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 1 – EU Legislation on Feed

Contract 2016 96 04 – Phase 2

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List of Abbreviations

ABP	Animal By-Products
AMR	Antimicrobial Resistance
BCP	Border Control Post
BSE	Bovine Spongiform Encephalopaty
CA	Competent Authority
CCP	Critical Control Point
CED	Common Entry Document
CLP	Classification, Labelling and Packaging
CRL	Community Reference Laboratory
CVED	Common Veterinary Entry Document
DEP	Designated Entry Point
DG SANTE	Directorate General for Health and Food Safety
DNA	Deoxyribonucleic Acid
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FBO	Food Business Operator
FeBO	Feed Business Operator
FH	Feed Hygiene
FHR	Feed Hygiene Regulation
FM	Feed Materials
GM	Genetically Modified
GM Feed	Genetically Modified Feed
GMO	Genetically Modified Organism
HACCP	Hazard Analysis and Critical Control Points

IC	Intra Comunnitary
MBM	Meat and Bone Meal
MRL	Maximum Residues Limit
MS	Member States
PAP	Processed Animal Proteins
PCB	Polychlorinated Biphenyls
PCR	Polymerase Chain Reaction
Q&A	Questions and Answers
RASFF	Rapid Alert System for Food and Feed
REG	Regulation
RNA	Ribonucleic Acid
SRM	Specific Risk Material
TC	Training Coordinator
TRACES	Trade Control and Expert System
TS	Training Session
TSE	Transmissible Spongiform Encephalopathy
USA	United States of America
VMP	Veterinary Medicinal Products

Topic 1: General overview

Specific objectives of Topic 1:

Objective 1: Provide a brief introduction to how the EU works, meaning **how decisions are taken at EU level**, who takes those decisions, which **EU institutions** are involved in the **decision-making process**, and the description of the **different types of legal acts** adopted to be enforced by the MSs.

Objective 2: Describe the **evolution of the feed law** in the last two decades and show in a practical way how to download **consolidated legislation**. This evolution is shown with the **White Paper on Food Safety** as a starting point, to be continued **chronologically** with the introduction, focusing on the feed aspects of the **General Food Law**, as well as its main achievements i.a. the establishment of EFSA and the RASFF. To conclude with the legislative part, the **most important definitions** considering feed are also taken into consideration together with other aspects of the **Feed Marketing Regulation**, like **product labelling and classification**. An infographic is used to present the historical development and evolution of the EU Feed legislation.

Objective 3: Demonstrate the **importance of the feed sector in the EU's economy**, as well as the market share of the **EU feed sector from a global perspective**.

This topic consists of three theoretical modules dealing with:
- EU system and introduction to feed legislation (Module 1.1);
- General food law principles & requirements (Module 1.2);
- Feed marketing and use (Module 1.3).

Module 1.1 EU system and introduction to feed legislation

Tutor(s):	Jose Costa / Marot Hibbey
Duration:	45 minutes
Format:	Theoretical presentation
Aids if any:	Infographic

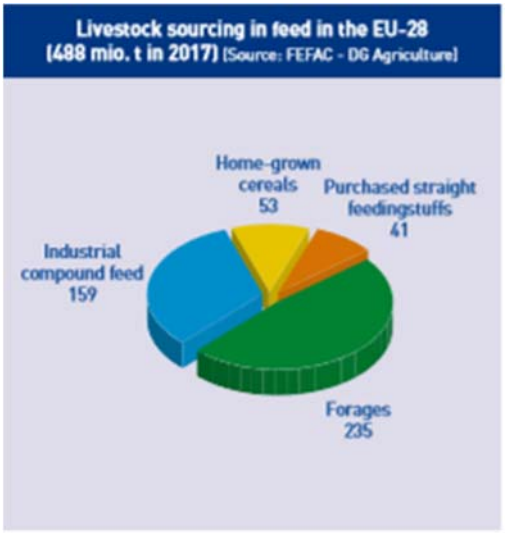
Module Description
• Some feed key figures: importance of feed in the EU economy - internal production and international trade. • Some future challenges for animal nutrition in the food chain. • Short introduction of the decision making procedures in the EU and interactions between the EU institutions. • Infographic overview of the legal framework - most important regulations and directives dealing with feed: the evolution of feed law in the last decade is taken into consideration, highlighting the main legal acts to be enforced by MSs at all stages of production, processing and distribution of feed to ensure feed safety. • Demo: access to consolidated versions of the EU feed legislation.
Group discussion: Practical aspects of Comitology under the ordinary legislative procedure

Key concepts, information and messages for this module

The production of feed is an important end for European agricultural products, given the fact that most of the materials used on feed production are agricultural products listed in Annex I of the Treaty. Furthermore, feed is of crucial significance for the 11 million livestock farms in the EU because it represents the greatest expense. Other key figures on the feed sector of the EU-28, according to the last data published by FEFAC, are:

- 22 million people working regularly in farming;
- farming and food sectors together provide nearly 44 million jobs in the EU;
- meat and other animal products in the EU-28 represented app. 176 bio. € in 2017, i.e. 41% of the total value of farm production;
- animal feed is the most important livestock production cost factor and represented up to 61% of the farm gate value of poultry in 2017;

The pie chart shows the distribution and total amount of feed used in the EU in 2017. In 2017 the EU-28 share of the global compound feed production (1,053 mTons) was 15 % (159 mTons), USA: 16,4%, China: 17,7%.



The global feed production should be increased due to an increased need of food of animal origin by the population. There are also some future challenges related to protein scarcity due to the climate changes, dependence on world market and prices fluctuation.

The EU decision-making

EU decision-making involves various European institutions, in particular:
The European Parliament, which represents the EU's citizens and is directly elected by them. The European Parliament has three main roles: (1) debating and passing European laws with the Council, (2) scrutinising other EU institutions, particularly the Commission, to make sure they are working democratically, (3) debating and adopting with the Council the EU's budget.

The **European Council**, which consists of the Heads of State or Government of the EU Member States and sets the EU's **general political direction and priorities**, and deals with complex or sensitive issues that cannot be resolved at a lower level of intergovernmental cooperation. It does not exercise legislative functions.

The **Council of the EU**, which represents the governments of the EU Member States, has the following main responsabilities:

- passes EU laws; in most fields it legislates with the European Parliament;
- coordinates the Member States' policies, for examle, in the economic field;
- develops the EU's common foreign and security policy, based on guidelines set by the European Council;

- concludes international agreements between the EU and one or more states or international organisations;
- adopts the EU's budget, jointly with the European Parliament.

The **European Commission**, which represents the interests of the EU as a whole, has the following main roles:

- proposes new laws to the Parliament and the Council;
- manages the EU's budget and allocates funding;
- enforces EU law (together with the Court of Justice);
- impact assessment;
- represents the EU internationally, for example, by negotiating agreements between the EU and other countries.

Generally, it is the European Commission that proposes new laws that must aim to defend the interests of the Union and its citizens, not those of specific countries or industries. It is the European Parliament and Council that adopt the EU legislation. This EU's standard decision-making procedure is known as '**ordinary legislative procedure**' formally known as 'codecision'. Once EU legislation has been adopted, the Commission ensures that it is correctly applied by the EU member countries through implementing acts adopted by comitology. In fact, within feed legislation many decisions are taken by comitology through the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), for example the authorisation of additives or amendments of certain annexes of the Regulations. The documents, agendas and reports of those committees can be found in the Comitology Register in DG SANTE web:
http://ec.europa.eu/transparency/regcomitology/index.cfm?CLX=en.

Feed legislation
EU law is most often formulated as regulations, directives, decisions or recommendations. It is the responsibility of the MS to adopt national rules/execution measures with the aim of achieving the targets of the EU legislation in the given MS. The participants are shown how the feed legislation evolved over the past, since the adoption of the White Paper on food safety, and how they are linked to cover every possible aspect needed for ensuring food chain safety. As most of the pieces of legislation are repeatedly updated, a short presentation is be held on how to download consolidated legislation from the EUR-Lex.

Module 1.2 General food law principles & requirements

Tutor(s): Jose Costa / Marot Hibbey
Duration: 30 minutes
Format: Theoretical presentation

Module Description
• Introduction to the EU integrated approach on food safety (White Paper – "farm-to-fork" approach). • General Food and Feed Law: scope, objectives and requirements on general food law with specific focus on feed safety, traceability, import/export requirements and obligations of feed operators (including export on non-authorized EU feed to third countries). • EFSA as European Authority for food/feed risk assessment. • Legal basis of the RASFF system: relevance of the system for feed as compared with food;

information flow; Link with TRACES.
Group discussion: Importance and practical consequences of notifications and data on feed notifications concerning the last RASFF annual report; specific issues to be considered when managing feed-related notifications; understanding of the non-compliances; evolution in time

Key concepts, information and messages for this module

The White Paper on Food Safety was adopted with the aim to totally change, improve and modernize the legislation which previously regulated this field in the Community of the 90's. This thorough reform was justified due to repeated food safety crises which resulted in important financial losses, as well as in decreased consumer confidence. The new concept of the White Paper is based on comprehensive and integrated risk analysis approach, resulting in a legislation overarching the whole food chain.

Regulation (EC) No. 178/2002 (General Food Law)
The main principles of the White Paper on Food Safety were implemented by the 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 provides the general framework for those areas not covered by specific harmonised rules. It lays down definitions, principles and obligations covering all stages of food/feed production and distribution. This integrated **"farm-to-fork" approach** is now considered a general principle for the EU food safety policy to protect consumers' interest, including fair practices in food trade. Meanwhile, it harmonizes general principles and requirements in order to ensure the free movement of food and feed in 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 for private domestic consumption.

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

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

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

Articles on Feed Law which are of particular 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 underpin Food Safety policy, however the precautionary principle may be used where appropriate.

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

Article 9: Transparency.

Articles 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. FBOs 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 FHR (Annex II).

Article 20: Responsibilities for FeBOs, feed manufacturers, and farmers have the primary responsibility for feed safety, for withdrawal or recall of the product, a food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health.

Rapid Alert System for Food and Feed (RASFF)
General Food Law creates RASFF which is a rapid alert system network for the notification of a direct or indirect risk to human health deriving from food or feed. The Commission and EFSA, MSs, EEA countries, Switzerland, certain third countries are the members of the network. Each member of the network shall immediately inform the Commission on any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed. The Commission shall immediately transmit the information to other members. A notification may take the form of an alert, border rejection, information, or news. It is advisable to recognise their diffrences in order to allow proper classification and actions in case of risk for the food chain.

	ALERT	INFORMATION	BORDER REJECTION	NEWS
HEALTH RISK	SERIOUS	POTENTIAL	SERIOUS	UNLIKE
DISTRIBUTION	IN THE EU MARKET	NOT REACH THE EU MARKET	REJECTION AT THE EXTERNAL BORDERS	EXTERNAL MARKET
MEASURES	IMMEDIATELY	FURTHER CHECKS AND ANALYSIS	REINFORCE CONTROLS ON IMPORT CONTROLS, AVOIDING RE-ENTERING INTO THE EU	NOT NEEDED
ACTION	WITHRAWAL	FOLLOW UP		NOT NEEDED

Previous notifications are uploaded in a searchable tool called RASFF portal. An annual report on the previous years can be downloaded from:
http://ec.europa.eu/food/safety/rasff/reports_publications_en

Conditions to fulfil for initiating a RASFF notification:

- risk on animal or human health is established (prohibited materials are found or contaminants above the established level);
- product is on the market;
- rapid action of the CAs is needed.

Module 1.3 Feed marketing and use

Tutor(s): Stefania Buschbacher
Duration: 45 minutes
Format: Theoretical presentation

Module Description
• General overview of Feed Marketing and Use Regulation: main objectives and key changes as compared with previous legislation. • Categories and characteristics of feed. • Safety and marketing requirements. • Status of highly concentrated additives and transitional measures. • Claims in feed and scientifical substantiation: the case of dietetic feed. • Guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products. • Short reference to other rules applicable to feed with an impact on marketing of feed (Animal by-products, Feed-ban, GMO, etc. • Overview on forbidden substances and materials prohibited or restricted in animal nutrition with specific mention to packaging material and the implications of the zero-tolerance. • Rules and tools to verify the classification of a substance/product as feed: the use of specific decision trees.
Group discussion: Practical cases on classification of substances/ products as feed

Key concepts, information and messages for this module

This module intends to provide the basic definitions and rules to properly classify substances or their mixtures.

This is relevant to understand what types of products are under the feed legislation. Therefore, the proper classification of some substances as biocides, veterinary medicines or other type of product is the key sometimes to make a decision about the proper classification of products in the market.

The following feed definitions must be taken into consideration:

- Feed materials

- Feed additives
- Premixtures of feed additives
- Compound feed

Complete feed	Complete feed
	Complete milk replacer
	Dietetic complete feed
Complementary feed	Complementary feed
	Mineral feed
	Complementary milk replacer
	Dietetic milk replacer

- Medicated feed

There are products on the market that may be classified in more than one category. The general criteria to classify them are explained, together with the legislative acts that may be used to support proper classification of substances or mixtures

Feed additives and premixtures are not intended to be supplied directly to animals. It is required that they are supplied through a prior dilution as complementary or complete feed.

Farmers who produce compound feed exlusively for the animals in their own holding can do it by using premixtures or complementary feeds. It is important to differentiate premixtures from complementary feeds because the requirements established under feed hygiene rules are much stricter when premixtures are used to include feed additives in compound feeds.

Also, the particular case of highly concentrated dietetic feeds is introduced, although it is discussed in more detail in the specific topic dedicated to this type of feed.

Feed may only be placed on the market, if it:

1. is safe, has no direct adverse effect on the environment or on animal welfare;
2. is sound, genuine, unadulterated, fit for its purpose and of merchantable quality;
3. is labelled, packaged and presented as per Feed Marketing Regulation;
4. complies with the technical provisions on impurities and other chemical determinants set out in Annex I to Feed Markering Regulation.

Article 13 of the feed marketing regulation: The labelling of feed materials and compound feed may draw particular attention to the presence or the absence of a substance in the feed, to a specific nutritional characteristic or process or to a specific function related to any of these, if:

1. it is objective, verifiable by CAs, understandable by users;
2. scientific substantiation is available when placing on the market;
3. or is about optimisation of nutrition, protection, support of physiological function;
4. it does not refer to curing, preventing or treating a disease (except: Coccidiostats).

The Commission updates the list of intended uses (dietary claims) in Directive 2008/38.

Distinction between complementary feeds and premixes:
A complementary feed needs to comprise at least 2 feed materials (by definition of compound feed), and it shall not contain levels of feed additives higher than 100 times the relevant fixed maximum content in complete feed (5 times for coccidiostats) (Art. 8.1).

There is a specific derogation from the limit above for dietetic feeds:
100 times limit can be exceded if the product fulfils the dietary purpose in respect of the intended use (Art. 8.2). There is also a transitional measure concerning those products: products referred to in Art.8.2 may remain on the market until decision is taken if:
Already placed on the market legally until 01.09.2010, and application as dietary feed submitted until 01.09.2010.

Questions and answers related to Topic 1

Will be provided with the Second Interim Report.

Topic 2: Feed hygiene

Specific objectives of Topic 2:

Feed hygiene rules

The EU legislation on food safety repeatedly refers to **feed as a sensitive stage** in the beginning of the food chain. The reason for that is that food chain safety is dependent on the safety of feed, which in that sense, has an impact on public health. The main purpose for FHR is obvious to this: to **protect consumer health**. For controlling hazards in food and feed safety, HACCP system was recognized by Codex Alimentarius as an effective tool. Consequently, **HACCP system became part of the food & feed safety legislation**. FeBOs are classified by the FHR in a number of groups (annex I FeBOs and annex II FeBOs), or within the annex II FeBOs two further groups can be separated - one for the ones to be registered, and another, to be approved. Activities in and out of the **scope of FHR** are described. This section provides some information on what kind of charactersitics the **different types of FeBOs** have, providing a practical approach on how to classify them into the right categories, which finally results, for both CA staff and operators, in having **information on the set of rules applicable** to the given activity. The **rules themselves are also explained as per FeBO activities**. Clear explanaition is provided on how to categorize **borderline activities.** The topic on registration and approval is extended far beyond the scope of the FHR, and other relevant EU legislation is explained in details to cover all possible registration schemes FeBOs have to know of. As part of FHR **import and export conditions** are also highlighted.

This topic consists of four theoretical modules along with a practical one dealing with:

- Feed hygiene – general overview (Module 2.1);
- Registration and approval of feed establishments (Module 2.2);
- Rules on Feed hygiene: Primary production (Module 2.3);
- Practical activity on FH rules (Module 2.4);
- Rules on Feed hygiene: Other than primary production (Module 2.5);

Module 2.1 Feed hygiene – general overview

Tutor(s): Stefania Buschbacher
Duration: 30 minutes
Format: Theoretical presentation

Module Description
• General overview of the Feed Hygiene regulation: scope, general obligations and requirements at each step of the feed chain; guide to good practices; feed imports.
Group discussion: Practical cases for the application and the derogations of feed hygiene requirements (the definition of small quantities and local level shall be discussed with national examples given, as well as EU & National CGP).

Key concepts, information and messages for this module

This module is intended to ensure the understanding of the main principles and rules of the feed hygiene regulation as an introduction topic for other more specific topics regarding the rules for

registration/approval requirements and specific provisions of Annex I and III for primary producers, as well as Annex II and HACCP for activities other than primary production.
The first part of the topic is dedicated to clarifying the scope of the feed hygiene regulation and to differentiating primary production from activities other than primary production (borderline examples are used to clarify it).

The key concept is that all FeBOs must comply with Annex II and HACPP except those in primary production and some associated activities, which must comply with Annex I and III. For farmers preparing feed exclusively for their animals, they must produce the feed by using complementary feeds and not feed additives or premixtures (silage additives are excluded from this rule).

Also, the main principles on which the regulation is based are explained, namely:

- Responsibility for Feed Business Operators;
- The need for registration/approval;
- Implementation of HACCP principles;
- Equivalence of the feed safety requirements for feeds imported into the EU territory from third countries;
- Registration/approval of representatives;
- The use of guides to good practices as a voluntary tool to achieve the objectives of the regulation.

Other relevant provisions of the regulation:

- Reference to notification through the RASFF system of hazards that may affect animal health, human health or the environment;
- Mandate to Member States to establish penalties that are proportionate in case of finding non-compliances.

Module 2.2 Registration and approval of feed establishments

Tutor(s): Stefania Buschbacher
Duration: 45 minutes
Format: Theoretical presentation

Module Description
• Types of feed establishments, rules applicable for their registration and approval - highlight of critical points, practical examples of activities which are out of the scope. • Guidance document on the implementation of certain provisions of the feed hygiene regulation. • On-the-spot visit by CA and conditions for establishments' approval. • Suspension and/or cancellation of establishments' registration or approval. • EU register of FeBOs: (http://ec.europa.eu/food/food/biosafety/establishments/feed_list_en.htm)
Group discussion: Practical cases on double registration of the FeBO (food industry, processing plants, processing of crude vegetable oil, oleo chemical and biodiesel industry, fat blending, detoxification establishments, medicated feed production).

Key concepts, information and messages for this module

Background: Feed business operators are obliged to obtain registration or approval for the purposes of their production. Depending on the type of activity they wish to perform, they need either to have their establishments approved or registered, or their activities approved.

Specific legislation, under which the above obligations are in force:

- Feed hygiene Regulation (EC) No. 183/2005, as amended by Regulation 225/2012 on approval of establishments manufacturing products derived from vegetable oils intended for feed. Other regulations may establish additional requirements for registration or approval of Feed Business Operators (Feed Marketing Regulation (EC) No. 767/2009, Animal by-products Regulation (EC) No. 1069/2009, TSE-Regulation (EC) No. 999/2001, Medicated Feed directive (EC) No. 90/167).

Approval of feed business establishments according to FHR:

Certain establishments of FeBOs can operate only if approved by the CA. Approval is required:

1. When the establishment has one or more of the following activities:
(a) manufacturing and/or placing on the market of feed additives covered by Regulation (EC) No. 1831/2003 or products covered by Directive 82/471/EEC and referred to in Chapter 1 of Annex IV to this Regulation;
(b) manufacturing and/or placing on the market of premixtures prepared using feed additives referred to in Chapter 2 of Annex IV to this Regulation;
(c) manufacturing for placing on the market, or producing for the exclusive requirements of their holdings, compound feedingstuffs using feed additives or premixtures containing feed additives and referred to in Chapter 3 of Annex IV to this Regulation.

2. Under the national law of the Member State where the establishment is located.

3. If required by a Regulation approved by the European Commission (Comitology procedure):
(a) New approval obligation for additional types of establishments is in force under Regulation (EU) No. 225/2012 amending feed hygiene regulation specified above;
(b) Producers of coccidiostats/histomonostats;
(c) According to Annex VIII of Regulation 767/2009, detoxifying establishments shall also be authorised.

For the purpose of registration or appoval feed business operators shall:
(a) notify the appropriate competent authority of any establishments under their control, active in any of the stages of production, processing, storage, transport or distribution of feed, in the form required by the competent authority with a view to registration;
(b) provide the competent authority with up-to-date information on any establishments under their control as referred to in point (a), including notifying the competent authority of any significant change in activities and any closure of an existing establishment.

The approval and registration requirements for FeBOs are the same.
Requirements for CAs with a view to registration (in this sense: including approval) of the establishments of FeBOs.

The CA shall maintain a register or registers of all establishments. It is obligatory to publish this register, including all primary producers (primary producers of food do not have to be published) showing each activity, approval number, if applicable, in the form shown in Annex V of FHR. The EC compiles a homepage[1] showing all the lists provided by MSs.

The CA shall take account of the systems already existing for the collection of data and request the notifier or the applicant to provide only additional information which guarantees compliance with the conditions of the FHR.

- All registered companies, including primary producers
- EC compiles lists of MS' approved establishments.

Procedure for approval is different from the procedure for registration (FeBOs cannot start certain types of production without approval).

1. On-site visit by CA: prior to start up. The CA checks if requirements of the FHR relevant for the activities the establishment intends to perform are complied with;
2. Conditional approval may be granted if the infrastructure and equipment requirements are fullfilled. It can last maximum 3 (+3) months;
3. Full approval and generation of an approval number (α + ISO code of MS + max. 8 numbers).

Procedure for registration:

1. No on-site visit by CA is required prior to start up;
2. Notification to CA of the data specified under 1.4;
3. No approval number is needed.

One of the topics still under discussion is the need to register some types of establisments, taking into account that feed business operators and farmers shall only source and use feed from establishments which are registered and/or approved in accordance with the FHR.

Where does the feed chain start on the basis of COM Guidance Document is under discussion.
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

[1] http://ec.europa.eu/food/food/biosafety/establishments/feed_list_en.htm

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.

From those findings we can conclude that the producer is responsible to define the intended use of its product. We can also conclude, 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 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 FeBO in which the product originates need 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 the 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.

Module 2.3 Rules on Feed hygiene: Primary production

Tutor(s): Stefania Buschbacher
Duration: 45 minutes
Format: Theoretical presentation

Module Description
• General and specific provisions for implementing feed hygiene at primary production

(production, handing, storage, mixing feed on farm). • Good animal feeding practices. • EU system established for guides - EU and national guides. • Guides and recommendation to good practices at primary production level: overview.
Group discussion: Potential risks at primary production level, including feed of plant origin production and animal husbandry.

Key concepts, information and messages for this module

In this module, the requirements for primary production and associated activities are explained in detail by referring to Annexes I and III of the Feed Hygiene Regulation.

ANNEX I

Hygiene-provisions

1. Prevent, eliminate or minimise hazards with the potential to compromise feed safety. FeBOs shall ensure, as far as possible, that primary products produced, prepared, cleaned, packed, stored and transported under their responsibility are protected against contamination and spoilage. FeBOs shall meet those obligations by complying with appropriate Community and national legislative provisions relating to the control of hazards, including measures to control **hazardous contamination** such as the one arising from the air, soil, water, fertilisers, plant protection products, biocides, veterinary medicinal products and handling and disposal of waste, and measures relating to plant health, animal health and the environment that have implications for feed safety, including programmes for the monitoring and control of zoonoses and zoonotic agents.
2. FeBOs shall take adequate measures, in particular to keep **clean** and, where necessary after cleaning, to disinfect in an appropriate manner facilities, equipment, containers, vehicles used for producing, preparing, grading, packing, storing and transporting feed, to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of feed to use **clean water** whenever necessary to prevent hazardous contamination.
3. FeBOs shall take adequate measures, in particular, to prevent, as far as possible, animals and pests from causing hazardous contamination, to store and handle **wastes** and hazardous substances, separately and securely, so as to prevent hazardous contamination, to ensure that **packaging materials** are not a source of hazardous contamination of feed, and to take account of the results of any **relevant analyses** carried out on samples taken from primary products or other samples relevant to feed safety.

Record keeping

FeBOs shall keep records related to measures put in place to control hazards, in an appropriate manner and for an appropriate period, commensurate with the nature and size of the feed business. FeBOs must make relevant information contained in these records available to the competent authority. FeBOs must, in particular, keep records on any use of plant protection products and biocides, of genetically modified seeds, any occurrence of pests or diseases that may affect the safety of primary products, the results of any analyses that have importance for feed safety, the source and quantity of each input of feed and the destination and quantity for each output of feed.

Guides to good practice

It is recommended that where national and Community guides referred to in Chapter III of FHR are drawn up, they shall contain guidance on good practices for the control of hazards in primary production of feed. National and Community guides have been drawn up by MS and a collection is available at: https://ec.europa.eu/food/safety/animal-feed/feed-hygiene/guides-good-practice_en

ANNEX III
Farmers shall comply with the provisions set out in Annex III when feeding food-producing animals. In that sense good animal feeding practice means compliance with conditions for:

- pasture grazing;
- stable and feeding equipment;
- feeding including storage and distribution;
- feed and water;
- personnel.

Module 2.4 Exercise on FH rules

Tutor(s): Stefania Buschbacher
Duration: 30 minutes
Format: Working groups + Debriefing

Module Description
Practical exercise on different activities and their environment as feed business operators. Participants have to evaluate some activities as potential FeBO, identify two/three major risks associated with them and the eventual mandatory HACCP implementation. Afterwards the questions are discussed in groups. If applicable, examples of additional national measures adopted on specific obligations that must be required for some particular FeBO/ national rules for feed hygiene requirements implementation, such as derogations (i.e. small quantities and local level), shall be described.

Key concepts, information and messages for this module

This presentation makes participants aware of the wide scope of the feed hygiene regulation by supplying different examples of feed establishments and by requesting them to classify as establishments having an activity included under the primary production concept or an activity that is not included in primary production.

Examples include farming activities, transport (by road and by ship), chemical industries, food recycling establishments, food industries.

Also, participants are requested to name several hazards that may be frequently associated with the activities.

Module 2.5 Rules on FH: Other than primary production

Tutor(s): Stefania Buschbacher

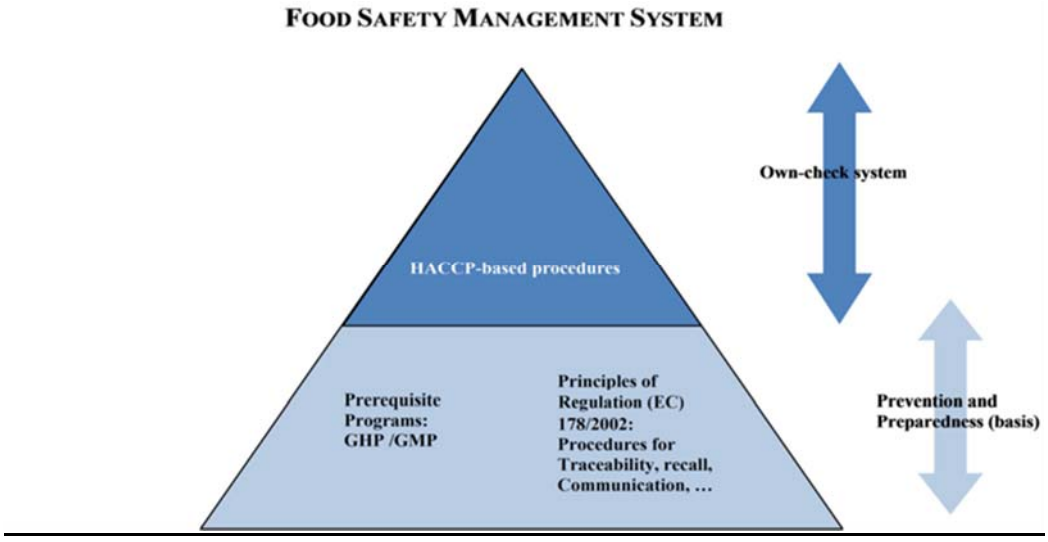
Duration: 75 minutes

Format: Theoretical presentation

Module Description
• Specific provisions as regards activities other than primary production. • Manufacturing additives/premixtures/ compound feed containing additives/premixtures - Requirements regarding facilities and equipment, personnel, production, quality control, storage and transport, record keeping, complaints and product recall. Prerequisite feed hygiene programme. Risks to consider at feed business operators' establishments. • Safety control and sampling: dioxins monitoring.
Group discussion: Potential risks at feed business operators.
• Introduction to HACCP methodology: phases and principles; presentation of the 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; usual CCPs
Discussion on the situation in the represented countries and issues encountered.

Key concepts, information and messages for this module

Commission note on HACCP and flexibility 2016/C 278/01
Commission published the above note to help FBOs and CAs to apply in the EU the HACCP system and flexibility in a harmonized way. The Note can be used also for FeBOs. The Note contains a detailed description on the HACCP system which is described in the presentation and below. The Note contains assistance charts and tables on decision trees for CCPs, examples of prerequisite programs (calibration, waste, cleaning, pest, etc.), and operational prerequisite programs (like blenching process in the deep-freezing industry or washing process for vegetables). Flexibility is essential to remain risk based and to avoid overloading FBOs. The purpose of flexibility within an FSMS is to seek for proportionality of control measures by adaptation to the nature and the size of the establishment.



Annex II FeBOs

For operations other than those referred to in Article (5)1 in FHR, including mixing of feed for the exclusive requirements of their own holdings when using additives or premixtures of additives with the exception of silage additives, feed business operators shall comply with the provisions of Annex II. FeBOs carrying out operations other than those referred to in Article 5(1) in FHR shall put in place, implement and maintain a permanent written procedure or procedures based on the HACCP principles.
Annex II FeBOs have to comply with the conditions on quality control, dioxin monitoring and complaints system.

Quality control

A qualified person is needed for quality control and an internal/external laboratory with adequate staff and equipment has to be available. Quality control plan must be drawn up in writing and implemented, and include checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications – and the destination in the event of non-compliance – from processed materials to final products. Documentation related to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability. Samples of ingredients and of each batch of products manufactured and placed on the market or of each specific portion of production (in the case of continuous production) are to be taken and stored.

Dioxin monitoring

Increased frequency of dioxin analysis in the case of certain establishments (processing or producing crude vegetable oils, animal fat, fish oil, blended fat, biodiesel, compound feed) is to be considered.
Derogations for increased level of dioxin monitoringare established.
Increased responsibility for laboratories in the case of identifying batches with exceeding levels of dioxin are defined.

Complaints

System on complaints and product recall shall be considered, made up of registering and processing complaints and a system for the prompt recall of products in the distribution network based on written procedures, including the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

HACCP

HACCP is mandatory for Annex II FeBOs. HACCP is a process control system consisting of 7 principles (as specified by (6)2 in FHR), or 12 phases according to ISO-standard. Prerequisite programmes constitute an important precondition for HACCP systems. Prerequisite means that before implementing HACCP all feed safety control systems must be in place.

The 12 points are (where 7 principles of HACCP are included):
Assemble HACCP team and validation team;
Description of products;
Identify intended use;
Construct Flow Diagram;
On site confirmation of flow Diagram;
Hazard analysis based on probability x seriousness;
Determine Critical Control Points based on decision tree;

Determine critical limits for CCPs;
Monitoring CCPs;
Define corrective measures;
Validation and verification of HACCP plan;
Documentation and registration of HACCP plan.

Questions and answers related to Topic 2

Will be provided with the Second Interim Report.

Topic 3: Feed ingredients & contamination

Specific objectives of Topic 3:

The concept of feed marketing was basically changed with the adoption of the Feed Marketing Regulation. This new concept is introduced here together with detailed presentation of its main benchmarks like the **catalogue of feed materials**, **register of feed materials** (together with an **on-line demonstration** on how to achieve it, how to notify to it, and how to search in it).

Former foodstuffs can be used for feed more efficiently without substantial changes to the legislation, still maintaining the safety of the feed supply chain. The current practice among MSs varies substantially. Therefore Guidelines were recently published by the Commission in order to guarantee a common approach in all MS on certain food no longer intended for human consumption. The activities of this topic also cover **GM feed**. Scope and basic principles of the EU legislation in relation to GM food and feed are introduced, with special attention to the **authorisation procedure**, the **EU Register of GM food/feed** and to the **low level presence of non-approved GMOs** in imported feed. As for the inspectors some control aspects are important, where rules on labelling and traceability of GMOs and special sampling schemes are presented in a practical way.

Another item for this topic are **TSEs**, a rather specific group of progressive, transmissible and fatal diseases, affecting the brain and central nervous system of many animals, including humans. A key expert is invited to share his views with the participants on this kind of diseases, and on the **feed ban, as continuously adapted** to the actual degree of the risk involved. This feed ban, together with the **ban on intraspecies recycling**, are the most important control tools for reducing the prevailence of the infectious agent, and finally for the **eradication** of the disease. **FeBOs** complying increased levels of safety provisions may require **special authorisations** derogating from certain prohibitions of the feed ban. Participants are equally provided with a detailed description of this domain.

This topic also covers **ABPs**, as an important source of protein rich feed materials, however, constituting an increased level of risk. This section makes the participants understand which the **main principles** of the ABP regulations are, which **categories of ABPs** have been drawn up, which rules for **IC trade** apply, and which **requirements** FeBOs dealing with feed materials of animal origin should comply with and **how this compliance should be verified by the CAs**. The requirements for using ABPs for feed for pets and for feed for farmed animals are also part of the presentation.

The importance of **microbiological contamination of feed** is another objective highlighted under this topic. Main microbiological characteristics for **Salmonella** are given, as the most important microbe in the feed industry. Its specific environmental needs are described. Having introduced the **relevant legislative framework**, the lecturer clearifies which **sampling plans**, **sampling** or **sterilisation methods** are preferable. **Risk management tools** available for FeBOs are shown with a **focus on Salmonella,** how to prevent and reduce contamination, how to kill Salmonella. The right evaluation of the analytical results is shown.

Undesirable substances in feed are introduced to the participants by explaining to them the possible **origins** of contaminations, the **relevant legislative framework**, as continuously adapted to the indentified level of risk, **detoxification**, as a possible risk management tool, and an overview of **specific contaminants**, like dioxins, pesticides or mycotoxins.

This section covers an introduction to the EU legislation on **feed additives and premixes**, together with the relevant provisions on their **authorisation**, **marketing and labelling**. As these products at a certain degree may fall within the scope of the **Classification, Labelling and Packaging Regulation (CLP)**, the consequences of this are presented to the participants.

This topic consists of five theoretical modules, all of them linked through some kind of practical activity (case study, quiz, or exercise) dealing with:

- Feed materials (module 3.1);
- GM feed (module 3.2);
- Feed ban (module 3.3);
- Animal by- products in animal nutrition (module 3.4);
- Microbiological contamination (module 3.5);
- Undesirable substances (module 3.6);
- Additives in feed (module 3.7).

Module 3.1 Feed materials

Tutor(s): Jose Costa / Marot Hibbey
Duration: 60 minutes
Format: Theoretical presentation

Module Description
• Feed materials used in the EU. • Explanation of the feed material catalogue and feed material register. • COMMISSION Notice on the use of former foodstuff as feed and the concept of circular economy and food waste combact. • Breadth of different sources of new feed materials (i.e. insect meals, algae, other aquatic proteins, etc): advantages and potential hazards associated with them. • Catalogue of Feed Materials *vs* Register of Feed Materials. • Demo: access to Register of Feed Materials.
Group discussion: Catalogue / Register of Feed Materials.

Key concepts, information and messages for this module

Feed materials (FMs) can be used in the EU **without premarketing authorisation**. The reason is that FMs do not represent a high degree of risk. In the past, however, FMs were sources of important contamination incidents. To be in a better position regarding reactability for CAs in such cases it was decided to establish registers for FMs. One of them is the **Catalogue of FMs** established by Regulation (EU) No. 68/2013 and recently ammended by Regulation (EU) No. 2017/1017. This is made up of three files: PART A: GENERAL PROVISIONS is about **special provisions**. PART B: GLOSSARY OF PROCESSES: contains a **vocabulary** showing the most common processing methods available for the feed industry, together with a description of which one means what. PART C: LIST OF FEED MATERIALS contains a **list of FMs in 13 categories**. The catalogue is a result by industry and EU authorities' efforts.

FMs presented in the catalogue are the ones which have been used in the EU traditionally and proved to be safe. For that reason a **simplified labelling** requirement is also shown for each of them under the last column. N.B.: the listed items **cannot be used per se** for all the animal species. **Other rules**, like the feed ban, ABP regulations are to be taken into consideration.

Experience, however, has shown in the past that registers, even if not exhaustive ones, may be **restrictive for innovation**. For that reason, an **on-line register** for feed materials has also been developed (EU Feed Materials Register). The EU **feed industry** takes care of this register, which also includes the screening and deleting of false (unsuitable) notifications. Being an on-line register, it has a very simple and **always updated** lay-out which can be easely notified into, and the operator is supposed to upload the name and the description of the product, together with some identification data on the FeBO itself. The latter is not shown, it is just for the CA in case **urgent information is needed on a FeBO**.

Feed marketing, however, is continuously facing new challanges even after the 2009 adoption of the Feed Marketing Regulation. An actual challenge stands with the **'circular economy'** concept. This is targeted in the maximum possible reduction of wasted food, which is highly justified economically, as well as morally. The Commission is currently challenging the food and feed legislative framework on how **former foodstuffs** could be used for feed more efficiently without substantial changes of the legislation, still maintaining the safety of the feed supply chain. The current practice among MS on how the provisions are influencing the use of former foodstuffs varies substantially. For that reason and to facilitate the feed use of certain food no longer intended for human consumption, with and without products of animal origin, guidelines have been established by the EC according to Commission Notice 2018/C 133/02. Those guidelines should assist the national and local competent authorities and the operators in the food chain in applying the relevant Union legislation. Given the permanent link to the scarcity of protein source in the EU there remains the need to identify **sources of new feed materials**. There are promissing possibilities available from the worldwile practice of ensuring protein constituents in the feed diets, however, new feed sources always constitute a **higher degree of hazards** associated with them, which must be examined before their use. These questions are discussed in detail during this module.

As the EU lacks protein sources in animal husbandry, new FMs are very important. Products of insect or of alga and aquatic origin could be identified as very promising future protein resources. Pros and Cons are described under this item.

Module 3.2 GM Feed

Tutor(s): Stefania Buschbacher
Duration: 90 minutes
Format: Theoretical presentation + individual exercise + working groups + debriefing

Module Description

- GM Feed (emphasis on consisting of, containing or produced from GMOs).
- "Genetically modified organism" vs "gene editing".
- Scope and basic principles of the EU legislation in relation to GM food and feed, with special attention to the authorisation procedure, the EU Register of GM food/feed and on the low level presence of non-approved GMOs in imported feed.
- Search in the EU Register of authorised GMOs.
- Synthesis and explanation of the specific EU rules concerning the labeling and traceability of GM feed, including some examples of labels.
- Sampling and analysis of GM feed for which an authorization is pending or has expired.

Group discussion: Feed additives produced from GMOs.

Case study/exercise on GMOs labeling - application of the 0.9% threshold level for labelling in case botanical impurities of other plant species are present in feed materials. Participants evaluate the analytical report of a feed in the light of Reg. EC 679/2011 and the consequences for correct interpretation of laboratory results.

Key concepts, information and messages for this module

In 2003, two new Regulations were adopted by the EU Council and Parliament in order to deal specifically with genetically modified (GM) food and feed. The first of these, Regulation (EC) No. 1829/2003 (called "GM Food/Feed") is the main piece of legislation that deals with the general framework for regulating genetically modified (GM) food and feed. It establishes the EU authorization procedure for GM food and feed and also the labeling rules. The second piece of legislation, Regulation (EC) No. 1830/2003, complements the first Regulation and mainly focusses on specific traceability rules and some additional labeling provisions.

In order to complete the picture, there are also two EU Directives in the field of GMOs. Directive 2001/18 mainly deals with the release of GMOs into the environment (cultivation, field trials). Finally, Directive 2009/41 covers the use of GM micro-organisms under contained use conditions (laboratory scale).

Scope - Products covered

The GM Food/Feed Regulation applies to three types of products:

- genetically modified organisms (= "living" organisms that are still able to reproduce) for food and feed use;
- food and feed containing GMOs (partially or totally);
- food and feed produced from or containing ingredients produced from GMOs.

On the other hand, products "produced with" a GMO are out of the scope of the Regulations. They concern, for example, animal products (meat, milk, eggs, etc.) derived from animals that were fed with GMOs and processing aids used during the production of food or feed.

Definition of GMO as laid down in Art. 2 of Dir. 2001/18
Living organism (except human beings) in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
e.g. GM maize, soybean, oilseed rape, … with increased resistance to certain insect pests and/or tolerance to total herbicides.

Definition of 'contained use' means any activity in which microorganisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment

Court of Justice of EU PRESS RELEASE No 111/18 Luxembourg, 25 July 2018

Unlike transgenesis, mutagenesis is a set of techniques which make it possible to alter the genome of a living species without the insertion of foreign DNA. Mutagenesis techniques have made it possible to develop seed varieties which are resistant to selective herbicides.
Confédération paysanne is a French agricultural union which defends the interests of small-scale farming. Together with eight other associations, it has brought an action before the Conseil d'État (Council of State, France) in order to contest the French legislation which exempts organisms obtained by mutagenesis from the obligations imposed by the directive on genetically modified organisms (EC 2001/18). In particular, that directive provides that GMOs must be authorised following an assessment of the risks which they present for human health and the environment and also makes them subject to traceability, labelling and monitoring obligations.
Confédération paysanne and the other associations argue that mutagenesis techniques have evolved over time. Prior to the adoption of the GMO Directive, only conventional or random methods of mutagenesis were applied in vivo to entire plants. Subsequently, technical progress has led to the emergence of in vitro mutagenesis techniques which make it possible to target the mutations in order to obtain an organism resistant to certain herbicides. Confédération paysanne and the other associations take the view that the use of herbicide-resistant seed varieties carries a risk of significant harm to the environment and to human and animal health, in the same way as GMOs obtained by transgenesis.
It is in this context that the Court of Justice has been requested by the Conseil d'État to determine, in essence, whether organisms obtained by mutagenesis are GMOs and whether they are subject to the obligations laid down by the GMO Directive.
In today's judgment, the Court of Justice takes the view, first of all, that organisms obtained by mutagenesis are GMOs within the meaning of the GMO Directive, in so far as the techniques and methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally. It follows that those organisms come, in principle, within the scope of the GMO Directive and are subject to the obligations laid down by that directive.
The Court states, however, that it is apparent from the GMO Directive that it does not apply to organisms obtained by means of certain mutagenesis techniques, namely those which have conventionally been used in a number of applications and have a long safety record. The Court nevertheless specifies that the Member States are free to subject such organisms, in compliance with EU law (in particular the rules on the free movement of goods), to the obligations laid down by the GMO Directive or to other obligations. The fact that those organisms are excluded from the scope of the directive does not mean that the persons concerned may proceed freely with their deliberate release into the environment or with their placement on the market within the EU. The Member States are thus free to legislate in this area in compliance with EU law, in particular with the rules on the free movement of goods.

Authorisation Procedure – EU Register of GM Food and Feed

To be eligible for authorisation, food and feed containing, consisting of or produced from genetically modified organisms (GMOs) must not:

- Have adverse effects on human health, animal health or the environment;
- Mislead the consumer;
- Differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

Applications for authorisation are to be made to a 'national competent authority'. The application is without delay, forwarded to the European Food Safety Authority (EFSA) which informs the Commission, Member States and the public on the application.

During this risk assessment process, Member States may send comments to EFSA on the application. In parallel, the Community Reference Laboratory (ISPRA, Italy) tests and validates the method of detection and identification as proposed by the applicant. In case the application also covers the cultivation of a GMO, EFSA has to delegate the environmental risk assessment to a Member State.

The Commission, as risk manager, has three months to draft a decision granting or denying the authorization in the European Union's Official Journal.

Authorisations are valid throughout the European Community for ten years on a renewable basis, and they are entered into a publically available Community Register of Genetically Modified Food and Feed (see http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

Low level presence of non-approved GMOs

From a legal point of view, the presence of non-approved GMOs in imported products is not allowed (zero-tolerance). The harmonisation of rules for the controls of non-authorised GM feed that is pending approval for more than three months or feed materials that were authorised in the EU but for which the authorisation has not been renewed or will not be renewed due to phasing out is thus addressing the current uncertainty that EU operators face when placing feed on the market. This was done by Regulation EC 619/2011 (in force since 15 July 2011). This Regulation covers only GM feed material (not applicable to food!)

It sets a technical tolerance for the presence of non-approved GMOs at 0.1 %. This is the lowest level of GM material considered by the EU Reference Laboratory for the validation of quantitative methods. It is the lowest level where results are satisfactorily reproducible between official laboratories when appropriate sampling protocols and methods of analysis for measuring feed samples are applied.
It harmonises the sampling procedures and analytical testing protocols in all EU countries, and the way the results of analysis have to be presented and interpreted.
The Commission is keeping an up to date list of GM material fulfilling these conditions on its website (see http://ec.europa.eu/food/food/biotechnology/harmonisation_of controls_en.htm).

Labelling and traceability

All the products covered by this Regulation are subject to compulsory labelling, which shall enable consumers to be better informed and will offer them the freedom to choose/ buy products consisting of, containing or made from GMOs.
In general, all food and feed products containing GMOs and/or products “produced from” GMOs must be labelled as such. The words ‘genetically modified (name of the organism)’ or ‘produced from genetically modified (name of the organism)’ must be clearly visible on the labels of these products (in

the same font size as the other declarations on the label). This GMO labelling should be done in the list of feed materials (in parentheses after the name of the feed material) or as a footnote to that list.

There is one exemption to this general rule: food and feed products which contain a proportion of GMOs of less than 0.9 % of each ingredient (e.g. feed material) do not have to be labelled as GMO on the condition that the presence of the genetically modified organism is adventitious or technically unavoidable.

Traceability enables GMOs and their products to be traced throughout the production chain. This system is based on the transmission and holding of information by each operator.

The specific rules on traceability for feed containing or produced from GMOs are presented. Specific rules for prepackaged produts are also introduced.

All this information regarding traceability should be transmitted throughout the feed chain: from the first time the product is put into the market (e.g. import) until the end user (which is the farmer in case of feed).

Module 3.3 Feed ban

Tutor(s): Christophe Keppens
Duration: 45 minutes
Format: Theoretical presentation + Group exercises
Aids if any: Quizizz Internet Tool

Module Description
• TSE prevention, eradication, control strategy and role of the feed-ban. • Feed-ban requirements and analysis. • Overview of current possibilities and future changes – legal framework. • EU register of FeBOs applying derogations of specific conditions on feed ban.
Group discussion: Practical cases on the application of the derogations of feed ban requirements.
Exercise on interpretation of feed-ban analytical results.

Key concepts, information and messages for this module

What is a prion?

Prions or Proteinaceous infectious particles are particles that originated from certain proteins that are present, amongst others, in brains. They are abnormally folded versions of those proteins. An important characteristic of prions is that they cannot longer be broken down by proteases. However, the most peculiar feature of prions is the ability to provoke a change in proteins that are still in the normal configuration upon contact. This ignites a chain reaction resulting in the situation that all source proteins in the cell will have the altered, misfolded configuration. The affected neurons in the end die, giving raise to neurological signs in the animals which will eventually die of the disease. Prion diseases were for a long time a mystery. The diseases proved to be experimentally transferable

and therefore were counted with the infectious diseases. But the agent causing the disease was smaller than any bacterium or virus known. In 1982 Stanley B. Prusiner proposed a new infection principle and launched the term prion. In 1997 he received therefore the Nobel price in medicine, but at the time he first proposed his theory that proteins could cause these mysterious diseases, few of his colleagues believed him. It was the greatest discovery of microbiology in the 20th century since until then the doctrine was that pathogens contained DNA or RNA that withhold the genetic codes of these living organisms. Now a new agent was able to reproduce itself without a genetic code but only with the product of the biosynthesis.

How to eliminate prions

Prions are highly resistant to disinfectants, heat, ultraviolet radiation, ionizing radiation and other routine methods of decontamination and sterilization. No single method has been shown to be 100% effective against prions. For example, the classic treatment of 121°C for 15 minutes will result in a complete sterilisation for bacteria, viruses and fungi, but has little or no effect on prions. Even the very harsh pressure sterilisation method 1 of the animal by-products Regulation (133°C for 20 minutes (at 3bars moist heat)) will only have a 3 log reduction in infectivity as result.

For this reason the main barrier for elimination or reducing the disease in the animal population is a physical barrier. One must prevent potential infected material from coming into contact with susceptible animals (or humans).

The TSE prevention system

Given the tenacity of prions, the BSE (or generalized TSE) prevention system does not rely on one single barrier for the disease. The system depends on multiple ban, treatments or barriers that the causing agent must overcome. The multiplication cycle of BSE and the main barriers are illustrated in the figure.

These main barriers are the removal of Specific Risk material (SRM) within the feed and food chain, the requirement to render animal by-products and finally the feedban. Surveillance, and the stamping out (culling) of disease after a positive case, are often seen by the general public as the measure that must prevent mad cow disease. However, this requirement has only limited impact on the whole population since detection is far from certain. This measure is used to see the effectiveness of the real preventive measures. This is the reason, together with the changing epidemiological situation, why the age of testing for BSE for slaughtered or dead animals was more 'volatile' than the SRM list of materials, feedban or animal by-product rules.

The feedban

Based on the findings that the causing agent is transferred via the reuse of animal proteins a ban on the feeding of mammalian processed animal protein to cattle, sheep and goats was introduced in July 1994. Cases born after this ban are called 'born after the ban (BAB cases). The ban was expanded in January 2001 with the feeding of all processed animal proteins to all farmed animals being prohibited, with certain limited exceptions. This is to ensure that there is no cross-contamination between feed containing PAP intended for species other than ruminants and feed intended for ruminants. Only certain animal proteins considered to be safe (such as fishmeal) can be used, and even then under very strict conditions. The cases born after this ban are called 'born after the reinforced ban (BARB cases).

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

The feedban is laid down in Article 7 and annex IV of Regulation (EC) 999/2001 (the TSE regulation). The feedban (what can be fed?) can be summarized in the table.

The regulation also lays down other requirements to ensure a complete separation through the feed and food chain by preventing cross-contamination with unauthorised animal proteins.

How the authorised materials must be made/produced is laid down in the animal by-product Regulation (RE 1069/2009 and 142/2011). Thus one can say that the TSE Regulation says what can still be fed and the ABP regulation imposes how these feedingstuffs must be made. The two sets of legislation work together to ensure safe feedingstuffs as regards TSEs. Commission Regulation (EC) 103/2009 amending Annexes VII and IX to the TSE Regulation sets out a ban on the use of milk and milk products coming from classical scrapie infected flocks for feeding ruminants.

On 1 June 2013 an important modification of the feedban took place, i.e. the reauthorisation of processed animal proteins (PAP) of non-ruminants to aquaculture animals. This relaxation could only be done after the development of new analytical techniques enabling the identification of ruminant proteins in those PAP. On 1 July 2017 the last modification was done by authorising insect PAP of 7 farmed insect species for aquaculture animals. This created an important outlet for the upcoming insect industry of Europe. The 7 authorised species are Black soldier fly (Hermetia illucens), Common Housefly (Musca domestica), Yellow Mealworm (Tenebrio molitor), Lesser Mealworm (Alphitobius diapernus), House cricket (Acheta domesticus), Banded cricket (Gryllodes sigillatus) & Field cricket (Gryllus assimilis). Since the common name of insects is often mixed up or multiple common names are in use, be sure to use the Latin names as reference.

The next step is to enable the feeding of non-ruminant PAP to other non-ruminants, taking into account the anti-cannibalism ban as laid down in the ABP regulations. In order to take this step again new analytical techniques will need to be developed in order to verify the absence of proteins of the species to which the PAP will be given.

Analysis used to test conformity

The official analytical method for the detection of constituents of animal origin in feedstuffs is the microscopic examination technique. The method specifies the examination of treated samples under compound and stereo-microscopes at several magnifications to identify bone constituents mainly. In 2013, a second official method was added to the toolbox of the control authorities in the EU a PCR method. The PCR or Polymerase Chain Reaction enables through genetic amplification the detection of well-defined taxonomic related DNA. In the first half of 2013 the method for ruminant DNA was already available in the EU. The implementation for other species was under development (next one would be porcine DNA).

Module 3.4 Animal by-products in animal nutrition

Tutor(s): Christophe Keppens
Duration: 60 minutes
Format: Theoretical presentation + group exercises
Aids if any: Quizizz Internet Tool

Module Description
• Principles of the ABP regulation. • ABPs categorisation and risks. • ABP requirements for the feed industry and operators checks by CA to verify compliance. • Traceability requirements within one country and the way ABP are moved between MS.
Group discussion: Practical cases on the application of requirements for ABP and derived products not intended for human consumption.
Exercise related to checks and the role of feed inspectors to verify that suppliers and clients are authorized to send/receive/use ABP/derived products.

Key concepts, information and messages for this module

What are ABPs?

Two basis questions one needs to ask himself to determine if a product is an ABP. First, is the product of animal origin and second is it not destined for human consumption? The first question is often considered 'too narrow'. One only considers the most obvious parts of animals like meat and bones, dead carcasses. However, every part or product of an animal must be considered. Blood, hoof chips, discarded exoskeletons... all answer the first question positive. So, think beyond the obvious and take anything of an animal into account. The second question, however, is sometimes considered 'too small' and sometime 'too large'. When answering this question too small one confuses the words 'not destined for' with 'not suitable for'. The correct wording (not destined for) reflects an intention (by decision) or a ban (by law). The decision not to send something for human consumption can be pure commercial, having nothing to do with the quality or safety of the product. So not to destine it for human consumption can be decided by the will of the operator or by law (one may not send it for human consumption).

When answering the previous two questions positively, the next question to answer is if the products are not explicitly taken out of the scope. A last question to solve is to see whether an end point is applicable. The end point was introduced for ABP that do not have a natural end point where they 'seize to exist' like when they are orally fed to animal, destroyed by burning or taken up by the soil as fertilizer. Some ABP will last a long time. Therefore, the EU legislation foresees the option for the legislator to put an end to the ABP requirements when the safety issues are satisfactory addressed.

How are ABPs categorised?

All ABPs are put into one of three possible categories. Category 1 is the category where ABPs carrying a TSE risk, the risk of banned products or contaminants are put into. The list is an exhaustive list. Category 3 is also an exhaustive list and comprises ABP of 'healthy animals'. Category 2 material is an open list, meaning when one cannot find a description of the ABP in category 1 or 3 it automatically falls into category 2. ABPs like manure or ABPs containing residues of authorised product all fall into category 2.

Which destinations are possible?

The destinations of ABP are many. The higher the risk category, the more limited the possible destinations are. Rendering (or processing as it is called in the ABP regulations) is used as an intermediate step. In this step the water is taken out of the material, the remainder is split into fat and proteins.

The classic destinations of category 1 material are (co-)incineration, or combusted (as a biofuel). These are the most common routes for category 1 disposal. However legally, and if (a big if) the other applicable legislation permits, it can even be used in cosmetics, medicines and medical devices also technical destinations are possible if the competent authority permits it after being proven that the use is safe.

Category 2 can in addition of the category 1 destinations, be used for biogas, composting, fertilisers and soil improvers. For category 3 the option of feeding is open (if the feedban does not ban it). Of course the legislation foresees some specific derogations to these general destinations and takes into account specific situation (like crises and natural catastrophes).

How are ABPs processed into feed materials?

Before ABPs can be used in animal feeding they need to be processed in some way to make them safe, and/or suitable for feeding. For each of the feedingstuffs still allowed by the feedban in Regulation (EC) no. 999/2001 specific requirements apply for the raw materials, heating, etc (see annex X for feeding materials and annex XIII for petfood).

Three systems for feeding animals with ABP

The use of animal by-products (ABP) in feed can be divided into three distinct types of feeding. Each type have his peculiarities, requirements and types of operators involved.

First one can use ABP as feedingstuffs in the feed of farmed animals, i.e. animals held by humans to use a certain part of the animal. This type of feeding is the most critical type since there will be direct contact between the feeding chain and humans, bringing the risk of zoonoses with it. No wonder then

that this destination is one of the most regulated, with the most restrictions. Different bans must ensure the safe use of some of these materials, preventing a.o. the spreading of BSE, Salmonella and other dangers to humans, via animals through feed.

A second type of feeding is the feeding of pet animals, i.e. the feeding of animals kept by humans for their companionship. The restrictions and required treatments are listed in Annex XIII of Regulation (UE) No. 142/2011.

A third and last type of feeding is what is called in the regulation 'special feeding purposes'. This is the feeding of all kinds of specific types of animals like zoo and circus animals, bird of prey, wild animals, etc. Which types of operators are involved in this sector and what do they need? An overview of which categories can be used and type of animals of destination are presented.

How must I transport the ABP and derived products in the feed chain?

For all these types of feeding specific rules on how these products must be placed into the market are imposed. The participants receive a comprehensive overview on how to transport and label ABP and how the list of operators available on the internet can be used to perform checks on ABP operators.

Module 3.5 Microbiological contamination

Tutor(s): Christophe Keppens
Duration: 90 minutes
Format: Theoretical presentation + group exercises
Aids if any: Quizizz Internet Tool

Module Description
• Microbiological contaminants of importance in feed - Which contaminants are important and in which kind of feeds. • Overview of the EU legal framework and strategy. • Sampling methods and plan. • Methods of sterilisation. • Focus on salmonella and risk management tools available to the feed business operators. • Some national strategies.
Group discussion: Performance of sampling plans and discussion.
Exercise on microbiological contamination prevention and/or elimination.

Key concepts, information and messages for this module

Which microbiological contaminants?
In feed materials and compound feed different microorganisms can be present. In its 2008 microbiological risk assessment on feedingstuffs for food-producing animals, the Panel on Biological Hazards from EFSA identified Salmonella spp. as the major hazard for microbial contamination of feed. Campylobacter, Listeria monocytogenes, Escherichia coli O157: H7 and Clostridium sp. are other microbiological hazards but for which feed is regarded as a far less important source for

contamination. In addition, antimicrobial resistant bacteria, or antimicrobial resistance genes can be transmitted via feed.

Over 2500 different serotypes of Salmonella have been identified. Although many of these serotypes are capable of initiating localized gastroenteritis in humans, Salmonella enterica serovar Enteritidis and Salmonella enterica serovar Typhimurium represent the most significant foodborn pathogen serotypes.

Multiplication of Salmonella

Salmonella growth requires warmth (35-37°C is optimal), a moisture content greater than 12% and a pH between 4,5-9,0. It is no coincidence that the gut of many animals can provide Salmonella everything it needs to thrive. When animals become infected most Salmonella are carried in the gut of the animals and subsequently contaminate the environment, including the animals, feathers, skin and feet. By this way, Salmonella then spreads within the herd or flock.

EU legislation on microbiological contaminants

The EU legislation is for the moment not very assertive for microbiological contaminants in feed. Hence, one must resort to the more general legislation in which feed is sometimes part of a more general approach. Directive 2003/99/EC states that the MS must monitor different zoonoses, including salmonellosis. This monitoring must also include the feed part of the food chain. Regulation (EC) 2160/2003 lays down the obligation of the MS to implement a control program against Salmonella. So these two general pieces of legislation can form the basis of the national monitoring programmes and the measures in case of positive findings. The remaining question is then what is a positive find, hence what is the norm applicable to feed for Salmonella? At present no overall feed norms are implemented in the EU nor are there initiatives to lay them down in the near future. Only a general obligation in article 5 point 3 of Regulation (EC) 183/2005 states that “feed business operators must comply with specific microbiological criteria and implement measures to meet targets”. What these specific targets are, is until now not laid down. The only feedingstuffs that have clear EU limits for Salmonella (and enterobacteriaceae) are animal by-products (e.g. bloodproducts, gelatin, fishmeal...). In the implementing regulation (EU) 142/2011 of Regulation (EC) 1069/2009 it is stated that Salmonella must be absent in 25g (n=5, c=0, m=0 and M=0) (for enterobacteriaceae the limit is n=5, c=2, m=10 and M=300 in 1g).

Sampling, of primordial importance

Sampling is an often overlooked area when microbiological information of the products or the system is gathered. The goal of sampling is to have a sample that reflects the situation of the batch or system that is subject to the investigation. Since we want to be certain that a detected contamination in the feed came from the sample and not of the hands of the person collecting the sample or of the material used for the collection, hygienic sampling cannot get too much attention. In a study where the mill personnel and researchers collected samples from many of the same location the results of the samples of the mill personnel showed 43,75% positive samples, while only 7,32% of the research samples where positive. A simple, practical sampling procedure and material fit for job must therefore be available for the inspector together with sterile materials for sampling and transport of the sample.

A procedure indicating how the asseptic method should be implemented during feed sampling, a sampling technique, hot spots description (which are parts of the feed or infrastructure of a feed plant with a higher chance of Salmonella presence) and how the samples should be stored and transfered to the lab is a must.

Risk management tools

STEPS TOWARDS CONTROL OF MICROORGANISMS IN THE FEED MILL

Control of microbial pathogens in feeds and feed mills involve procedures to:

Exclude pathogens from the feed. Prevent multiplication of the organism in the feed. Kill pathogens within the feed and prevent recontamination.

EXCLUDING THE PATHOGENS FROM THE FEED

First- The primary route of entry in the feed is via the ingredients, vermin within the mill or cross contamination in the mill. It is important to obtain clean ingredients. High-risk products are animal proteins, oilseed meals, such as soybean, cottonseed, rapeseed, palm kernel and canola, grain and grain byproducts, such as wheat millings. However, any ingredient can be contaminated. Buying from reputable suppliers that implement pathogen control measures is the first step.

Second - Verify the ingredient quality by checking the ingredient for signs of infestation (such as bird or rat faeces), moisture, insects or rodent attack before acceptance. Truck and rail cars should be checked for cleanliness.

Third - Maintain a clean receiving area. Feed spillage should be cleaned up immediately in order not to attract birds and rodents. The receiving area should be free of pests, have a hard-surfaced floor and be well drained and covered. Treadmills collect dust which is a source of contamination. Air currents and machine vibrations can cause accumulated dust and dirt to drop from the treadmills into the feed ingredients. Thus treadmills, false ceilings, overhead beams and girders must be regularly cleaned.

Fourth- Control dust. Dust or caked material should be eliminated as much as possible. These materials provide the microorganisms a medium for survival or growth. A dust collection system is important. Venting to the outside must be separate from the intake. Install filters. Filters should be installed on intakes through which air is being drawn to cool pellets. A schedule should be established to replace filters frequently and routinely. Circulating air from the finished product area to the raw ingredients area will minimize airborne contamination.

Fifth- Clean up feed spills. These spills provide a medium for the pathogens and cause cross-contamination. Only reuse the material if it is visual clean and recovered quickly. Always discard wet material.

Sixth- Store the feed in proper conditions. Separate bulk mash feed for pelleted feed. Pelleted feed can easily be cross contaminated by feed that has not been heat treated. Pack feed in new or properly sanitized bags or recipients. The structures, containers or bins should be able to keep out moisture. Specific bins should be designated exclusively for storage of high-risk ingredients (see above). Dedicated delivery lines for these high-risk ingredients is a plus.

PREVENTING MULTIPLICATION OF PATHOGENS IN FEED

The lack of moisture is the primary reason microorganisms mostly cannot multiply in feed. So the prevention of multiplication will focus on moisture prevention. First, obvious sources of moisture such as roof leaks, uninsulated pipes or areas where wind can blow in rain must be eliminated. Water should not be used to clean the feed installations unless there is no alternative.

High humidity areas of conveying equipment are a second ideal reason for the contamination of feed passing through the installation. Avoid dead ends in this conveying equipment. Third, when a heat treatment is used (pelleting of extrusion) the cooler is the ideal vehicle to multiply and transfer pathogens. Dust and cakes must be eliminated by dry-cleaning procedures. Disinfection of the cooler can help addressing persistent microbiological problems.

KILLING THE PATHOGEN AND PREVENT RECONTAMINATION

The killing of certain spore-forming pathogens requires temperatures of 121°C for 15min. This method is the standard to presume complete sterility (except prions). This treatment is not implementable in feed mills. There are only two practical methods to reduce pathogens in feed: pelleting or extrusion and chemical treatment. Pelleting will not eliminate pathogens form feed and feeds can be recontaminated after the pelleting process. For Salmonella control, however, pelleting has shown to be effective, but it depends highly on the formula. Extrusion of expansion overcomes some quality issues linked to pelleting and it involves higher temperatures than pelleting. Thus it should be more effective. However, all these methods involve a cooling afterwards to remove excess heat and moisture. As stated above, this is a critical stage in the method. In addition, heat treatments have no residual activity, so feed are not protected afterwards against recontamination.

Chemical preservatives are used to kill pathogens in feed. Most of the internationally used products contain propionic or formic acid or salts of these acids. Formic acid has been shown to be more potent than propionic acid, however the result is influenced by the 'history' of the feed (heat treated or not). Formic acid is at present the only additive authorized in the ‘hygiene condition enhancers’ group. Formaldehyde has been shown to prevent the multiplication of pathogens. However, formaldehyde is at present not authorized in the EU and the application as a hygiene enhancing additive was denied, due to carcinogenic risks when inhaling the product.

Module 3.6 Undesirable substances

Tutor(s): Kristina Roerbo

Duration: 90 minutes

Format: Theoretical presentation + working groups + debriefing

Module Description
• Undesirable substance in feed: occurrence and origins. • Main principles and objectives of the EU requirements. Highlight on the most recent and upcoming changes. • Overview of other rules related to chemical contaminants in feed (like dioxin monitoring, pesticide residues, mycotoxins). • Detoxification processes: criteria and legal requirements.
Group discussion: Maximum Admissible Levels *vs* Maximum Residue Limits vs Guidance Values.
Exercise on chemical contaminants: • Participants have to answer a series of questions related to maximum contents/action tresholds of undesirable substances, or maximum residues limits of pesticides, in feed. • Real analysis reports are provided for evaluation by the participants.

Key concepts, information and messages for this module

The first EU legislation on undesirable substances dates back from 1974 (Directive 74/63/EEC). After a whole series a severe food and feed crisis in the EU, the Directive 2002/32/EC was adopted. The general principles of the EU rules concerning the presence of chemical contaminants in feed are embedded in the directive. Products intended for animal feed may be imported marketed and used in the EU only if they are sound, genuine and of merchantable quality. It is explicitely foreseen that it is

forbidden to import, market or use feed that does not comply with the provisions of the Directive, including the maximum levels as fixed in annex I of the Directive. If maximum levels are exceeded, investigations should be triggered by Member States and feed business operators in order to to identify the sources and origin of the undesirable substance and steps should be taken to reduce or to eliminate these sources. The scope of the Directive only applies to feed and not to drinking-water for animals. According to the directive it is not possible to “dilute” contaminated feed. Detoxification of contamined feed is allowed by chemical treatment. A new detoxification regulation entered into force in 2015 (2015/786), and requires approval of detoxification method by EFSA, and national approval of the detoxifying company.

Annex I sets maximum levels for heavy metals and nitrogenous compounds, certain mycotoxins (aflatoxin B1, rye ergot), certain inherent plant toxins (free gossypol, hydrocyanic acid, theobromine, volatile mustard oil), organochlorine compounds (aldrin, dieldrin, DDT, endosulfan, and other « old » pesticides), dioxins and PCB’s, harmfull botanical impurities (Datura spp, Crotalaria spp, Brassica spp, Ambrosia spp …) and coccidiostatika as feed additives in non-target feed following unavoidable carry-over. Different maximum levels are set for different types of feed. Besides maximum levels, the Directive 2002/32 also sets “action thresholds” for dioxin and dioxin.like PB´s. It is important to note that no withdrawal from the market is needed on condition that the maximum levels as fixed in annex I are respected. In Regulation 183/2005 and Regulation 152/2009 additional specific measures are set for Feed Business Operators regarding analysis for dioxins and PCBs.

A scientific opinion from EFSA concluded that the the presence of Deoxynivalenol, Zearalenone, Ochratoxin A and Fumonisins in animal feed exhibit toxic effects in several animal species, but is not a greater problem in food of animal origin for human consumption because of very limited carry over to meat, milk and eggs. It was agreed to collect more data on the presence of these mycotoxins, and a EU Recommendation 2006/576 on the collection oaf data was set in force. The recommendation also introduces guideline values to limit the presence of these mycotoxins, as upper guidance values. For feed for more sensitive animals, it shalld be ensured that lower guidance values are applied. As regards T-2 and HT-2 toxins the carry over from feed to food of animal origin are also very limited. Based on the same arguments as above (large year to year variation in occurrence, depending from climatic conditions), the EU Commission adopted a Recommendation 2013/165/UE in order to collect more data by monitoring. For these two mycotoxins investigations shall be undertaken in case of repetitive findings. Indicative values are set; these are, purely based on occurrence data, and not on safety.

The Regulation 396/2005 covers all agricultural products intended for both food and feed. MRLs are set for each combination of a crop (annex I) with an active substance (annexes II/III). These MRLs have been set on the basis of an acceptable daily intake (ADI) and Good Agricultural Practices (GAP) and are continuously being updated. MRLs apply only for feed when the products can be considered used both as food and feed; this means that the Feed Business Operator and Competent Authority have to assess at product level, if the product can also be used as feed. If so the MRL applies. If not, no MRL applies. MRLs also apply to the same products after processing, if adjusted to take account of dilution or concentration during the process (the so-called processing factors). Where no MRL is set, a general default MRL of 0.01 mg/kg applies. As regards feed, a specific category (code no. 12) of products is included in annex I of the Regulation: “crops exclusively used for animal feed”. Currently this category is still empty and the individual products are not yet listed. As for contaminants with maximum limits in the directive for undesirable substances, a ban on dilution also applies for pesticide residues.

Module 3.7 Additives in feed

Tutor(s): Kristina Roerbo
Duration: 120 minutes
Format: Theoretical presentation + exercise + debriefing

Module Description
• Scope and basic principles of the EU rules concerning authorization and marketing of feed additives. • Current labeling provisions for feed additives and premixtures including the CLP Regulation. • Feed additives authorizations: EU approval procedure for feed additives with a detailed description of the role of EFSA, the CRL and the EU Commission in this process. • Authorisation of Feed Aditives produced from GM microorganisms strains. • Overview of the existing guidelines and guidance documents for feed additive applications. • Requirements for production and export of Feed Additives non-authorized in the EU. • EU Feed Additive Register: Demo and general overview on the information contained in the EU Register of Feed Additives, the new numbering system for feed additives, the ongoing re-evaluation procedure for existing feed additives and the withdrawal from the market of certain feed additives.
Group discussion: EU Register of Feed Additives.
Exercise on categorization and labelling of feed additives / premixtures: • Participants have to answer a series of questions related to the labeling of feed additives / premixtures. • Real labels are provided for evaluation by the participants.

Key concepts, information and messages for this module

During the first presentation the general objectives and scope of the EU rules on feed additives (Regulation 1831/2003) will be summarized, the different categories and functional groups of feed additives will be highlighted and a detailed overview of the labelling rules for feed additives and premixtures will be given. In this presentation rules regarding non-EU-authorised additives for export will be mentioned. In a second presentation, the EU authorisation procedure for feed additives will be explained and the distinctive roles of EFSA, the EU Commission and the European Union Refererence Laboratory (EURL) will be specified. In the 3th presentation, the background and purpose of the EU Register of Feed Additives will be presented and the participants will be made more familiar with the information contained in this Register and where to find it. Finally in the 4th presentation possible new rules regarding non-EU-authorised additves for export will be reviewed. With these theoretical modules as a background, participants will then be presented for 2 practical exercises. Participants will have to wwork in groups and find mistakes, inconsistencies and gaps on a label of a feed additive or a premixture based on the information that wereas given to them.

Feed additives are defined as substances, microorganisms or preparations which are intentionally added to feed or water in order to favourably affect the characteristics of feed, animal products, animal production, the colour of animals or the environment, satisfy the nutritional needs of animals or having coccidiostatic or histomonostatic effect. 5 categories of additives are set for this purpose. Within these categories, feed additives are further allocated to one or more functional groups as described in Annex I to Regulation 1831/2003. The EU Commission has the power to establish new

additive categories or functional groups, in case this is necessary as a result of technological progress or scientific development. Premixtures are defined as mixtures of different feed additives or mixtures of one or more feed additive with feed materials or water used as carriers. They are not intended for direct feeding.

It is important to note that antibiotics can no longer be authorised as feed additives. Since 2003, the use of antimicrobial growth promotors has been phased out in the EU and a complete ban on the marketing and use of these substances is applicable since January 2006. Processing aids, which are substances that are intentionally used in the processing of feed in order to fulfil a certain technological purpose during treatment or processing, are not considered to be feed additives.

Non-EU authorised additives cannot be marketed in EU, but according to art. 12 in regulation 178/2002, they can be marketed in third countries if safe. Regulation of import, manufacturing, holding and export of non-EU authorised additives have been discussed in the PAFF-Committee. There are at the moment no specific community rules on this area, but some rules have been discussed.

All feed additives placed on the market or imported in the European Union must be covered by an authorisation under Regulation 1831/2003. This means that each feed additive has to undergo a series of tests to demonstrate safety and efficacy. Feed additives and premixtures, when marketed in the EU, have to respect the labelling rules as fixed in Regulation 1831/2003 and shall not be presented in a manner that may mislead the user. Regulation 1831/2003 sets out labelling requirements for additives and premixtures, in article 16 and annex III. The name, ID-number and functional group have to be included, together with information on the responsible company. Directions for use and any safety recommendations also have to be present on the label, together with batch reference number and date of manufacture. Annex III provides specific labelling requirements depending on the category or functional group. Finally, there might be other horizontal labelling requirements that should be respected, e.g. GMO labelling.

Feed additives may not be put on the market unless an EU authorisation has been given after a scientific evaluation. This authorisation procedure is fully harmonised at EU level. There are 3 main EU institutions that are involved in this authorisation procedure, (1) The European Food Safety Authority (EFSA) that is competent for the risk assessment of the feed additives, (2) The EU Reference Laboratory (EURL) that is competent for the evaluation of the methods of analysis, and (3) the EU Commission that is competent for granting (or denying) the authorisation of the feed additives. Based on the outcome of the EFSA assessment the EU Commission shall prepare a draft Regulation to grant or to deny authorisation. The proposal is presented to the Standing Committee on the Food Chain and Animal Health (SCoFCAH), section “Animal Nutrition”. Based on the discussions and input from the Member State experts, the EU Commission modify their proposal, and a formal vote is given. Each Member State has a certain voting weight depending on the population number of the Member States. If a Qualified Majority voting in favour is achieved, the proposal is adopted. New authorisations that are generally granted for a period of 10 years. After these 10 years, the authorisation may be renewed for another 10 years. Currently, there are still a significant number of existing feed additives that are authorised “without a time limit”. This system however will be gradually ‘phased out’ and these authorisations also will be converted into 10 years authorisations once the re-evaluation of these existing products is finalized. For feed additives, most authorisations are granted on a generic basis.

Every feed additive that is authorised is entered in the EU Register of feed additives (= EU positive list of authorised feed additives). This Register was established in November 2005 based on an EU wide notification procedure for “existing” products. Under the “existing” feed additives are included: additives already authorised in application of EU Directive 70/524/EEC, silage additives for which no EU harmonisation existed, amino acids, their salts and analogues and urea and its derivates that were coming over from Directive 82/471 on bioproteins. The Register is maintained and regularly updated by the EU Commission and is made public via the website of the EU Commission. The authorisations for the products in annex II, i.e. additives that are not going to be re-evaluated and -approved, will be withdrawn by the EU Commission.

Questions and answers related to Topic 3

Will be provided with the Second Interim Report.

Topic 4: Application in the feed industry: field visits

Specific objectives of Topic 4:

A field visits to a feed mill is organised with the aim of increasing the experience of the participants on:

- what the lay-out of a typical production line is used in the EU for compound feed (or premix, or petfood) production;
- how a feed inspector should get prepared to a field visit;
- which the main points of interest are, where the attention of a feed inspector should be directed to during an on-the-spot control;
- how official control with auditing technics can be performed within the given timeframe;
- how legislation provisions should be verified against, or conferred with, the practical findings;
- how the control should be concluded in the office after the on-the-spot visit.

An additional visit to an Entry Point/Designated Entry Point/Border Control Post (EP/DEP/BCP) located at a sea port level is also foreseen, in order to get the knowledge and recognise the best practices necessary to control feed imported from third countries.

Module 4.1 Field visit preparation

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

Module Description
• General introduction to a feed mill and to an EP/DEP/BCP organisation and functioning. • Specific documentation of the company/-ies. • Specific national guidelines (if applicable). • Goals and expectations related to the visit(s). • Logistical organisation.

Key concepts, informationand messages for this module

Participants are prepared for the field visit.
Preparation of logistical arrangments:

- suitable clothing;
- behavioural and accident prevention rules (keep with the group);
- health rules;
- confidentiality rules (e.g.: no picture policy);

Preparation of professional goals:

- a detailed questionnaire is compiled, which interrogates all the aspects of a FeBO an inspector might need for a general control of the establishment; the questionnaire is transferred to all FeBOs which were volunteering to be the subject of the visit; answers are reducted for the participants;participants are given the data from the questionnaire;

- the pre-control preparation of the inspector is imitated by going through the data with the participants so that they become acquainted with the activities performed, type of raw materials used, and end products produced in the establishment.

Data also include key information on quality control, like CCPs, corrective actions, etc.

In case of EP/DEP/BCP a characterisation file of the competences, premises and controls carried out in the feed is available.

Module 4.2 Field visits

Tutor(s): Jose Costa / Marot Hibbey
Duration: 375 minutes
Format: Field visits

Module Description
Visit of 1 FeBO (feed mill, preferably with advanced technology, using coccidiostats and veterinary medicines) + 1 EP/DEP/BCP. Whenever possible, participants are accompanied by a local inspector in charge. Each visit follows the same process: • Presentation of the company, feed hygiene requirements implementation, potential restrictive points faced by the FeBO in the past to comply with the legal provisions and how they were resolved. • Presentation of the EP/DEP/BCP by the competent authority and demonstration of the procedures and techniques used for feed import control. • Participants perform a visit of the plant/establishment/EP/DEP/BCP premises 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 field visit is used to challenge the acquired knowledge of the participants. The FV consists of visiting one FeBO and one Entry Point/Designated Entry Point/Border Control Post for feed import control. The local feed inspector or someone else from the CA is present during the visit to answer questions from the participants on CA controls.

The representative of the FeBO introduces the facility indicating the main production profiles. After this the factual visit of the production line takes place. If possible, pictures are taken by the TC only, for the purposes of debriefing only. Participants are invited to check the facility, production line, hygiene conditions, storage facilities, labelling, cross contamination and flushing material management, documents, data from the questionnaire, etc. They may also challenge the inspector and the quality control manager by asking questions on unclear points, or on CCPs with the aim of identifying shortcomings which could be improved, if any.

During the visit to EP/DEP/BCP at sea port where control of feed imported from third countries occurs, the representative of the CA presents and demonstrates the adequate procedures and techniques for feed import control. Participants are invited to check the facilities and conditions for import control. Whenever possible a pratical case is considered.

Module 4.3 Field visits debriefing

Tutor(s): Jose Costa / Marot Hibbey
Duration: 30 minutes
Format: Field visit

Module Description
Closing of the field visit in sub-groups (same groups as for 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 in plenary session.

Key concepts, information and messages for this module

The debriefing of the field visits takes place after that and the memory of participants is supported by a range of pictures taken by the TC on spots where shortcomings could be or were possible to be detected. The pictures are projected in the training room. Participants are invited to share their personal findings with the group. TC gives a feedback on those findings on the basis of EU legislation and on national guidlines, and a synthesis is given on the findings.

Questions and answers related to Topic 4

Will be provided with the Second Interim Report.

Topic 5: Feed labelling

Specific objectives of Topic 5:

The Feed Marketing Regulation created a well operating legal basis for the marketing and labelling of feed in the EU. Main benchmarks are explained under this topic to the participants:

- General overview of labelling rules both for feed materials and compound feed.
- Compulsory and voluntary labelling.
- Claims.
- Labelling of feed additives in compound feed.
- Analytical tolerances for discrepancies between the labelled compositional values of a feed material or compound feed and the values analysed in official controls.
- Labelling rules of specific feed products set out in other EU legislation: labelling of GM products, labelling of products subject to the feed ban.
- EU codes of good labelling practice for compound feed for food producing animals and for petfood.

This topic consists of one general theoretical module, divided into 5 parts, all of them linked to a practical activity (case study, quiz, or exercise) dealing with:

- Feed labelling rules and tolerances (module 5.1);
- Practical exercise on feed labelling (module 5.1).

Module 5.1 Feed labelling rules and tolerances

Tutor(s): Sabine Kruse
Duration: 135 minutes
Format: Theoretical presentation + working groups / debriefing

Module Description
• General overview of labelling rules, both for feed materials and compound feed: compulsory and voluntary labelling. • Use of claims. • Labelling of feed additives in compound feed. • Analytical tolerances for discrepancies between the labelled compositional values of a feed material or compound feed and the values analysed in official controls. • Specific labelling dispositions related to feed ban and GM feed. • Labelling of feed intended for export to third countries. • Codes of good labelling practices of compound feed for food producing animals and pet animals.
Group discussion: Feed labelling requirements.
Exercise on feed labelling: • Real labels of different kinds of feed (feed materials, complementary feed, complete feed, dietetic feed, etc) are provided for evaluation by the participants. • Participants are asked to elaborate a partial checklist with the legal labelling dispositions in force. • Comparison with an existing checklist to verify the label's compliance.

Key concepts, information and messages for this module

Labelling requirements for feed materials and compound feed

- From general to specific requirements; General requirements for labelling and presentation; labelling of the feed shall not misled the user.
- Mandatory general and specific labelling requirements for feed materials and compound feed.
- Labelling of additives in compound feed.
- Alternative labelling requirements for special compound feed.
- Additional labelling requirements for feed intended for particular nutritional purposes.
- Additional labelling requirements for non-compliant feed materials and compound feed.
- Derogations from the labelling provisions.
- Use of the EU-Catalogue of feed materials and the codes of labelling for compound feed.
- Working groups: Practical evaluation of labels using check lists.

Analytical tolerances

- Objectives: harmonisation of the control of correct labelling within the EU.
- Total tolerances for analytical constituents (all potential not systematic and random errors that occur from the production of feed to the analytical result).
- Technical tolerances for the declaration of additives in compound feed.

Responsibility for labelling

- Responsible person for labelling.
- Transmission of labelling information through the feed chain.

Claims

- Requirements and restrictions for claims.
- Scientific substantiations of claims.

Questions and answers related to Topic 5

Will be provided with the Second Interim Report.

Topic 6: Feed with specific purposes and borderline products

Specific objectives of Topic 6:

This section is used for informing participants on products which are not typical feed but which still fall under the scope of the feed legislation. **Dietetic feed** again is covered here with the subcategories which belong to this legal group of products (real dietetic feed with particular nutritional purposes, high-concentrate products).

Legislation governing the domain of **medicated feed** is introduced. The different **definitions** of products (VMP, medicated premix, intermediary product, medicated feed) are presented. The production of medicated feed needs a special **interaction** between the farmer, the veterinarian and finally the feed mill. This interaction supported by **model documents** set out in EU legislation is introduced to the participants. Rules for the prescription, production, placing on the market, **intra-community trade**, import and use are explained. The new **regulations on VMPs and medicated feed** are to be mentioned, the main benchmarks of the latter are explained. It is obvious that **antimicrobial resistance**, a **major challenge** for the today animal husbandry, is covered under this topic. As per AMR **statistics** are shown to underpin the **overuse** of AM substances in the human and in the animal branch together with statistics on the increased need for AM against **multiresistant strains**. Possibilities for decreasing the need for treatments and for better targetting the treatments are explained.

Borderline issues: Every categorization creates borderline questions. Principles are provided in line with Recommendation (EC) 2011/25 which helps product categorization for competent authority staff as well as for operators. It is highlighted that decisions cannot be made based only on one principle; all of them shall be taken into consideration on a case-by-case basis. A weighing is to be made, and the decisions remain in some cases still arbitraty. Decisions taken previously shall also be taken into consideration. The decision must be based on the definitions and product descriptions available in the legislation in force. This unit shows which product groups should be taken into account with which definitions or descriptions when a product with unknown classification is to be classified.

This topic consists of four theoretical modules (with one case study on the last item) dealing with:

- Dietetic feed (module 6.1);
- Medicated feed (module 6.2);
- Antimicrobial resistence (module 6.3);
- Borderline products (module 6.4);

Module 6.1 Feed for particular nutritional purposes

Tutor(s): Alessandro Baiguini
Duration: 30 minutes
Format: Theoretical presentation + discussion

Module Description
• Requirements regarding feed intended for particular nutritional purposes (PARNUT). • List of intended uses: application and amendment of the list, practical examples, helping tools and discussion. • Comitology procedure for PARNUT authorization.

Discussion on:

- Practical cases of labelling dietetic feed and placing it on the market.
- Real labels are provided for evaluation by the participants.

Key concepts, information and messages for this module

There are two pieces of legislation to take into consideration when talking about dietetic feed (feed intended for particular nutritional purposes) which includes a specific group of products intended to feed animals with particular nutritional requirements related to a temporary or permanent physiological condition (e.g. recovery after surgery, liver damage): Regulation (EC) No. 767/2009 and Directive 2008/38/EC.

The module includes a review of relevant definitions, the procedure for updating the list of intended uses, the specific labelling requirements for dietetic feed. Topics covered:

1. Definitions.
   a. Particular nutritional purpose.
   b. Feed intended for particular nutritional purposes.

2. Placing on the market of dietetic feed.
   a. The marketing of dietetic feed is limited to the feed that complies with the provisions of the list of intended uses (Directive 2008/38/EC).
   b. The contents of feed additives in feed materials and complementary feed may exceed the level of 100 times the relevant fixed amount content in complete feed if the conditions mentioned above are met.
   c. Complementary feeds that exceed the 100 factor and that were legally marketed before September 2010, may remain in the market until a decision is made if an application for updating the list of intended uses was submitted before September 1st, 2010.

3. For each particular nutritional purpose, there is an entry in the table of the Annex. Entries are made in six columns.
   a. Column (1). Particular nutritional purpose
   b. Column (2). Essential nutritional characteristics
   c. Column (3). Species or categories of animals
   d. Column (4). Labelling declarations
   e. Column (5). Recommended length of time
   f. Column (6). Other provisions

4. Procedure to update the list of intended uses:
   a. The Commission, in order to amend the list of intended uses, must receive a valid application
   b. The dossier is made available to Member States “without delay”
   c. The Commission is considering valid the application and within 6 months of the receipt of the application a regulation shall be adopted
   d. If there are some doubts, the Commission shall seek the opinion of EFSA within 3 months

5. Specific labelling requirements for dietetic feed:
   a. Mandatory requirements under Articles 15 (general), 16 (feed materials), and 17 (compound feed) of Regulation (EC) nº 767/2009 are also applicable to feed intended for particular nutritional purposes
   b. The qualifying expression “dietetic feed”

c. The particulars for the respective intended use (columns 1 to 6)
d. An indication that the opinion of a nutrition expert or veterinarian should be sought before using the feed or before exceeding its period of use

Use of claims in the labelling of feed intended for particular nutritional purposes is permitted only when feed materials or compound feed that satisfy the specific requirements of the list of intended uses. Then the use of the term "dietetic feed" is compulsory.

Module 6.2 Medicated feed

Tutor(s): Alessandro Baiguini
Duration: 30 minutes
Format: Theoretical presentation + discussion

Module Description
• Current concept of veterinary medicine, medicated premixture and medicated feed. • Medicated feed at each stage: veterinary prescription, production (including unavoilable carry-over), placing on the market, intra-community trade and use. • Requirements for manufacturers of medicated feed-interplay. • Practical medicated feed issues and revision of the legal framework for veterinary medicinal products - New regulation regarding the production, marketing and use of medicated feed – Regulation (EU) 2019/4. The changes are highlighted in the presentation, even if the Regulation will not be applicable from 28 January 2022. • Medicated feed not authorized for prevention diseases and/or promoting animal production.
Group discussion: Medicated feed EU legal requirements, national approaches and difficulties regarding medicated feed.

Key concepts, informationand messages for this module

Medicated feed is regulated under Directive 90/167/EEC. Therefore, specific rules for the implementation of the Directive have been established by Member States. The contents of the Directive are described with reference to some issues that may lead to different interpretation or approaches by Member States.

Directive 90/167/EEC establishes the conditions governing the preparation, placing on the market and use of medicated feed. These three topics are covered during the presentation of the Directive with reference to some of the specific problems related to the production of medicated feed.

The presentation focuses on the definitions laid down in the Directive 90/167/EEC and in Directive 2001/82/EC on the Community Code relating to veterinary medicinal products (VMPs), as medicated can be considered as a specific type of feed obtained by mixing feed material with a medicinal product which must be produced and authorized in accordance with the legislation on VMPs.

Aspects related to the authorization, to the mixing procedures, to the premises and facilities of the operators and to the staff are important to obtain the goal to produce safe feed with a good homogeneity and stability.

Some rules for production have to be respected in order to avoid an interaction between the different ingredients of the medicated feed, to avoid the carry-over of residues coming from previous production and to be sure that in the final feed there are not the same active substances (e.g- coccidiostats) coming from the additive and from the premix used.

It is important that the operator is recording the data on the production and that the user is also able to show, in the case of an official control, the fulfillment of the requirements on production, traceability and respect of withdrawal periods.

Medicated feed can be used under the derogation of Article 11 of Directive 2001/82/EC and in that case the withdrawals periods have to be adapted accordingly by the veterinarians.

Medicated feed can be distributed only after a veterinary prescription has been signed. Under Annex A of Directive 90/167/EEC a model for veterinary prescription is published.

Labelling is the tool that permits to inform the user that the feed is containing a medicinal active substance with specific indications in relation to the disease(s) to cure or to prevent, the species of destination, the posology and the withdrawal period. In the case of transport of loose food the indications that are normally on the label must be on the commercial document of the medicated feed.

Annex B of Directive 90/167/EEC contains the certificate model for the intracommunity trade of medicated feed, which is possible if the medicated premixes used for the production of the feed to be exported contain the same active substances as those authorised by the MS of destination.

Member States shall not prohibit, limit or set obstacles to intracommunity trade of medicated feed manufactured in accordance with the Directive and prepared with medicated premixes that contain the same active substances as those authorized by the MS of destination.

The new Regulation that will repeal Directive 90/167/EEC introduces some new requirements which should reduce administrative burdens for the operators, permit a more homogeneous application of the rule in the different EU MS and reduce the risk of the development of antimicrobial resistance.

Regulation (EU) 2019/4 on the manufacture, placing on the market and use of medicated feed will repeal Directive 90/167/EEC and is introducing some new requirements which should reduce administrative burdens for the operators, permit a more homogeneous application of the rule in the different EU MSs and reduce the risk of the development of antimicrobial resistance.

Module 6.3 Antimicrobial resistance

Tutor(s):	Alessandro Baiguini
Duration:	30 minutes
Format:	Theoretical presentation + discussion

Module Description
• Overview of the antimicrobial resistance problematic and the global fight against AMR. • Common uses of antimicrobials in animal nutrition. • Tackling the spread of antimicrobial resistance: The “ONE HEALTH” Action plan. • Animal feeding strategies, good practices regarding the reduction of overuse and misuses of

antimicrobial medicines – the role of the veterinarian and of the animal holder. • Maximum residues limits for antimicrobial agents in non target feed.
Group discussion: Medicated feed EU legal requirements, national situation and difficulties regarding AMR.

Key concepts, informationand messages for this module

Antimicrobial Resistance (AMR) is the ability of microorganisms to resist antimicrobial treatments, especially antibiotics. It is a natural phenomenon that happens when microorganisms are exposed to the pressure of anti-infective agents and that can be increased in case of overuse or misuse of those substances.

Antimicrobial resistance occurs naturally and usually through genetic changes. However, the misuse and overuse of antimicrobials is accelerating this process. In many places, antibiotics are overused and misused in people and animals, and often given without professional oversight.

The attention must be not only on pathogens bacteria but also on commensal bacteria as the resistance can be transferred from the latter to the first ones.

AMR is an increasingly serious threat to global public health that requires action across all government sectors and society.
AMR not only has a direct impact on human and animal health - due to the failure in the treatment of infectious diseases - but also carries a heavy economic cost (increasing healthcare costs, prolonged hospital stays, treatment failures, and significant number of deaths).
25.000 patients die annually in the EU alone as a result of infections caused by resistant bacteria and globally this number could be as high as 700.000.

10 million are the deaths per year projected between 2015 and 2050 if current rates of resistance increased by 40%. Only 0.7 million of these additional deaths would occur in North America or Europe, with the largest numbers in Africa and Asia.

The EU Commission has foreseen, in its Communication to the European Parliament and the Council “Action plan against the rising threats from Antimicrobial Resistance”, 12 actions and 7 areas where measures are most necessary:

- making sure antimicrobials are used appropriately in both humans and animals;
- preventing microbial infections and their spread;
- developing new effective antimicrobials or alternatives for treatment;
- cooperating with international partners to contain the risks of AMR;
- improving monitoring and surveillance on human and animal medicine promoting research and innovation;
- improving communication, education and training.

The Commission **launched second Action Plan that** focuses on supporting Member States, particularly in establishing, implementing and monitoring their National Action Plans, bringing together EU funds and instruments in order to promote innovation and research against AMR and strengthening its leading role in the global *fora*, notably within the international organisations and with major trade partners.

It is a responsibility of all stakeholders (farmers and pet owners, veterinarians, food and feed business operators) to act responsibly in order to use veterinary medicinal products (VMPs) as it is foreseen in the summary of the products characteristics, in the right amount, following the golden rule "as little as possible, as much as necessary", respecting withdrawal periods and following a precise diagnosis and veterinary prescription.

Member States are involved in the evaluation of the consumption of VMP, in policies oriented towards the reduction of the use of medicines and the proposals for new regulations regarding VMPs and medicated feed (repealing Directive 2001/82/EC of 6 November 200 on the Community code relating to veterinary medicinal and Directive 90/167/ECC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community) will have provision specifically dedicated to antimicrobial resistance.

Module 6.4 Borderline products

Tutor(s):	Alessandro Baiguini
Duration:	60 minutes
Format:	Theoretical presentation + case study in working groups

Module Description

• Background and difficulties (regarding legal status, trade, etc).
• Legislation and recommendation to distinguish features of product types. Criteria and how to apply them:
  - Feed material – Feed additives
  - Biocidal products
  - Veterinary medicines
• Distinction between premixtures and complementary feed.
• Nutritional supplements.
• Role of the central CA, disagreement or doubt between CA and FeBOs.

Group discussion: Use of COMMISSION guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.
Case study based on some concrete descriptions of products: participants have to determine whether a certain product is indeed a feedstuff and if so, which type of feed it is.

Key concepts, information and messages for this module

By implementing Article 7 of EU Regulation 767/2009, the EU Commission has established Recommendation 2011/25 fixing guidelines and criteria in order to better distinguish between feed additives, feed materials, biocidal products and veterinary medicinal products.

Besides this, EU Regulation 767/2009 clarifies the distinction between premixtures and complementary feed.

The distinction between feed materials, feed additives and other products such as veterinary medicinal products or biocidal products has big implications on the conditions for their placing on the market, depending on the relevant applicable legislation. For some products a pre-marketing authorization is required at EU or national level, for some others not. Also the labelling requirements

and applicable maximum levels for the presence of undesirable substances are different for the different products.

The EU Commission has adopted guidelines (EU Recommendation 2011/25) clarifying on the distinction between feed materials, feed additives and other products such as veterinary drugs.

The criteria proposed in the Recommendation, for the distinction between feed additives and feed materials, should not be applied subsequently but simultaneously in order to create a certain "profile" of each specific product, taking into account all its characteristics. It is also important to note that none of the criteria can be used exclusively or can take precedence over another.

The criteria that can be taken into consideration in order to distinguish between feed materials and feed additives are the following:

1. Production and processing method (simple/complex)
2. Chemically defined substance (no/yes)
3. Level of standardisation or purification (low/high)
4. Safety of product: need for max. level in feed (no/yes)
5. Mode of use: incorporation rate in feed (high/low)
6. Function of product in feed (nutrient/additive)

Regarding biocidal products, on the basis of Article 2(2) of Regulation 528/2012 of the European Parliament and of the Council, it can be concluded that biocidal products that are already covered under the scope of the feed legislation (e.g. Regulation 1831/2003 or Regulation 767/2009), are not biocidal products but are to be considered as feed. Otherwise said, there is a precedence of the feed legislation over the legislation on biocidal products.

Regarding veterinary medicinal products based on Article 2(2) of Directive 2001/82/EC of the European Parliament and of the Council, it can be concluded that, if after consideration of all the characteristics of an unclassified product, the conclusion is that it might be a VMP, it should be considered as a VMP. Otherwise said, in case of doubt, there is a clear precedence of the VMPs legislation over feed legislation, except for authorised feed additives like coccidiostats.

Another logic derivation that can be made from the current provisions is that medicated feedingstuffs are not VMPs but according to recital 3 of Regulation (EC) No 767/2009, a form of feed containing medicated pre-mixes and being subject to a prescription by a veterinarian.

Finally, based on the definition of 'particular nutritional purpose' as established in Regulation767/2009, the borderline between "feed" and "veterinary medicinal products" is set. In fact, the rules on feed for particular nutritional purposes allow that, under strict conditions, certain more "medicinal" claims are made for feed.

Questions and answers related to Topic 6

Will be provided with the Second Interim Report.

Topic 7: Imports and official controls

Specific objectives of Topic 7:

This section's main target is to give the participants a very detailed description on the rules applicable for the control of products produced in the EU as well as for the process of import of products coming from outside the EU.

Official controls
This presentation informs participants on the concepts, requirements and obligations of the Control Regulation. The scope of the Regulation covers CA controls on food, feed, etc. Inspection techniques are detailed in the regulation and are shown to the participants. Differences between inspection and audit are explained. Description of the audit process is provided. A **new Regulation (Reg 2017/625)** repealing the 882/2004 Regulation has been adopted after long years of drafting. The changes are highlighted in the presentation, even if the Regulation will not be applicable from 14 December 2019.

Import rules
Requirements on feed import are laid down in **more than one piece of EU legislation** depending on the type of **products** (non-animal origin feed, ABP and other animal origin feed, medicated feed) or on the main subject of the legislation (882/2004 or the FHR). Feed which is proven to have been produced with rules at least **equivalent** to the ones applicable in the EU can be allowed for import to the EU.

For products of animal origin third countries and third country establishments are introduced to a **list** of which the import is allowed by EU legislation. The same system has been envisaged for feed of non-animal origin. However, this concept is not yet operational, and, as a transitional measure, a **representative established in the EU** shall be identified to bear the responsibility on the product safety. If the feed of non-animal origin belonging to list is identified as being **high-risk product**, the number of controls should be adapted and reinforced.

Import conditions are explained, like which product may enter, which **type of entry points**, which documents are to be filled in for which type of products, which products should be accompanied with a **CVED**, and which with a **CED**. Conditions for prior notification, for documentary control, identity checks, and physical checks and conditions for veterinary chechs are presented. Possible destinations are shown for rejected feed. Specific requirements on the **importation of Cat3 ABPs** destined for feed production for farmed animals are shown. Specific requirements for petfood are also a part of the introduction. Also the current emergency measures adopted by the COM are explained. Practice on **deciding acceptance and rejection** is shown.

This topic consists of two theoretical modules (each of them interrupted by a case study, a group discussion or by virtual visit of a BCP) dealing with:

- Feed official controls (module 7.1);
- Import from third countries (module 7.2);
- Case study on feed control (module 7.3);
- National good practices and guidelines (module 7.4);

Module 7.1 Feed official controls

Tutor(s): Alessandro Baiguini

Duration: 180 minutes

Format: Theoretical presentation + case study in working groups + debriefing

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. • Requirements for control activities and inspectors.
Group discussion: Most suitable techniques for feed official control.
Case study – What can be done to check a HACCP plan on a feed business • How to check the identification of critical control points. • How to check the validation's step.
• Methods and techniques for control (inspections, identity and physical control).
Group discussion: Most suitable methods and techniques for feed official control.
Practical exercise on feed control: allow participants to consider the appropriate type of checks to foresee as inspectors under the feed official control, according to different given examples
• Sampling and analytical methods used in the context of feed official controls – Official methods for sampling. • Sample management: taking, preparing and packaging the samples. • Quantitative requirements.
Group discussion: Adequate sampling and analytical methodology for feed physical official control, pending on the nature of the analysis (chemical *vs* microbiological analysis).
Practical exercise on the most suitable sampling procedure for some specific feed presented for physical control, according to the nature, size and presentation of different given feed examples and the pretended analysis.

Key concepts, information and messages for this module

The objective of this topic is to give an overview of the scope and objectives of the official control regulation (Regulation (EC) No 882/2004 adopted by the European Parliament and the Council On 29th of April 2004) focusing on the responsibilities and obligations of the Member States and respectively National Competent Authorities, requirements for control activities and inspectors, as well as on the most suitable methods and techniques for control (inspections, identity and physical control with sampling for analysis).

This topic consists of 3 theoretical parts.
The first one deals with:

- Scope and objectives of the feed official control
- Responsibilities and obligations of the national competent authorities
- Implementation of official controls - risk based approach
- The new regulation on official controls

The second one deals with:

- Hazards in the feed sector

- Risk categorisation
- Objectives and parts of a feed monitoring plan
- Preparation for an audit

The third one deals with:

- Sampling methods used in the context of feed official controls
- Official methods for sampling - Quantitative requirements
- Sample management: taking, preparing and packaging the samples

Exercises dealing with the relative topics are foreseen.

Regarding the first step, the participants have to discuss in groups about what can be done to check HACCP plans, how to check the identification of CCPs and how to check the validation steps. The participants have to answer, for a specific type of feed, to the following questions:

- Which are the major hazards to control in the feed production chain;
- Which are steps of the feed chain to control;
- Which are the types of operators that are subject to controls;
- Which are the most adequate official control techniques to adopt;
- Which are the regulations and directives that have to be taken into consideration for the official control of the feed sector.

In the exercise on sampling and inspection activity the participants have to define what are the relevant provisions laid down in the legislation to apply in specific given cases.

Module 7.2 Import from third countries

Tutor(s):	Jose Costa / Marot Hibbey
Duration:	90 minutes
Format:	Theoretical presentation + discussion + virtual visit
Aids if any:	Virtual visit to a BCP

Module Description
• Requirements for imports of feed coming from third countries. • Third countries representatives- “Gate Keeper”. • Official controls - Animal vs non animal feed - location (EPs/DEPs BCPs), procedures, types of checks, actions following official controls. • Increased control for high risk products. • Emergency measures.
Group discussion: Specific feed consignments imported from third countries and presented for free circulation at EP/DEP BCP.
Video on import controls demonstrating import of feed and sampling procedures in a harbour with different conditions. 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

Import of feed into the EU: Feed imported into the EU must satisfy the general requirements laid down in Regulation 178/2002/EC and the import conditions laid down in Regulations 882/2004/EC and 183/2005/EC. Imported feed shall comply with at least **equivalent requirements** as feed produced in the EU.

General requirements for the import of feed are laid down in Article 23 (1) in the FHR. The conditions are as follows:

- Third country of dispatch appears on a list of third countries from which imports of feed are permitted;
- Establishment of dispatch appears on a list of establishments from which imports of feed are permitted;
- Feed was produced by the establishment of dispatch or by another establishment appearing on the list referred to in point (b) or in the EU;
- Feed satisfies the requirements laid down in EU feed legislation.

Irrespective of provisions in Article 23 of Feed hygiene Regulation the interim measures laid down in Article 24 are still in place. As 11 years after the publication of Regulation 183/2005/EC the list of third countries and the list of establishments in third countries are only defined for products of animal origin (142/2011, Article 30). Therefore the provisions from Article 6 of Directive 98/51/EC are still applicable for import of feed of non-animal origin. The import of certain products of non animal origin from third countries is only allowed though representative of third country establishment. Each third country establishment shall have at least one representative who keeps a register of the imported products and declares that the establishment of origin complies with the EU rules. As the list of representatives of TC establishments is not publicly available, this represents some difficulties for the implementation and harmonization of import controls of feed of non animal origin.

Points of entry: designated entry point for high risk feed of non animal origin, border control posts for products of animal origin. CA shall require prior notification on the arrival of the product to the border. A model certificate (CED, CVED) is to be used for the purpose. Part I must be fulfilled by the FeBO (or its representative). Then comes the documentary control which includes every document on identification of the product and other documents required by legislation. The next step is the identity check which aims at establishing that the documents really correspond to the content and the labelling of the product is what is in the packaging. The next step is the physical check which may include everything from the means of transport to the labelling, or, if the product is identified by legislation, by national control plan or by suspicion for sampling, to take sample for laboratory analysis (regular control).

Certain products of non-animal origin should be subject to increased control. This means prior notification (CED), entry via DEP, 100% documentary check, increased physical check and entry only if lab result is negative.

Products on animal origin should arrive through a BCP, prior notified by a CVED, and be subject, on the top of the above, to veterinary checks and released only if the lab result is in conformity. The above checks are to be made against general criteria and specific criteria which are listed per product in the annexes of the ABP regulations. An example: feed of animal origin for farmed animals must be entirely of Cat 3 materials, should come from listed establishments of listed third countries with a health certificate. As pet food may be made of products of animal origin, the same criterion is to be ensured for imported batches.

A special import scheme is laid down for emergency measures which are linked to certain products which proved to be extremely risky in the past, most probably due to a special contamination crisis. A sad example is the Fukushima accident which also resulted in the adoption of a distinct regulation

specifying maximum limits for radionuclides contamination for the products originating in the concerned geographical area.

If the product proves to be compliant, the inspector filles in the respective part II of the CED, or CVED. In the opposite case CA shall reject the consignment, and shall decide a final destination for the product (treatment, re-dispatch, destruction, rendering, other use, etc. paid by the importer). In this case Part IV of the CED, or CVED must also be filled in accordingly.

The visibility of import operations are supported with virtual visit in a BCP.

Module 7.3 Case study on feed control

Tutor(s): Jose Costa / Marot Hibbey
Duration: 60 minutes
Format: Working groups / debriefing

Module Description
Case study on feed control - evaluation of a real feed label (feed materials/compound feed) and the conrrespondent analytical results: • Comparability with the result from animal constituents' detection (microscopic and/or PCR methodologies). Participants have to evaluate the presence of animal constituents in the label of a given feed and interpret and decide on the obtained results for animal constituents' detection as described on the respective analysis report. • Comparability with non-compliance results due to the presence of residues of coccidiostats or mycotoxins above the maximum admissible level, salmonella and enterobacteriaceae contamination. • Comparability with non-compliance results due to divergencies from compositional labelling of compound feed

Key concepts, information and messages for this module

Participants are driven into real life conformity assessment situations based on a number of different real analysis reports. Documentation and data on the products sampled and other results of the physical control are provided for. They are invited to conclude if the product is acceptable or not, and if yes, under which conditions. They are asked what measures would they take and how. One of the documents refers to a consignment of fishmeal originating in a third country. Accompanying document is the CVED. The sample taken are analysed for constituents of animal origin, and for the presence of Salmonella and Enterobacteriaceae contamination. The results are be in conformity for Enterobateriaceae. It is expected that participants recognize that they are not in conformity with the microbiological criteria for import according to Annex X of Reg. (EU) 142/2011.

After having classified the case, participants are invited to provide for measures that are relevant to the contamination case (e.g.: border refection, treatment, RASFF notification).

Other contamination cases are also be used for the purpose, like the case of a compound feed with residues of coccidiostats exceeding maximum permitted levels as unavoidable carry-over. Other case could be documentation of analytical constituents, for that case participants are challenged to give a try to apply tolerances of Regulation 767/2009 (EC) and analytical method uncertainty.

Module 7.4 National good practices and guidelines

Tutor(s): Jose Costa / Marot Hibbey

Duration: 60 minutes

Format: Theoretical presentation + working groups + plenary and synthesis

Module Description
• General requirements for planning, implementing and verifying the efficacy and efficiency of the national feed official control. • National examples of systems and tools focused on specific requirements (for instance evaluation of the adequacy of the HACCP plan, cross contamination and homogeneity test, national guidelines, codes of good practices, national criteria of rules …). • Register of EU and National guides under the feed sector: (https://ec.europa.eu/food/safety/animal-feed/feed-hygiene/guides-good-practice_en).
Group discussion: National CGP and guidelines to promote compliance and monitoring of feed legal requirements.
• General discussion on practical examples on the implementation and controls of the feed law compliance (including DG Health and Food Safety's reports (extract), national guides or other documents) to allow the participants to identify national good practices/ strengths and share potential good practices in their country. • Evaluation of the extension and the complementarity between the available options. • Reference to Private Certification Schemes (PCS) and interaction with the feed official control: European Court of Auditors Press Release on EU food safety system.

Key concepts, information and messages for this module

It is explained to the participants which are the key elements for ensuring an **effective national control system**:

- country-wide identification system of operators establishements together with activities as a basis to ensure an effective National Control Programme;
- risk ranking of operators establishments to define a general number of inspections for regular situations;
- risk ranking of products for the identification of matrix-contaminants relations;
- financial decision on the risk levels that should be dealt with;
- internal audits, supervision for control authorities.

Other documentary support for inspectors:

- national document with sampling criteria;
- standardised report formats (samping, inspection);
- guidelines for harmonized approach of the CA for the case of non-conformity;
- IT tool;
- guidelines for FeBOs on measures in the case of non-conformity;
- national guides adopted for control purposes;
- national guides for FeBOs on how to comply with legal requirements (on homogeneity, or cross contamination).

Guides to good practice

It is recommended that where national and Community guides referred to in Chapter III of FHR are drawn up, they shall contain guidance on good practices for the control of hazards in primary production of feed. National guides have been drawn up by MS and a collection is available at:

https://ec.europa.eu/food/safety/animal-feed/feed-hygiene/guides-good-practice_en

Private Certification Schemes

Reference to Private Certification Schemes (PCS) is envisaged and discussion is promoted in order to understand possible interactions and benefits for the feed official control.

Questions and answers for Topic 7

Will be provided with the Second Interim Report.

Reference documents

1	**Regulation (EC) 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 amendments
2	**Regulation (EC) 183/2005** of 12 January 2005 laying down requirements for feed hygiene and amendments
3	**Regulation (EU) 16/2011** of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed and amendments
4	**Regulation (EC) 767/2009** of the Council of 13 July 2009 on the placing on the market and use of feed and amendments
5	**Commission Recomendation 2011/25/EU** of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products
6	RASFF (Rapid Alert System for Food and Feed) annual report
7	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
8	Guides of Good Practice: COCERAL/COPACOGECA
9	Guides of Good Practice: FEFAC/FAMI QS/ FEDIAF/AAF-FEDIOL
10	EU register of FeBOs: http://ec.europa.eu/food/food/biosafety/establishments/feed_list_en.htm
11	**Commission Regulation (EU) 68/2013** of 16 January 2013 on the Catalogue of feed materials
12	EFIP (European Feed Ingredients Platform)
13	**Directive 2002/32/EC** of 7 May 2002 on undesirable substances in animal feed and amendments
14	**Regulation (EC) 396/2005** of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
15	**Commission Recommendation 2006/576/CE** of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding
16	**Commission Recommendation 2016/1319/UE** of 29 July 2016 amending Recommendation 2006/576/CE on the presence of deoxynivalenol, zearalenone and ochratoxin A
17	**Regulation 1829/2003** of 22 September 2003 on genetically modified food and feed
18	**Regulation 1830/2003** of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
19	**Regulation 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
20	**Regulation 429/2008** of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives
21	EFSA and CRL guidance documents
22	**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
23	EU Register of feed additives
24	**Regulation (EC) No 1831/2003** of the European Parliament and of the Council of 22 September 2003

	on additives for use in animal nutrition.
25	**Regulation (EC) 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
26	**Regulation (EC) 1069/2009** of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption
27	**Regulation (EU) 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
28	**Directive 2008/38/EC** of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes
29	**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
30	COM (2011) 748: Communication from the Commission to the European Parliament and the Council, Action plan against the rising threats from Antimicrobial Resistance.
31	**Regulation (EC) 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
32	**Regulation (EC) 152/2009** of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed and amendments
33	**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
34	**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
35	**Regulation (EC) 136/2004** of 22 January 2004 laying down procedures for veterinary checks at Community border control posts on products imported from third countries
36	**Regulation (EC) 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
37	**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
38	**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
39	**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
40	**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
41	**Commission Regulation (EU) 691/2013** of 19 July 2013 amending Regulation (EC) No 152/2009 as regards methods of sampling and analysis
42	**Commission Regulation (EU) 2015/786** of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive

	2002/32/EC of the European Parliament and of the Council
43	**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
44	**Regulation (EU) 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
45	**Regulation (EU) 884/2014** of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009
46	**Regulation (EU) 2015/175** of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins
47	**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
48	**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
49	**Commission Notice 2018/C 133/02** - Guidelines in order to guarantee a common approach in al MS on the use of certain food no longer intended for human consumption
50	**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
51	**Commission Implementing Regulation (EU) No 451/2012** of 29 May 2012 on the withdrawal from the market of certain feed additives belonging to the functional group of silage additives
52	**Commission Implementing Regulation (EU) No 230/2013** of 14 March 2013 on the withdrawal from the market of certain feed additives belonging to the group of flavouring and appetising substances
53	**Commission Implementing Regulation (EU) 2017/1145** of 8 June 2017 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives