Feed labelling Regulation (Regulation (EC) 767/2009). Borderline is defined as the maximum content of feed additives in complementary feed and in feed materials, where feed materials and complementary feed shall not contain levels of feed additives higher than 100 times the relevant fixed authorised maximum content in complete feed and 5 times in case of coccidiostats and histomonostats.

Borderline between Annex II farms with registration and Annex II farms with approval obligation is linked to the use of sensitive or risky materials. In cases of production of compound feed with coccidiostats, histomonostats and other zootechnical additives, and production of medicated feed, approval is requested, or drying of feed with the use of direct heat approval may be requested.

Guides: During the development of the Feed Hygiene Rugulation (FHR), it was decided to encourage the sectors to develop guides to good practices. The idea behind this inclusion was that operators regrouped in association have a better knowledge of their process and therefore are better supported to explain the feed hygiene requirements in detail regarding the specificities of their activities. The FHR mentions that the Commission and the Member States shall encourage the development of EU and National guides to Good Practices. This means that the competent authorities shall cooperate with the sectorial associations to develop such guides. If the guides exist, the competent authorities shall encourage the use of them. It is important to understand the relevance of those guides for the harmonization on the implementation of the feed hygiene requirements by the FeBO. The competent authorities should see those guides as a tool to improve the sanitary situation in their countries. In addition to FHR, Article 10(2)(d) of Regulation No. 882/2004 (still applicable even if repealed by 2017/625 applicable as of 14.12.2019) imposes on the competent authorities to take into account, during control activity, the use of an EU guide or a National guide established in accordance with the EU legislation by FeBO. The use of those guides is voluntary. No one may force an operator to use a guide. Therefore, they may not be used in a certification system obliging the operator to buy its incoming materials to an operator using the same guide.

FAMI-QS and FEFAC guides contain user friendly model calculations for homogeneity which can be used for premix and compound feed production. The two guides also contain user friendly description on how to measure carry-over, and how to reduce the carry-over rate.

There are also some National Guides available. The DG SANTÉ webpage allows access to all the EU and National Guides to Good Practice in the Feed domain:
(https://ec.europa.eu/food/safety/animal-feed/feed-hygiene/guides-good-practice_en)

Module 1.2 Registration and approval of feed establishments

Tutor(s): Marot Hibbey

Duration: 75 minutes

Format: Theoretical presentation + case study in working groups

Module Description
• Types of feed establishments and rules applicable to their registration, approval and/or authorisation – EU and National Guides. • COM Guidance document on the implementation of certain provisions of the feed hygiene regulation. • Food establishments vs. feed establishments. • Practical examples of activities which are out of the scope. • On-spot visit by CA and conditions for the establishment's approval. • Suspention and/or cancellation of establishments' registration or approval. • EU register of FeBOs (http://ec.europa.eu/food/food/biosafety/establishments/feed_list_en.htm.) • Highlight of critical points according to the developed activity.
Group discussion: Registration and approval of feed business establishments. During the discussion the application of COM Guidance document on the implementation of certain provisions of the feed hygiene regulation, as well as EU & National Guides will be highlighted.
Case study on registration, approval and specific authorization

Key concepts, information and messages for this module

FeBOs are to be registered or approved or given a specific authorisation according to the following pieces of legislation:

- Feed hygiene Regulation - Regulation (EC) No. 183/2005 (registration/approval)
- Animal By-products Regulation - Regulation (EC) No. 1069/2009 (registration/approval)
- TSE-Regulation – Regulation (EC) No. 999/2001 (authorisation, specific authorisation)
- Feed Marketing Regulation - Regulation (EC) No. 767/2009 (approval)
- Medicated Feed Directive 90/167/EC (new Medicated Feed Regulation No 2019/4) (approval)
- Directive 98/51/EC, Article 6 (registration of EU representatives of establishments in TCs)

The main principle is that FeBOs shall not operate without registration or approval (exception: small quantities and local level). The register shall contain all data required by the above legislation. The list of approved FeBOs shall be published.

FeBOs with the following activities are to be approved on the basis of the FHR:

- due to **dioxin risk**: processing crude vegetable oil, fat blending, manufacturing of biodiesel, oleochemical manufacturing of fatty acids;
- due to risks of sensitive chemicals: FeBOs producing, trading: antioxidant **additives** with fixed maximum limits, carotenoids and xantophils as sensory additives, all nutritional additives, all zootechnical additives, all coccidiostats;
- due to risks of sensitive chemicals: FeBOs producing, trading: **premixes** containing vitamin A or D, trace elements Cu or Se, 'other zootechnical additives', coccidiostats;

- due to risks of sensitive chemicals: FeBOs producing: **compound feed** with coccidiostats, 'other zootechnical additives';
- FHR contains references to other EU or national legislation which imposes approval obligation: FeBOs producing medicated feed, detoxification establishments and/or other national schemes (direct drying of feed).

Possible CCPs are highlighted to show where most frequently the risks may occur. Risk management tools are shown as regards homogeneity, carry-over and flushing material management, as CCPs which have the most important influence on the final product as regards chemical contamination. Best practice is shown based on national practice and on the FAMI-QS EU guide.

FeBOs with the following activities are to be approved on the basis of the Feed Marketing Regulation:

- establishments with detoxification activities of feed with exceeding levels of banned or undesireable substances (as described in Annex VIII);
- establishments producing high concentrated products (as described in Article 8.2).

FeBOs with the following activities are to be given a (special: S) authorisation (A) on the basis of the TSE regulation:

- A: production of feed for non ruminants using fish meal, DCP, TCP, blood products of non-ruminants and production of feed for aquaculture using PAP of non-ruminants as feed material;
- SA: production of compound feed containing PAP of non-ruminant origin for aquaculture animals in establishments which also produce compound feed intended for other farmed animals, except fur animals;
- SA: production of compound feed for ruminants, in establishments which also produce compound feed containing fish meal, DCP, TCP, blood products of non-ruminants, for non-ruminant farmed animals;
- SA: use and storage of compound feed containing PAP, including fish meal, derived from non-ruminants, DCP, TCP and blood products derived from non-ruminants, in farms keeping farmed animal species for which the compound feed is not intended;
- SA: production of PAP of non ruminants in processing plants processing ruminant animal by-products;
- SA: production of compound feed other than milk replacers for ruminants in establishments which also produce milk replacers containing fishmeal intended for unweaned farmed animals of the ruminant species.

FeBOs with the following activities are to be registered on the basis of the ABP Regulation:

- establishments or plants which are active at any stage of the generation, transport, handling, processing, storage, placing on the market, distribution, use or disposal of animal by-products (ABP) not intended for human consumption and derived products.

FeBOs with the following activities are to be approved on the basis of the ABP Regulation:

- processing of ABPs by pressure sterilisation, by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or by alternative methods authorised in accordance with Article 20;

- manufacturing of pet food;
- storage of derived products intended to be used as feed, excluding establishments approved or registered in accordance with FHR.

FeBOs with the following activities are to be approved based on the Directive 90/167/EEC:

- manufacturing of medicated feed.

FeBOs with the following activities are to be registered on the basis of the Directive 98/51/EC:

- representatives of establishments in TCs.

Where does the feed chain start: It is not easy to define where the feed chain starts.
When defining borderline between operators, the intended use of the material is the most important. To define the borderline between FBOs and FeBOs and other operators we can use some requirements from the FHR. Article 5 (6), for example, establishes that feed business operators and farmers **shall only source and use feed from establishments which are registered and/or approved in accordance with the Feed hygiene Regulation**. The same question is additionally clarified by Annex II, Production, point 8: *"The labelling of the products shall clearly indicate whether they are intended for feed or other purposes.* ***If the producer declares that a certain batch of a product is not intended for feed or food use, this declaration shall not be subsequently altered by an operator at a later stage of the chain".***

The practice on how these legal constraints are dealt within MSs varies between them. For that reason, and due to a high commitment on the 'circular economy' and reduction of waste, the Commission has established guidelines in order to guarantee a common approach in all MSs on the use of certain food no longer intended for human consumption, which have been recently published under Commission Notice 2018/C 133/02. These guidelines assist the national and local competent authorities and the operators in the food chain in applying the relevant Union legislation. The Commission Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 contributes to a harmonised interpretation on where the feed chain starts.

We can conclude that the producer is responsible to define the intended use of its product and that only food grade foodstuffs can be forwarded to feed without further processing *at a later stage of the chain*. In some cases very minor part of the production goes to feed!!! The feed chain starts with the producer of bio-ethanol, biogas, pharmaceutical or chemical industry, quarry, etc. In those cases, incoming materials are not of food or feed grade quality. Establishment shall be registered as FeBOs, if they have the intention to sell their product as feed, and they label it accordingly. In the opposite case, when those operators do not know that their product will somehow reach the feed branch at a later stage, they do not need to get registered as FeBOs. In this latter case the product may only reach the feed branch if a registered/approved FeBO makes the product safe for that use. Proper hazard analysis in the frame of HACCP is of the most important in defining intended use as feed grade.

In some other cases (bran, wheat bran from milling industry, sugar beat pulp from sugar industry, potato peelings from chips industry, even bread from bakery and fresh fruit and vegetable, bread, composed products, candies, biscuits from supermarkets), the chain may start in establishment that is primarily a **food business operator**. The obligation on registration depends on whether the product goes first to a former food processing FeBO, or for direct use as feed to a farmer, for

example. In the previous case the FBO in which the product originates not require registration, whereas in the latter case, it needs. Incoming raw materials enter as food grade, and therefore the rule under Article 5 (6) does not apply. HACCP principles shall be used to define the intended use as feed.

The slaughterhouse may place on the market raw pet food, dairy plant cheese whey and ABP processing plant PAPs, animal fat. In establishments as mentioned above, the feed chain begins in the food business or in an ABP-plant. Establishment shall be registered also as FeBO.

Feed mills, compound feed producers, premix producers: Feed chain begins still before the feed mill and premix production plant: any material entering the establishment shall have the status of feed, and come from supplier, who is registered as feed business operator. The rule under Article 5(6) shall apply.

Import – feed materials, feed additives: In fact, the feed chain begins with third country establishment, however, the importer is the beginning of the feed chain in the EU. Importer shall request the purchase of feed grade products from the supplier in third country (establishment). Any material that is later placed into the EU market identified as feed or is used as feed, shall be imported as feed (or food). Amendment of purpose of use shall not be permissible in a subsequent phase of distribution. Product status may be changed only through processing in an establishment of a FeBO carrying out the processing.

New concept on former foodstuffs (FF) according to the EU guidelines under Commission Notice 2018/C 133/02:

- Definition: FF from food processing and marketing;
- According to both the previous and the current version of the Waste Framework Directive, and the nation legislation based thereon, a by-product of non-animal origin that meets the cumulative criteria of the WFD (other use is lawful and certain, it is produced as an integral part of the production process, it comes from the producer not from retail activities) is not waste. On that basis wheat bran, for example, is a feed material and can be sold by the Food BO if it gets registered as a FeBO.
- According to the new version currently in force of the WFD even final products of non-animal origin originating in a retail distribution may remain out of the scope of the WFD, if among others they fall within the scope of another EU rule, like Regulation EC 767/2009. Of course, national legislation should also be taken into consideration due to the fact the WFD is a directive, and operators must pay attention if the national legislation has already adopted the new concept.
- Products of animal origin fall always in the scope of ABP regulation before they can be used as feed materials. ABP rules and TSE rules must be taken into consideration for the proper judgement on the lawful use of those products of animal origin.
- Waste cannot be marketed as feed; this is beyond question. However, was the status as waste really established through a deep evaluation of the respective legislation? In FBOs establishment the term waste is sometimes used to identify products which cannot be used as food anymore. If these products are not contaminated, they are not waste, and can be expoited as feed concerning their nutritional value;
- Food lying on the floor during processment is waste for food use, but not necessarily as a feed; Food with expired validity date: if safe can be used as feed if under the HACCP quality control scheme this is confirmed;

- Food packaging materials and labels are not informative for feed use, they are considered contamination to be removed (‚feed with excessive levels of packaging material');
- No re-labelling is needed, accompanying docs for bulk products are acceptable;
- Traceability is a permanent obligation;
- Feed materials (FM) do not need durability dates, however, if the FM is a former foodstuff which is highly perishable, new durability days may be established.

Module 1.3 FeBO control measures

Tutor(s): Marot Hibbey / Sandrine Amsler
Duration: 90 minutes
Format: Theoretical presentation + discussions
Aids if any: n.a.

Module Description
• Control measures expected by FeBO. • Current feed-ban provisions combined with the specific applicable requirements when producing, transporting, storing and using feeds containing animal byproducts (ABP) and derived products not intended for human consumption. • EU register of FeBOs applying derogations of specific conditions on feed ban.
Group discussion: How feed inspectors can do checks to verify that suppliers and clients are authorised to send/receive/use ABP/derived products.
• Quality control plan as hygiene requirement for FeBO and obligations on dioxin monitoring according to the different types of activities. • Quality control plan as requirement for FeBO to avoid and monitor unavoidable carry over residues of Veterinary Medicinal Products (VMP) in non-target feed (current and future requirements for production, placing on the market and use of medicated feed).
Group discussion: Dioxin and VMP residues monitoring.

Key concepts, information and messages for this module

The objective of this module is to give an understanding on the current feedban requirements as established by Regulation (EC) No. 999/2001 combined with the specific requirements applicable when producing, transporting, storing and using feeds containing animal by-products (ABP) and derived products not intended for human consumption, as established by Regulation (EC) No. 1069/2009, implemented by Regulation (EU) No. 142/2011, highlighting the adequate control activities to be considered at FeBO.

Introduction to TSEs: progressive, transmissible and fatal diseases caused by prions, affecting the brain and central nervous system of many animals and humans. The pathohystological picture is characterised with spongiform alterations of the brain tissue, which, at the levels of symptoms, result in i.a. wobbly movement. Prion diseases in animals: scrapie, bovine spongiform encephalopathy (BSE), chronic wasting disease, feline SE, chronic wasting disease, and in humans: nv-Creutzfeldt-Jacob disease, fatal familial insomnia.

Epidemiology of the disease: ABPs of infected animals are processed, and then used as feed materials in animal feeding. The prions are thought to move from the intestines along the nerves to reach finally the brain. It means that the industrial cycle of the use of animal protein (living animal-slaughtered animal-ABP-PAP-incorporation to feed-consumption by living farm animals) increases the prevalence of the disease.

Control possibilities: each step of the above production cycle can be attributed to an appropriate control measure: Feed can be made exempt from prions if the PAP of ruminant origin is excluded from the feed chain (removal of SRM, rendering of SRM and the whole body of the affected cattle, cohort killing, ban on intraspecies recycling, ban on recycling of ruminant protein, feed ban), and the possible recontamination ways are avoided (separation of concerned products (transport, production, storage, sampling and analysis conditions) and ban on import).

TSE roadmap: due to the smart politics on eliminating the ways of contamination, the prevalence of the disease had a vicious decrease. That means that sometimes very restrictive actions can be lifted. The current road map introduces gradually the relieved steps on the control through a revision of cohort killing actions, age limit for SRM removal, revision of the feed ban, and the obligation on rapid tests.

Feed ban as currently stipulated:

Summary of feed ban rules laid down in the TSE regulation 999/2001 annex IV (applicable as from 1 July 2017)

	Farmed animals other than fur animals			Pet and fur animals
	Ruminants	Non-ruminants (except aquaculture animals)	Aquaculture animals	
Ruminant Processed Animal Proteins (PAP)				
Non-ruminants PAP, **except blood meal**				
PAP form farmed insects (NEW as of 1 July 2017)				
Blood meal (PAP) from non-ruminants, excluding aquatic animals (= fishmeal)				
Fishmeal (PAP) (includes blood meal of aquatic animals)	In milk replacers for unweaned ruminants only		No fishmeal of farmed species X to same species X	
Blood products from non-ruminants				
Blood products from ruminants				
Hydrolysed proteins from non-ruminants and/or ruminants hides and skins				
Hydrolysed proteins other than those only derived from non-ruminants and/or ruminants hides and skins				
Gelatine and collagen from ruminants				
Gelatine and collagen from non-ruminants				
Di and tricalcium phosphate of animal origin				
Egg, egg products, milk, milk products & colostrum				
Animal proteins other than the above-mentioned ones				

Not authorised Authorised Authorised for certain types of animals

It can be clearly seen from this table that e.g.: PAPs of ruminant origin can only be used to produce feed for pets, fur or zoo animals.
The interdependance on which obligation is applicable to which type of products or labels and what

is the expected use of those products, is presented.

Interaction between feed, ABP and TSE (feed ban) legislations: The feed ban applies to the proteins of animal origin, which are described in Regulation EU 68/2013, recently amended by Regulation (EU) No. 2017/1017, as feed materials with compulsory declarations, in Regulation (EU) No. 142/2011 with compulsory processing methods and in TSE regulation with restrictions on use. e.g. **animal fat** is defined under the Catalogue of feed materials as fat of warm blooded land animals, which, according to the Regulation (EC) No. 142/2011 shall be entirely from certain subcategories of category 3 raw materials, processed according to processing method 1-7, or other method meeting the established microbiological standards, and, which is not mentioned under the feed ban provisions, meaning that this feed material can be expoited for all types of animals. Another example is processed animal protein, which, according to the catalogue of feed materials is obtained by heating, drying and grinding whole or parts of warm-blooded land animals from which the fat may have been partially extracted or physically removed, and which, according to Regulation (EC) No. 142/2011 shall come exclusively from certain subcategories of category 3 materials, processed according to processing method 1 (or, other methods referred in the table in case of different subcategories of PAPs), and the same PAP is subject also to the feedban provisions, meaning that it can be used for the purposes of the above table, and are equally subject to Annex IX of the TSE regulation which means that it can be imported to the EU if conditions set out in Annex XIV of Regulation (EC) No. 142/2011 are met. The reader is able to choose the material of the table that has to deal with, and can easily find all the provisions related to the different materials of animal origin.

Main issues that an official control of premises or vehicles dealing with protein of animal origin should cover (and include normal inspection techniques, like documentary checks, verification, physical checks: sampling and analysis):

- registration, approval, specific authorisation of establishments: this shall be controlled considering the details specified during the previous presentation;
- processing establishments: processing methods used to produce animal fat and PAP destined for feed purposes, raw materials used;
- premix producers: control of production of premixes of additives containing PAO;
- compound feed manufacturers (feed mill and homemixers): manufacturing of compound feed for (ruminant, non ruminant and aquaculture) farmed animals using derogated PAPs or other products of animal origin;
- intermediaries (others than processing plants): marketing of PAPs and animal fats;
- feed hauliers: transport of bulk PAPs, compound feed containing PAPs and animal fats;
- exploitations ruminant and mixed animal holdings;
- internal market: national and intracommunitary trade;
- import and export from and to TCs;
- identification of derogated PAO;
- establishments hygiene conditions:
    - prerequisites of feed hygiene regulation, HACCP, quality control;
    - measures against cross-contamination;
    - physical separation during production, packaging, storage and transport;
- measures of the feed ban concerning transportation unless an appropriate cleaning procedure is previously authorized by the CA:
    - feed for ruminants cannot be transported in the same vehicle which was used for the transportation in bulk of:

- PAPs from non ruminants (including fish meal);
- di/tri calcium phosphate of animal origin;
- blood products of non ruminants;
- compound feed for non ruminants containing the above three products;

  - non-ruminant farmed animals feed other than aquaculture animals in the same vehicle which was used for the transportation in bulk of;
    - PAPs from non ruminants and compound feed containing PAPs of non ruminants;
  - feed for ruminants cannot be transported in the same vehicle which was used for the transportation in bulk of:
    - milk replacers containing fishmeal for unweaned ruminants;
  - feed for farmed animals other than fur animals containing products of ruminant origin.

- labelling:
  - 'shall not be fed to ruminants': if the material contains
    - PAPs derived from non ruminants (including fishmeal);
    - blood products;
    - di/tricalcium-phosphates of animal origin;
  - 'shall not be fed to farmed animals except aquaculture animals and fur animals': if the material contains PAPs derived from non ruminants (excluding fishmeal);
  - 'shall not be fed to ruminants except unweaned ruminants' if the material contains fishmeal;
- traceability:
  - suppliers and buyers registered/approved/authorised
  - commercial documents, health certificates and traces notification of imported PAPs
  - record keeping for at least 5 years;
- farm level:
  - proper use, storage and distribution of feed;
  - disposal, use of organic fertilizers and soil improvers;
  - record keeping of each source and quantity of each imput of feed.
- sampling
  - annex I of Regulation (EC) No. 152/2009 as last amended by Regulation (EU) No. No. 691/2013;
  - size, presentation, nature, homogeneity;
- determination of constituents of animal origin in feed:
  - annex VI of Regulation (EC) No. 152/2009 as last amended by Regulation (EC) No. 51/2013;
    - microscopy - identification of morphological and histological features of animal components in feed;
    - PCR - DNA from ruminants.
- FeBO which also produces compound feed for ruminants must avoid cross-contamination through appropriate measures as follows:
  - regular sampling and analysis of compound feed for ruminants;
  - the frequency of sampling and analysis shall be determined on the basis of risk assessment carried out by the FeBO as part of its procedures (HACCP);
  - method of analysis is included in Regulation 152/2009/EC;
  - documentation must be available to the CA for 5 years;

- separation: manufacturing, storage, transport, packaging.

Total absence of unauthorised constituents of animal origin in compound feed for ruminants is to be ensured.

Quality control plan

A person responible for quality control must be designated and the operator must have acces to a laboratory with adequate capacity. This lab can be internal or external.

The quality control plan must be written, and concerns, from raw materials to final products, regular checks on products, critical points of the process, sampling procedure and frequency, and destination in case of non-compliance.

Samples must be taken from each ingredient and each batch placed on the market. There is one exception: for petfood, only samples of final products can be taken. These samples must be taken in sufficient quantity (around 500 g), identified and kept in conditions which do not lead to contamination or deterioration. Samples must be kept during a sufficient period, at least the storage life of the feed.

Dioxin monitoring

The history of dioxin contamination in feed shows that many feed materials can be a source of dioxin.

Dioxins are persistant organic pollutants (POPs) and are highly toxic to people.

They are produced mainly by incomplete combustion in human activities (incinerators) but they also exist in the natural environment. They concentrate in animal fat, accumulated as they move through the food chain. People can be exposed by contaminated food (95%).

After the dioxin crisis in Germany in 2011, Regulation 183/2005 was modified according to Regulation (EC) No. 225/2012 in order to include dioxin monitoring. This is the only compulsory own check in feed detailed described (if we except feed of animal origin). In 2015, an amendment of the above-mentioned regulation, according to Regulation (EU) No. 1095/2015, lead to precision on dioxin monitoring and new definitions.

Batch, refined oil, products derived from oils and fats, fat blending are defined in the regulation. The catalogue of feed materials (Regulation (EU) No. 68/2013 amended by Regulation (EU) No.2017/1017) was also amended in order to define some feed materials.

To supplement the HACCP system, own-checks must be carried out by some FeBOs if they place feed on the market. These analyses have to be done on incoming and outgoing products. In some cases, 100 % of the batches must be analysed, or according to the HACCP plan. A batch is no more than 1000 tons except for animal fats (5000 tons) and certain fish oils (2000 tons).

The operators which have to carry out such analysis are:

- Processors of crude vegetable oils

- Producers of animal fat
- Operators of fish oil
- Oleochemical industry
- Biodiesel industry
- Fat blending establishments
- Producers of compound feed for farm animals
- Importers

The analysis must be carried out by accredited laboratories and according to the methods of analysis established by Regulation (EC) No. 152/2009 (Annex VI as last amended by Regulation (EU) No 51/2013). The lab must inform the competent authority in case of non-compliances. There are conditions if the lab is placed in another Member State or in a third country.

There are derogations on the compulsory analysis. In particular, compound feed producers do not have to analyse the outgoing feed if the components of the batch have already been analysed and if the process does not lead to production of dioxin. It is known that process in a feed mill does not produce dioxins. Temperatures are not high enough.

Moreover, some of these operators have to be approved before placing feed on the market:

- Processors of crude vegetable oils
- Oleochemical industry
- Biodiesel industry
- Fat blending establishments

<u>Production of medicated feed:</u>

Medicated feed is an important route for administering veterinary medicinal products to animals, in particular to animals intended for food production. The new Regulation on Medicated Feed (Regulation (EU) 2019/4) aims to harmonise the production standards and marketing of medicated feed in the EU, and to reflect technical and scientific progress in this area including medicated feed for pets.

New regulation will replace the 1990's directive on the manufacture, placing on the market and use of medicated feed.

The harmonised rules will ensure that medicated feed can only be manufactured from specifically authorised veterinary medicinal products and by approved manufacturers in approved establishments.

Until now, the existing rules have been addressing the medicated feed for food producing animals, e.g. cattles, pigs or poultry. The proposed regulation includes manufacturing of medicated feed for pets, which is particularly useful for administering veterinary medicinal products to pets suffering from chronic diseases. The new rules also place a clear focus on tackling the antimicrobial resistance (AMR) through the following measures:

- prohibition the use of medicated feed for prophylaxis (preventive use) ban on medicated feed containing antimicrobial veterinary medicinal products;
- harmonised rules on prescription and use of medicated feed;

- avoidance of cross-contamination from veterinary medicines in feed.

Questions and answers related to Topic 1

Will be provided with the Second Interim Report

Topic 2: Official controls

Specific objectives of Topic 2:

The objective of this topic is to present an overview of the scope and objectives of the official control regulation, focusing on the responsibilities and obligations of the Member States and respectively National Competent Authorities. The requirements and criteria for control activities and inspectors, as well as the most suitable methods and techniques for control (inspections, documentary, physical control, sampling for analysis) are highlighted. It is intended that with the delivered knowledge, participants will be able to perform the activities in which are involved under the feed official control, using the most appropriate procedures for the expected efficacy and efficiency of the control actions. A virtual visit through 360° interactive pictures are presented for the discussion to identify what aspects of prerequisites will be necessary to investigate in order to assess the implementation of the prerequisites program in a compound feed manufaturer establishment. For deepening the knowledge on official sampling, a video on import controls demonstrating sampling is presented.

Module 2.1 Feed official controls & inspections

Tutor(s): Sandrine Amsler
Duration: 150 minutes
Format: Theoretical presentation / working groups
Aids if any: Virtual visit to a feed mill; Virtual visit to a BCP

Module Description
• Scope and objectives of the feed official control - Responsibilities and obligations of the national competent authorities. • Implementation of official controls - risk based approach. • Official controls, audits and inspections - differences. • Requirements for control activities and inspectors and guidance documents. • Methods and tools for control: inspections, documentary, physical control, sampling for analysis (official sampling methods). • Brief overview of the sampling procedure for feed official control. • Overview of the specificities of controls at primary production level.
Group discussion: How feed inspectors shall carry out checks under feed official control.
Exercise on control of the prerequisite's programs: A virtual visit through 360° interactive pictures in which one can navigate with the computer mouse. With the information obtained in the virtual tour, the participants have to identify what aspects about prerequisites are necessary to investigate/improve in order to assess the implementation of the prerequisites.
Practical exercise on checklist / support document for inspection.
• Requirements concerning imports from third countries and appropriate controls. • Third countries representatives.
Group discussion: Control activities of feed imported from third countries.

Video on import controls demonstrating import of feed and sampling procedures in a harbour. In the video, the sampling is under the responsibility of an accredited company for the purpose according to ISO 17020.

Key concepts, information and messages for this module

Feed official controls

Scope and objectives of the feed official control - Responsibilities and obligations of the national competent authorities.
Official controls are based on general requirements, operational criteria, coordination and delegation of tasks.

Official controls are carried out at any stage if the feed chain, under the "from fark to fork" approach.

They must:

- be part of MANCP;
- follow the existing feed law;
- be carried out on a risk based analysis;
- cover all FeBOs (primary producers, feed manufaturers, traders and other intermediaries;
- cover all type of feed (from feed materials to compound feed);
- cover all feed trade (EU trade, export and import of feed).

Regulation (EC) No. 882/2004 lays down the rules to be respected by MSs and the tasks of the COM with regards to the organisation and implementation of official controls. It will be replaced by Reg (EC) No. 2017/625 (after 14 December 2019). The new Regulation on official controls will repeal several regulations and amend others. It will also include plant health and ABP in its scope, in order to cover the whole agri-food chain. The transparency will be increased, there will be a common framework, the monitoring of residues will be more efficient, taking into account specificities of each MS. This new regulation will also increase cooperation between MSs.

According to the control regulation, a MANCP must be drawn up by MS, with the description of official controls, and reports must be sent annually to the Commission.

Implementation of official controls - Risk based approach.

Regulation (EC) No. 882/2004 requires that official controls are carried out by competent authorities at a frequency defined after risk analysis.

Criteria are set by this regulation:

- identified risks of feed and the use of feed;
- feed or food business operators' past record;
- the reliablity of self-checks of the operator;
- any information about potential non-compliance.

In feed, this means that CA must take into account: the weakness of HACCP plan, former results,

RASFF notification.

These criteria allow MS to identify FeBOs presenting the highest risks for public health.

Official controls, audits and inspections - differences.

Inspections and audits are part of official controls, as well as surveillance, monitoring, and analysis.

An inspection is the examination of any aspect of feed in order to verify that such aspect complies with the requirements of the feed legislation.

An audit is the systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives.

Requirements for control activities and inspectors and guidance documents.

The general rule is that official controls are carried out without warning. They are carried out at national level, intracommunitary trade and imports and exports from and to third countries.

Inspectors must be sufficient, trained, the training must be up to date. The following rules must be respected:

- Staff free from any conflict or interest;
- Staff with legal powers to carry out official controls.

Moreover, CA shall ensure the quality and consistency of official controls at all levels, respecting the following criteria:

- Effectiveness and appropriateness of official controls (internal and external audits);
- Appropriate and properly maintained facilities and equipments;
- Adequate laboratory capacity;
- Contingency plans prepared to operate in case of emergencies.

CA shall also ensure a good coordination between units of controls, at the different involved levels.

Some other requirements are set by the Regulation on official controls: transparency, suitable methods and techniques for sampling.

Methods and tools for control: inspections, documentary, physical control, sampling for analysis (official sampling methods).

Official controls must be carried out according to documented and harmonised procedures. For this purpose, checklists and guidelines can be drawn up in order to help the inspectors. These procedures must be up to date.

In Feed Hygiene, these methods allow CA to verify compliance with Annex II of Reg 183/2005.

An inspection deals with physical and documentary checks (procedures and records, labels). Official controls also check that the operator has implemented what he described in the file.

HACCP plan and implementation is a critical point to control.

A report has to be written after any inspection. This report shall include a description of the purpose of the official control, the control methods applied, the results of the official control and, where appropriate, the action that the concerned business operator should take.

A copy of the control report shall be provided to the concerned business operator, at least in case of non-compliance.

Official sampling and analysis methods are set by Regulation (EC) No. 152/2009.

For sampling, methods are described in this regulation for even or uneven substances, with the establishment of the number of incremental, global and final sample. The final sample is sent to the lab. In case of uneven distribution, the number of incremental samples has to be multiplied by 2.5.

In 2013, Regulation (EC) No. 691/2013 which amended Annex I of Regulation (EC) No. 152/2009 gave instructions for the sampling of large lots and for sampling on a farm.

If no official methods exist, methods of analysis must be recognised by international organisations (CEN or ISO) or other methods fitting the intended purpose or developed in accordance with scientific protocols that have been, as far as possible, validated.

Laboratories involved in the analysis of official samples shall be assessed and accredited in accordance with EN ISO/IEC 17025.

Overview of the specificities of controls at primary production level.

The purpose of inspections at primary production level is to verify how the operator meets the requirements of Regulation (EC) No. 183/2005.

Requirements of Annex I of this Regulation are consistent with those of Annex I of Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.

Some requirements for primary production are also provided by Annex III Regulation (EC) No. 183/2005 when feeding food-producing animals.

Third countries representatives.

There is a requirement in Regulation (EC) No. 183/2005 about the feed imported from third countries with a list of establishments and of third countries.

But as such lists do not yet exist for feed of non animal origin, transitionary measures are in place in MS. Thus, imports continue to be authorised under the former system foreseen by Article 6 of Directive 98/51/EC under the following conditions:

- National representative – ‘Gatekeeper’. Each MS sets rules for these gatekeepers.
- FeBO declares that the Third Country-Establishment complies with the EU legislation.
- FeBO keeps a register of the imported products.

These transitionary measures are related to some additives (anti-oxidants with maximum limit, carotenoids and xanthohylls, all nutritional additives, all zootechnical additives, coccidiostats and histomonostats), premixtures of additives containing vit A or D, Copper or Selenium, category 4d zootechnical additives, coccidiostats and histomonostats) and compound feed containing coccidiostats and histomonostats and category 4d zootechnical additives.

Requirements concerning imports from third countries and appropriate controls.

Similar to the feed produced in the EU, feed imported from third countries must be safe and wholesome. Official controls must then be carried out on feed imported from third countries.

Regulations (EC) No. 178/2002 and 183/2005 require controls on imported feed both of animal origin and non animal origin. Regulation (EC) No. 882/2004 establishes harmonised procedures for official controls on imported feed. There is a complementarity between controls on import of feed of animal origin and those on feed of non animal origin.

MS shall designate control post or particular points of entry in their territory which have access to the appropriate control facilities for different types of feed. There are EP (Entry Points), DPE (Designated Point of Entry) for feed of non animal origin and BCP (Border Control Post) for feed of animal origin.

Prior notification can be necessary, as well as the use of TRACES. The documents in use are CED (Common Entry Document) or CVED (Common Veterinary Entry Document).

Actions in case of non-compliance are also indicated in the general legislation, as well as what has to be done in case feed is placed on the market in another MS than the one where the control was carried out. European legislation provides a model of such a document which shall accompany the feed (annex A of Commission Directive 98/68/EC).

Feed of non-animal origin shall be subjected to regular official controls at the point of entry, on the basis of the multi-annual national control plan and in the light of potential risks. The controls shall cover all aspects of feed law, with regular checks or increased checks (according to Regulation (EC) No. 669/2009):

- Systematic documentary checks;
- Random identity checks;
- Appropriate physical checks, at a frequency based on criteria (Regulation (EC) No 882/2004).

CA has to increase the official controls on risky products, which are listed in Annex I of Regulation (EC) No. 669/2009:

- Systematic documentary check;
- Increased level of identity and physical checks (chemical and microbiological hazards) according to the known or emerging risk of the product.

In this case, the release for circulation can only occur after favourable results from analysis.
Regular reports are sent to the Commission.

For feed of animal origin, veterinary checks carried out at BCP, as required by Directive 97/78/EC

and Regulation (EC) No. 136/2004.

General conditions for import of feed of animal origin are set in Regulation (EC) No. 1069/2009 implemented by Regulation (EU) No. 142/2011.

Specific requirements are found in Regulation (EC) No. 999/2001 and (EU) No.142/2011.

In both cases, emergency measures can be adopted by the Commission in order to protect public health, animal health or the environment if internal measures are not sufficient to contain the risk. For example, feed from Japan must follow the levels of radionuclides stated in Regulation (EC) No. 2016/6 (last amended in 2017).

Concerning the frequency for physical control based on risk analysis, specific rules on imports and data from RASFF are also referred to.

Questions and answers related to Topic 2

Will be provided with the Second Interim Report

Topic 3: Feed safety management systems and HACCP implementation

Specific objectives of Topic 3:

The objective of this topic is to give a basic knowledge on good hygiene and safety issues on feed sector, namely the application of HACCP system in feed production, taking into account the principles contained in 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, the Codex Alimentarius and ISO standards, but allowing sufficient flexibility for all situations. Participants are acquainted with the main parameters of the HACCP in a feed plant, through theoretical approach and practical examples. Participants gain an insight into HACCP system of the feed plant and will be able to apply gained knowledge for the evaluation of HACCP plans during official control. Also cross contaminantion and homogeneity evaluation in a compound feed establishment is covered in order to ensure the production of safe and merchantable quality feed. Topic 3 also contains a video on private quality assurance schemes, where interaction between feed official control under the responsibility of Competent Authorities and such schemes is explained.

Module 3.1 Implementation and evaluation of HACCP in the feed sector

Tutor(s): Gino Cecchini
Duration: 90 minutes
Format: Theoretical presentation + discussion

Module Description
• Introduction to HACCP methodology and principles - 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. • Application of each step and principle to a feed mill: - Prerequisites programme - Hazard analysis - risk assessment - Reference to the more common risks in a FeBO establishment, including physical, chemical and biological associated with in-coming feed ingredients (classic and emerging ones, such as former foodstuffs and other new sources of proteins) and under different steps of the production process. - Critical control points determination (Codex Alimentarius decision tree) - Control measures and levels - Responsibilities • Evaluation of a HACCP plan in a feed mill - Verification concerning compliance, cleaning and/or sanitation controls, hazard analysis, prerequisites, HACCP plan, corrective actions, verifications, records, training, checklists.
Group discussion: HACCP methodology and its implementation by the FeBOs

Key concepts, information and messages for this module

The presentation explains how to understand the main parameters of the HACCP in a feed mill through a theoretical approach with practical examples and photos.

The main objective is to gain a practical insight into HACCP in the feed mill and to be able, with the aid of further material, to work in the setting up and evaluating of such a plan.
HACCP is a process control system relating to feed and food safety, which may be set up and applied in combination with other quality systems. It is a legal requirement in food and feed businesses, except for primary production.

The HACCP plan consists of the following phases and principles:

- Phase 1: Form HACCP team and validation team
- Phase 2: Description of products
- Phase 3: Record intended use
- Phase 4: Determine process information
- Phase 5: Test process information
- Phase 6: Define prerequisite program
- Phase 7: Principle 1 Hazard analysis (based on probability x seriousness)
- Phase 8: Principle 2 Determine Critical Control Points and control measures
- Phase 9: Principle 3 Determine standards for CCPs
- Phase 10: Principle 4 Monitoring CCPs
- Phase 11: Principle 5 Define corrective measures
- Phase 12: Principle 6 Validation and verification of HACCP plan
- Phase 13: Principle 7 Documentation and registration of HACCP plan

In the presentation each of these steps are covered in detail, with practical expamples, situations and charts taken directly from a feed-mill environment.

Specific sector Guidelines are shown, incuding the websites where such material can be downloaded.

Flexibility measures for the food sector according to Commission Notice 2016/C 278/1 are refered, as well as Codex compliant alternative approaches.

Conclusions state that HACCP, if kept relatively simple, properly applied and implemented, can be a very useful tool.

The presentation continues with the evaluation of a HACCP plan.

The topic has an initial overview of the theoretical aspects, basically the standard layout of the HACCP plan but then ventures into the reality of a producing feed mill with hand on examples.

Those who receive this module understand what is needed to verify, check and test HACCP before the auditing exercise. In detail, when verifying a HACCP system in a feed mill there is a need to get involved both in paperwork, as well as into the feed-mill to verify, through scoring forms if:

1. requirements are met;
2. corrective actions are required;

3. components of the prerequisites programme or HACCP plan are incomplete;
4. provide written comments and corrective actions.

In the presentation each of these steps is covered in detail, with practical examples, situations and modules related to the feed-mill.

Module 3.2 HACCP as a management tool

Tutor(s):	Gino Cecchini
Duration:	60 minutes
Format:	Working groups

Module Description
Examples and practical activity related to specific aspects such as: management of incoming feed ingredients, Standard Operating Procedures, decision making under ongoing operations and chain of responsibility, cut off points, feed ingredients contracts and characteristics, storage of ingredients.

Key concepts, information and messages for this module

HACCP in the feed mill cannot only be a theoretical book, kept in some office at the factory permises. This session looks into a few very practical aspects related to mould and toxin build up in cereals and its implications for the feed manufacturer. It is a very practical session which requires interaction, proposals with real answers from the participants. The objective is to sensitize on one of the many practical situations encountered in the day to day activity of a feed mill which has important consequences, if not properly managed, on the quality and safety of feeds. Prior to the practical exercise information is provided on the health and economical impact of moulds on animals. It shows that there are tangible drawbacks which can affect human, animal health and are of economical importance to the feed mill showing the loss of nutritional values and animal performance resulting from feeding mouldy grains. During storage of grains in silos how we can mitigate the onset and growth of moulds knowing the comfort range for a number of moulds.

The practical exercise requires the participants to act as a feed mill manager and decide on a strategic plan providing practical, workable answers for incoming bulk ingredient such as maize for considering the existing limitations in the standard national grain contracts.

Contracts & Suppliers
Maize specifications with critical and rejection limits
SOP for the workers at the point of discharge
Monitoring schedule for Maize
Training for workers, Hazard and Protective gear which is required by worker
Defining: What is/are the Point of Attention and /or Critical Point to be controlled?
Where does the sampling and monitoring take place?
What equipment is needed?
What training is needed?
Do we have values for non conformity and rejection limits?
What are the minimum and maximum ranges and values for Maize?

What are the actions to be taken?
Who is in charge and for what?
If rejection limits are reached when a decision is taken, who is responsible for the costs?
Record keeping.

At the end of the exercise a number of procedures are outlined which include:

1- Training of workforce
2- SOP in dealing with borderline situations
3- Physical facilities to deal with and solve a problem under pressure, (for example are there extra silos for stand by products?)
4- Authorization to make decisions: one way or the other any decision will have a cost
5- Written records for full traceability

And the solutions are linked to the HACCP plan for:

- Standard Operating procedures
- Rejection limits and action limits
- Organogram, line of responsibility
- Infrastructure and equipment
- Monitoring plan for Quality Control

Training (knowledge of equipment, corrective actions and appropriate decision making)

Module 3.3 Cross-contamination

Tutor(s):	Gino Cecchini
Duration:	60 minutes
Format:	Theoretical presentation

Module Description
• Cross contamination and carry over: problems and solutions. • Legal requirements for conducting cross contamination and homogeneity tests. • Guidances on homogeneity and cross contamination – EU / National Guides and recommendations. • Methodologies and evaluation of the results.
Group discussion: The most suitable tests for homogeneity and cross contamination evaluation.

Key concepts, information and messages for this module

The module covers real problems and practical examples, presenting common practices and potential solutions.

The main objective is to get the audience to know how a feed mill works, the logics and where point of attention or critical points are located and know where to look when non-conformities occur.

Cross contamination and carry-over between production batches are inevitable in the feed mill as shown in a number of studies (own checks at feedmill level, BEMEFA Study, Belgium etc).

That is why, if we want to minimize such risks, we need to familiarize ourselves with the feed mill characteristics, its key equipment and the production line system and sequences.

Overview of the production plant and description with photos of the main equipment which can be potentially involved in carry over and heterogeneity of feeds:

- Hammer mill
- Mixer/Microdosage/Transport systems and conveyors
- Pelletizer/Crumbler
- Coolers
- Compressed air system
- Dust extraction system
- Timers on shutters, conveyors & elevators
- Bins

The presentation provides practical insight on how to check if mixing is homogeneous and to assess carry over with the use of tracers using the Guidelines adopted at some MSs level and providing published data from reputable international bibliography such an reference journals and Feedstuffs magazine, with practical suggestions:

- The tracer should be contributed from only one source
- The tracer should be a micro-ingredient
- It should be quantified through a quick analytical procedure
- The analytical procedure should be inexpensive
- One should be able to interpret results objectively

When managing production some procedures can make a difference:

- Consider a choice of additives (powder, granular, coated, and electrostatic)
- Avoid electrostatic active ingredients
- Flush mixers and lines and pellet mills where drugs/species are not compatible
- Dedicated storage bins for medicated feeds
- Group like animal species (compatible drugs)
- Sequence properly production

Sequencing procedure for medicated feed production can help under the following scheme: producing first high dosage, then low dosage, or high concentration/long withdrawal to low concentration/no withdrawal then flush out then a grower and only at the end a finisher, dairy or layer feed can represent valid guidelines to minimize risks.

And summarising, practical suggestions are provided to the audience:

- ✓ Group all medicated productions
- ✓ Produce high dosage inclusion first then low dosage
- ✓ Flush at end of medicated production
- ✓ Flush material into medicated flush bin
- ✓ Produce first for other animals than dairy cows/finishers/layers
- ✓ Conduct regular tests for medicated residue level in non-medicated feeds

Correct and adjust this CCP, if necessary.

Guidances on homogeneity and cross contamination

A high level of manufacturing and mixing accuracy in mixing and/or production facilities is a precondition for ensuring the safety of animal feed, e.g. with respect to the maximum levels of feed additives laid down by law and the correctness of the information provided by business operators for feed labelling.

Annex II Section Facilities and Equipment point 2(b) and point 3(b) of FHR sets requirements for manufacturing and mixing accuracy:

> 2(b) Minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products…
>
> 3(b) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.

Certain Member States developed guidance documents to facilitate control on assessment of appropriatness of homogeneity and cross-contamination procedures implemented by FeBO. Currently a discussion is going on at SCoPAFF level for the adoption of a Guidance document for the evaluation of homogeneity of feed and the carry-over of undesirable substances.

Module 3.4 Private schemes

Tutor(s): Jose Costa / Snieguole Dzekcioriene
Duration: 75 minutes
Format: Theoretical presentation + video module + discussion
Aids if any: Video on private schemes

Module Description
• Quick introduction on private quality schemes applicable to the feed sector and examples: interaction with official controls - advantages and disadvantages. • Reference to Commission Communication – EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuff and European Court of Auditors Press Release on EU food safety system.
Group discussion: The applicability of PCS at national level.
Video module related to private certification schemes, links with legal requirement and contribution to harmonization of feed safety and international trade. Practical examples.

Key concepts, information and messages for this module

The objective of this task is to present / discuss interaction between Private Certification Schemes (PCS) and official control under the responsibility of the National Competent Authorities (NCA). It is intended to highlight the best examples of such interaction, and to discuss their advantages and disadvantages, as well as to consider the adequate legal framework.

PCS require operators to put in place their own quality control and sampling plans, besides introducing checks to assert the fulfillement of certain legal requirements. As such, PCS have the potential to complement or support elements of the system of official controls carried out by NCA in the feed sector, although the extent to which MS have explored or exploited this potential varies considerably.

Notwithstanding the fact, that private standards for certification of quality schemes are adopted in several MS, other MS may not be so familiar with such standards and their interaction with NCA. Therefore a video module related to private certification schemes (OVOCOM) is presented during this topic. The video includes objectives and structure of the standard, responsibilities in the area of feed safety, integration of legal requirements to the standard, certification and auditing of FeBO, cooperation with NCA, benefits and challengers of this cooperation.
This presentation is also intended to facilitate an exchange of experience between participants from different MS.

However, there are still outstanding questions and hesitations regarding the interaction between NCA and PCS:

- Verification/validation/recognition of scheme/standard by the national competent authority (NCA) concerning legal requirements (possibility of certification/auditing system by/with NCA; what would be the role of NCA on the validation/recognition of PCS in order to make it profitable as a complement of feed official control and compliance with relevant legal requirements).
- Verification/validation/recognition of the appropriateness of audit tools (check-lists, reports and guidelines), modalities, frequencies and duration of audits (unannounced inspections), auditor's qualifications and trainings, scope of certification (all legal requirements included?) (possibility of certification/auditing system by/with NCA; what would be the role of NCA on the validation/recognition in order to make it profitable as a complement of feed official control and compliance with relevant legal requirements).
- Competence, independence and impartiality of Certification Bodies (certified by a National Certification Body?), recognition by NCA.
- Supervision of auditor's and Certification Bodies performances (by whom and how?). Obligation for the National Certification Body to include auditors from NCA in order to be involved in the audit/certification scheme?
- Communication between NCA and PCS: channels, confidentiality, results of the audits, sanctions/follow-up measures. Interaction between NCA and PCS, when official control highlights repeated non-compliances with the applicable legislation.
- Appropriateness of PCS sampling plans regarding scope, statistical methodology, sampling method, requirements for laboratories (accreditation, validation of methods, methods parameters), their equivalence with the requirements applied in official control. Communication of sampling results to NCA.
- Legal recognition of PCS as valid for the purpose of complementarity with official control according national and/or EU legislation. Possibility of EU guidelines for the delegation of certain official control task to PCS, although under specific criteria/requirements.

Questions and answers related to Topic 3

Will be provided with the Second Interim Report

Topic 4: Application in the feed industry: field visit

Specific objectives of Topic 4:

The objective of this topic is to provide practical possibility for the participants to perform an audit of a real feed business operator establishment. Participants are able to assess the implementation of the legal requirements by feed business operator, to discuss about difficulties faced by FeBOs and solutions found for rectifying some situations. For the field visit participants are divided in several groups and have the possibility to discuss between themselves on the different aspects during the audit and during the evaluation of audit results. A follow-up discussion also gives a possibility to evaluate audit approaches used by different MSs and best practices which could be used.

Module 4.1 Field visit preparation

Tutor(s): Jose Costa / Snieguole Dzekcioriene
Duration: 30 minutes
Format: Theoretical presentation + working groups

Module Description
• Specific documentation of the company. • Specific national guidelines (if applicable). • Goals and expectations of the visit. • Logistical organisation. Preparation in small groups based on the documentation: gathering information, identification of precise questions and preparation of a brief guide to the visit.

Key concepts, information and messages for this module

The objective of this module is to prepare participants for the field visit in order to make the field visit effective and efficient as much as possible. Therefore, it is important to deliver information that allows participants to understand the plant production to be visited, as well as to recognize the main points for attention as inspectors in order to effectively identify non-conformities and/or constrains on the implementation of the applicable legal requirements. Participants are divided in several groups for the audit of a compound feed manufacturer plant. Besides some references on the most important feed hygiene requirements, the recognition of a compound feed line production and the points of attention for homogeneity and cross contamination, participants are also acquainted with the goals and tasks of the field visit, highlighting the most important steps to ensure feed safety in a line production. Specific information/documentation about the FeBO is presented (including type of FeBO, type of feed manufatured and production chracterisation, such as the targeted animals envisaged, type of additives used, feed materials used on the compound feed compostion, amount of production, technological characteristics of the production line and mixer, etc.) and specific national guidelines applicable by FeBO are discussed (if any). Working groups are asked to prepare themselves for the visit: study all relevant information/documents, prepare detailed questions for the audit. Logistical information is also presented prior to the visit.

Module 4.2 Field visit

Tutor(s):	Jose Costa / Snieguole Dzekcioriene
Duration:	240 minutes
Format:	Field visit

Module Description
Visit to a feed mill (compound feed manufacturer or premixes producer): • Presentation of the company, feed hygiene requirements implementation, potential restrictive points the FeBO faced in the past to comply with the legal provisions and how they were resolved. • Participants perform an "audit" of the plan and gather information in order to answer their questions. • Quick debriefing between sub-groups (exchange of observations). • Additional questions and closing of the field visit.

Key concepts, information and messages for this module

The objective of this module is to perform practical training on an audit to a compound feed manufacturer or premixes producer. During the audit, participants have to evaluate how requirements of Regulation (EC) No. 183/2005, or any other relevant, are implemented by FeBO.

During the field visit the FeBO gives a short presentation about the company, layout of the production line, feed hygiene requirements implementation, main aspects of HACCP plan implemented, problems faced by the company in the past and solutions used to rectify the situation.

After a technical and organizational presentation from the quality manager of the compound feed manufacturer, participants are divided in 2 groups for the visit of the plant.

Participants have to identify potential weaknesses of the FeBO, bearing in mind different aspects about FeBO characteristics (activity, type of feed produced, type of ingredients used, type of targeted animals, technical details about equipment and facilities, etc), afterwards they have the possibility to check in reality (by visual examination or by asking questions) how these potential weaknesses are managed by the FeBO. During the visit participants have the opportunity to raise specific technical questions of the production line and to understand eventual weak points on the legal dispositions compliance.

After the visit, there is a possibility for participants to ask additional questions to the company on their findings/observations.

According to the FeBO's presentation and the outcome of the visit, participants have to check the FeBO's compliance with the hygiene provisions of Annex II of Regulation (EC) No. 183/2005.

Module 4.3 Field visit debriefing

Tutor(s):	Jose Costa / Snieguole Dzekcioriene
Duration:	30 minutes
Format:	Working groups

Module Description
Closing of the field visit: • Discussion on difficulties and constraints encountered during the visit. • Syntheses of the answer they have and the subject they would like to deepen. • Reporting to the group and conclusions.

Key concepts, information and messages for this module

The objective of this task is to discuss the findings during the field visit, to clarify/explain remaining issues for participants, and to share practices for the performance of audits by inspectors of different MS.

Discussion on the findings and conclusion of the audit, summarizing of main aspects found and remaining questions are presented in a plenary session. Live discussion is expected, which facilitates exchange of practices between participants from different MS, and consequently the harmonization of control procedures to be adopted at EU level.

Questions and answers related to Topic 4

Will be provided with the Second Interim Report

Topic 5: Microbiological risk and control

Specific objectives of Topic 5:

The objective of this topic is to give theoretical background on microbiological contaminants issues, as well as the practical knowledge on how to manage the microbiological risk reduction and control system in the feed industry. The participants get a view on which management tools are available to the feed business operators for that purpose. Since, there are no established specific microbiological criteria at EU level, overview of feed microbiological criteria adopted by MSs at national level is discussed.

Module 5.1 Microbiological risk, criteria and controls

Tutor(s): Franck Brasseur
Duration: 60 minutes
Format: Theoretical presentation + practical exercise

Module Description
• Microbiological risk in feed production. • Sampling for control of microorganism. • Assessment of analytical results: positive / negative results and possible actions. • FeBO's common mistakes as regards HACCP implementation on microbiological risks. • Overview of feed microbiological criteria adopted by EU MS at national level.
Group discussion: Microbiological criteria at FeBO level.
Practical exercise related to the control of the HACCP implementation regarding salmonella

Key concepts, information and messages for this module

Article 15 in Regulation (EC) No. 178/2002 clarifies that feed shall "not be placed on the market or fed to any food producing animal if it is unsafe", i.e. "have an adverse effect on human or animal health or make the food derived from food-producing animals unsafe for human consumption.

The Regulation covers biological hazards, i.e. "hazard means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect".

Article 4 of Regulation (EC) No. 767/2009 further clarifies that "feed may only be placed on the market and used if:

(a) it is safe; and
(b) it does not have a direct adverse effect on the environment or animal welfare".

The marketing Regulation further declares that "the requirements set out in Article 15 of Regulation (EC) No. 178/2002 shall apply, mutatis mutandis, to feed for non-food producing animals".

The hygiene Regulation (EC) No. 183/2005 further stipulates that as a complement to the feed hygiene requirements, the Commission could set a common approach to microbial criteria. For the moment, no such approach has been taken concerning feed in light of the ongoing work by the

stakeholders to introduce a guide to good practice covering microbial criteria. However, microbiological criteria have been established for compound feed and non-animal origin feed materials in some MSs.

Futhermore, microbiological criteria are established for animal by-products and products derived from animal origin to be produced and marketed as feed materials or petfood, according to Annex X and XIII of Regulation (EU) No.142/2011.
The hygiene Regulation also requires that the feed business operators (except in primary production) shall "put in place, implement and maintain, a permanent written procedure or procedures based on the HACCP principles", i.e. the approach to handle microbial contamination shall be covered in the GMP/GHP (Good Manufacturing/Hygiene Practice) set out in the Regulation and in the HACCP-system.

Feed producing facilities presents good conditions for growth of microorganisms, such as Salmonella, i.e. nutrients, temperature, pH, water/water activity. But these conditions can also be used to restrict introduction, survival and growth of the microorganisms. It should be noted that Salmonella is an environmental microorganism and all feed materials pose a risk for introduction in the facilities. Together with other routes of Salmonella into the feed facilities (ex. personnel, pests, dust), in time all facilities will have an infection. The aim of the Salmonella program is to find Salmonella and take action to avoid that Salmonella or other microorganisms end up in the feed or in food products.

Questions and answers related to Topic 5

Will be provided with the Second Interim Report

Topic 6: The audit process

Specific objectives of Topic 6:

The objective of this topic is to give an overview of the legal and basic requirements for an auditor, with practical considerations for the preparation of an audit to a feed business operator, audit techniques and methods, performance of an audit, reporting of audit results and follow-up activities. The requirement for a risk-based approach is foreseen at EU level. However, no detailed requirements for the audits are given and the main publications on HACCP are focused on the construction and development of an HACCP-system. Therefore, this topic also highlights the evaluation of a HACCP plan during an audit to a feed business operator. An audit simulation is organized in order to allow participants to conduct an audit to a feed business operator and acquire required skills (or deepen their experience) for the auditing.

Module 6.1 Principles of an audit

Tutor(s): Franck Brasseur

Duration: 60 minutes

Format: Theoretical presentation + exercise

Module Description
Preparing the audit: planning, background and former audits results, documentation review and identification of high risk areas. Audit techniques and methods: • Stages of an audit, objective evidences, questioning techniques and record of information. • Reporting. Contents and quality of an audit report. Non-conformity categories and reporting. • Follow up activities.
Group discussion: Audits as feed official control technique
Practical exercises /questions related to the identification of risks

Key concepts, information and messages for this module

Details for official control are regulated by Regulation (EC) No. 882/2004 where it is stated that the official controls shall be proportional to the risk and previous experience of the feed business operator. It also states that the control should cover GMP (Good Manufacturing Practice), GHP (Good Hygiene Practice) and HACCP (Hazard Analysis and Critical Control Points).

Regulation (EC) No. 183/2005 (feed) and (EC) No. 1069/2009 (animal by-products) further state that it is the feed operators' responsibility to build their feed activities on GMP and HACCP. Regulation (EC) No. 183/2005 also underlines the need for flexibility. Feed legislation gives the responsibility for a safe feed production on the feed business operators and requires a commitment to the task to fulfil the GMP/prerequisite requirements and HACCP.

The GMP or the prerequisites are given in further details in the annexes of Regulation (EC) No. 183/2005 (I & III for the primary production and II for the others). The annexes cover:

- facilities and equipment;
- hygiene provisions;
- personnel;
- production;
- quality control;
- dioxin monitoring;
- storage and transport;
- record-keeping;
- complaints;
- product recall;
- good animal feeding practice (primary production).

With the national control program in place and the frequency of the established control, control plans for longer or shorter periods can be established and the focus can be moved to the audits of groups or single establishments.

The purpose of on-site assessment is to verify by auditing that the legal requirements are fulfilled and confirm that the procedures and practices described in the risk management system (GMP/prerequisites and HACCP) are implemented and maintained to guarantee safe feed products.

When/if discrepancies are noted, the evidence for non-compliances i.e. notes, copies of records, photos, etc. should be secured. In normal situations this documentation will not be used further, the company will accept the comments and take action, but it is not unusual that the auditor's remarks are challenged, and in these situations the gathered evidence can be crucial for future legal actions.

It is crucial that the auditor acts professionally and independently. The auditor shall not be biased by any relations that may influence any judgment, including gifts or other favours. The auditor shall be well trained/experienced in the field and updated on changes in legislation or what is "going on" in the field, i.e. keep their knowledge and practical touch "up to date".

The initial meeting gives the auditor the opportunity to present the legal basis for the control, the scope of the control and the planned steps of the audit i.e. initial meeting, walking the line, time for the auditor's consideration and conclusion, followed by a closing meeting. Information should be given concerning when a written report can be expected and the timeframe for the companies' expected actions on the report.

It is appropriate at the initial meeting to conduct documentary control of procedures that normally are not easily achieved or examined when walking the line. Time should be devoted on each question, and each question should be repeated in a different way to give a clear picture (why, who, when, how, frequencies, records, verification procedures, etc.)

Before assessing the production line, internal rules should be checked concerning walking routes,

hygiene precaution actions, protection gear, etc. The need to follow a clean to dirty route should be stressed, i.e. normally backwards along the production line to minimise the risk of microbial contamination.

In a compound feed establishment, there are normally a limited number of CCPs (if any) and it is possible to examine them in detail, i.e. why they are selected as CCPs, control measures, limits and monitoring.

This is a crucial step and it is worth spending some extra time considering corrective actions, validation and verification on both CPs and CCPs. It should be spoken to the operators and their practice should be compared with the requirements in the HACCP plan and written procedures.

Duting the conclusions, the auditor or the audit team should devote time to examine the gathered information, observe actions and prepare an oral presentation of the findings.

One of the more difficult and subtle tasks is to verify the management's understanding and commitments to follow the HACCP principles. Without this understanding and commitment, HACCP will stand on an unstable ground and the whole risk management can be disputed. The findings and impressions from the whole audit are part of this judgment, i.e. the:

- composition of the HACCP team (do they have the authority to enforce the HACCP plan);
- level of feed hygiene training and its application;
- technical knowledge within or available to the company;
- existence of satisfactory documented procedures and food safety management systems (and the practical use of them);
- compliance history of the establishment.

During the closing meeting, the findings should be presented - both what is positive and any remarks, which will later be part of the written reports. If there are any doubts on any specific point, or if the auditor(s) need to further assess any details before a conclusion, they should inform the company and explain that the outcome of this assessment will be presented at a later stage. If possible, a date should be given. Time should be provided to the company to respond and correct possible misunderstandings.

The company should be informed when the written report would be available and when the expected actions are to be taken by the company, i.e. latest date for a formal appeal on the report, when any remarks should be adjusted or a latest date for any action plan depending on the national administrative processes.

The report shall be given in compliance with the timeframe given to the company with clear information of the audit without any new surprises/remarks compared to the oral presentation given at the on-site closing meeting. The outcome of the audit should be written in a clear language, i.e. remarks and recommendations. The timeframe(s) should be repeated. It should be noted that the report shall give a clear message about what needs to be corrected, but it is the feed operators' responsibility to decide how the corrections shall be made.

After a series of audits, it is necessary to evaluate the outcome. The important things to consider are: "Was everything as expected or did any systematic discrepancies occur that may influence

coming audits, and/or is it necessary to prepare any additional information to the feed business operators?" Depending on the local risk and experience system, the audit(s) may influence the classification on the actual establishment and by those coming audit frequencies.

Module 6.2 Audit simulation of an auto-control system

Tutor(s): Franck Brasseur
Duration: 135 minutes
Format: Role play + working groups

Module Description
In this role-play, the tutor acts as Quality Manager of a FeBO and participants as control officers. Pictures, data and support documents of a feed business are available for evaluation. A documentary and "on site" audit is simulated. Each working group documents, reports and discuss any non-compliances they identified regarding hygiene, HACCP and/or traceability requirements and formulates audit conclusions.

Key concepts, information and messages for this module

Working groups have the task to perform an audit of the following feed business operators:

- feed business operator producing lineseed oil cakes;
- feed business operator producing compound feed using additives;
- feed business operator producing compound feed with the special emphasis on sampling plan;
- feed business operator producing compound feed with the special emphasis on hygiene requirements;
- feed business operator with the special emphasis on risk analysis performed by FBO.

During discussions following shall be evaluated:

What information is needed for the performance of an audit;
What documents are needed for the preparation of the audit;
Cross-contamination procedure for FeBO using feed additives;
Sampling plan and sampling reports of FeBO;
Risk analysis performed by FeBO;
Preparation of relevant questions which need to be given to the FeBO;
Preparation of audit conclusions.

Module 6.3 Discussion on flexibility

Tutor(s): Franck Brasseur
Duration: 15 minutes
Format: Discussion

Module Description

Examples of flexibility provisions, their implementation by FeBOs and the specificities or difficulties encountered during the controls.

Key concepts, information and messages for this module

Regulation (EC) No. 183/2005 (feed) and (EC) No. 1069/2009 (animal by-products) state that it is the feed operators' responsibility to build their feed activities on GMP and HACCP. Regulation (EC) No. 183/2005 also underlines the need for flexibility.

A guide was published by the Commission in November 2005 on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of HACCP principles in certain food businesses establishments. The guide emphasises the need for flexibility when HACCP principles are implemented at food business operators.

The guide states that:

- In certain cases it can be presumed that, due to the nature of the food business and the food that is handled by it, possible hazards can be controlled by implementing the prerequisite requirements. In such cases, a formal hazard analysis is not needed. It should be recommended that for such food businesses guides to good practice are established.
- In certain cases, the hazard analysis may demonstrate that all food hazards can be controlled by the implementation of the prerequisite food hygiene requirements.
- For certain categories of food businesses it may be possible to predetermine hazards that need to be controlled. Guidance on such hazards and on the control thereof can be addressed in a generic HACCP guide.

From the requirements listed it is clear that the national authorities need a system to handle risk and experience to focus the control and facilitate the control frequency. However, these guidlines are not aplicable to feed business operators.

Questions and answers related to Topic 6

Will be provided with the Second Interim Report

REFERENCE DOCUMENTS

1	**Regulation (EC) No. 178/2002** 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 ammendments
2	**Regulation (EC) No. 183/2005** of 12 January 2005 laying down requirements for feed hygiene and ammendments
3	Guidance document for the implementation of Commission Regulation (EU) No. 691/2013 of 19 july 2013 amending regulation (EC) no 152/2009 as regards methods of sampling and analysis
4	Guides of Good Practice: COCERAL/COPACOGECA
5	Guides of Good Practice: FEFAC/FAMI QS/ FEDIAF/AAF-FEDIOL
6	EU register of FeBOs: http://ec.europa.eu/food/food/biosafety/establishments/feed_list_en.htm
7	**Regulation (EC) No. 619/2011** of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired
8	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 C/2016/4608
9	**Regulation (EC) No. 999/2001** of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
10	**Regulation (EC) No. 1069/2009** of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption
11	**Regulation (EU)No. 142/2011** of 25 February 2011 implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
12	**Regulation (EC) No. 882/2004** of The European Parliament and The Council 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
13	**Regulation (EC) No. 152/2009** of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed and amendments
14	**Recommendation 2004/787/EC** of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003
15	**Directive 2002/63/EC** of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
16	**Regulation (EC) No. 136/2004** of 22 January 2004 laying down procedures for veterinary checks at Community border control posts on products imported from third countries

17	**Regulation (EC) No. 669/2009** of 24 July 2009 implementing Regulation (EC) No 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 Decision 2006/504/EC
18	**Directive 97/78/EC** of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
19	**Directive 98/68/EC** of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries
20	**Commission Decision 2001/881/EC** of 7 December 2001 drawing up a list of border control posts agreed for veterinary checks on animals and animal products from third countries and updating the detailed rules concerning the checks to be carried out by the experts of the Commission
21	**Commission Decision 2007/275/EC** of 17 April 2007 concerning lists of animals and products to be subject to controls at border control posts under Council Directives 91/496/EEC and 97/78/EC
22	**Commission Regulation (EU) No. 691/2013** of 19 july 2013 amending Regulation (EC) No 152/2009 as regards methods of sampling and analysis
23	**Commission Decision 2011/884/EU** of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC
24	**Regulation (EU) No. 2016/6** of 5 January 2016 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU). No 322/2014
25	**Regulation (EU) No. 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 Regulation (EC) No 1152/2009
26	**Regulation (EU) No. 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
27	**Regulation (EU) No. 2017/893** of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein
28	**Regulation (EU) No. 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
29	**Commission Notice 2018/C 133/02 -** Guidelines in order to guarantee a common approach in all MS on the use of certain food no longer intended for human consumption
30	**Directive 90/167/EEC** of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
31	**Regulation (EU) No. 2019/4** of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC