## II

(Information)

# INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

## **EUROPEAN COMMISSION**

## **COMMISSION NOTICE**

Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 laying down requirements for feed hygiene

(2019/C 225/01)

## Purpose of this document

This document is mainly directed at feed business operators and competent authorities, and aims to give guidance on the implementation of the feed hygiene requirements in particular on the registration of feed establishments.

## Note

This document is an evolving document and will be updated to take account of experiences and information from the Member States, from competent authorities, feed business operators and the Commission's Health and Food Audits and Analysis Directorate.

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## 1. INTRODUCTION

Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (¹) (hereafter 'the Feed Hygiene Regulation') applied as from 1 January 2006. It lays down general hygiene requirements to be followed by feed business operators at all stages of the feed chain, from and including primary production of feed, up to and including, the placing of feed on the market. Since the adoption of the Feed Hygiene Regulation, competent authorities of the Member States and stakeholders have requested to the Commission to clarify a number of aspects thereof. The aim of this guidance document is to respond to these requests.

The guidance document intends to address these requests within the existing legal framework. Therefore, it does not create any new legal provisions, nor does it seek to cover all provisions on these issues in an exhaustive manner. In addition, in some cases the wording of the guidance document concerning the application of the requirements for registration of feed business operators, is intended to explain some margin of manoeuvre in order for Member States to apply risk management considerations according to their own assessment of the situation or conditions in their territory.

This guidance document aims to assist feed business operators and national competent authorities in the food and feed chain to better understand and to apply the Feed Hygiene Regulation correctly and in a uniform way. It is however important to note that only the Court of Justice of the European Union is entitled to interpret Union law with final binding authority.

<sup>(1)</sup> OJ L 35, 8.2.2005, p. 1.

For a complete understanding of the different aspects of the Feed Hygiene Regulation, it is essential to be also familiar with other parts of Union legislation, and in particular with the principles and definitions of:

- Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (2) (TSE Regulation'),
- Regulation (EC) No 178/2002 of the European Parliament and of the Council 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 (3) (also referred to as the 'General Food Law' — GFL) (4),
- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (5),
- Regulation (EC) No 882/2004 of the European Parliament and of 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 (6) (7),
- Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed (8),
- Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (9) ('Animal by-products Regulation'),
- Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council 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 (10).

## 2. **DEFINITIONS**

'Feed hygiene' is defined in Article 3(a) of Regulation (EC) No 183/2005 as 'the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use';

'Feed' (or 'feedingstuff') is defined in Article 3(4) of Regulation (EC) No 178/2002 as 'any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals';

'Primary production of feed' is defined in Article 3(f) of Regulation (EC) No 183/2005 as 'the production of agricultural products, including in particular growing, harvesting, milking, rearing of animals (prior to their slaughter) or fishing resulting exclusively in products which do not undergo any other operation following their harvest, collection or capture, apart from simple physical treatment';

'Feed business' is defined in Article 3(5) of Regulation (EC) No 178/2002 as 'any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding';

<sup>(</sup>²) OJ L 147, 31.5.2001, p. 1. (³) OJ L 31, 1.2.2002, p. 1.

<sup>(4)</sup> Further information on Regulation (EC) No 178/2002 (including a separate guidance document) can be found on the Commission's web page using the following link: https://ec.europa.eu/food/safety/general\_food\_law/general\_requirements\_en

<sup>(5)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(6)</sup> OJ L 165, 30.4.2004, p. 1.

<sup>(7)</sup> With effect from 14 December 2019, Regulation (EC) No 882/2004 is repealed and replaced by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OJ L 95, 7.4.2017, p. 1).

<sup>(8)</sup> OJ L 229, 1.9.2009, p. 1.

<sup>(9)</sup> OJ L 300, 14.11.2009, p. 1.

<sup>(10)</sup> OJ L 54, 26.2.2011, p. 1.

'Feed business operator' (11) is defined in Article 3(b) of Regulation (EC) No 183/2005 as 'the natural or legal person responsible for ensuring that the requirements of the present Regulation are met within the feed business under their control';

'Placing on the market' is defined in Article 3(8) of Regulation (EC) No 178/2002 as 'the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves';

'Establishment' is defined in Article 3(d) of Regulation (EC) No 183/2005 as 'any unit of a feed business';

'Competent authority' is defined in Article 3(e) of Regulation (EC) No 183/2005 as 'the authority of a Member State or of a third country designated to carry out official controls';

'Animal by-products' is defined in Article 3(1) of Regulation (EC) No 1069/2009 as 'entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen';

'Derived products' is defined in Article 3(2) of Regulation (EC) No 1069/2009 as 'products obtained from one or more treatments, transformations or steps of processing of animal by-products';

'Pet' or 'pet animal' is defined in Article 3(2)(f) of Regulation (EC) No 767/2009 as 'any non-food producing animal belonging to species fed, bred or kept, but not normally used for human consumption in the Community';

'Fur animals' is defined in Article 3(2)(e) of Regulation (EC) No 767/2009 as 'any non-food producing animal fed, bred or kept for the production of fur, and which is not used for human consumption';

Former foodstuffs' is defined in Point 3 of Part A to the Annex of Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (12) as 'foodstuffs, other than catering reflux, which were manufactured for human consumption in full compliance with the EU food law but which are no longer intended for human consumption for practical or logistical reasons or due to problems of manufacturing or packaging defects or other defects and which do not present any health risks when used as feed'.

For the purpose of this guidance document, the following terms are defined as follows:

Food no longer intended for human consumption' means food which was manufactured for human consumption in full compliance with the Union food law but which is no longer intended for human consumption, as set out in Chapter 1.2. of the Guidelines for the feed use of food no longer intended for human consumption (13).

Food retailers may place food on the market as such, in compliance with the provisions of the food law, to feed business operators for its transformation into feed, as set out in Chapter 3.2.2.(b) of the Guidelines for the feed use of food no longer intended for human consumption.

Food no longer intended for human consumption does not include:

- Food additives, food enzymes and food flavourings as referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (14),
- Food supplements as referred to in Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (15),

<sup>(11)</sup> In the context of the Feed Hygiene Regulation.

<sup>(12)</sup> OJ L 29, 30.1.2013, p. 1.

<sup>(13)</sup> Commission Notice 2018/C 133/02 (OJ C 133, 16.4.2018, p. 2).

<sup>(14)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(15)</sup> OJ L 183, 12.7.2002, p. 51.

— Catering waste as referred to in Article 8(f) of Regulation (EC) No 1069/2009 and point 22 of Annex I to Commission Regulation (EU) No 142/2011.

'Processing plant' means an establishment within the meaning of Article 3(d) of Regulation (EC) No 183/2005 that manufactures feed using treatment processes referred to in part B of the Annex to Regulation (EU) No 68/2013.

## 3. OBLIGATIONS OF FEED BUSINESS OPERATORS

All food and feed business operators must comply with the general principles and requirements of food law laid down in Regulation (EC) No 178/2002.

In addition, feed business operators must comply with all EU feed legislation, including in particular:

- the Feed Hygiene Regulation: they must ensure that all the requirements laid down in the Regulation are met within the feed business under their control in order to ensure feed safety and traceability;
- the Animal by-products Regulation: where they handle feed of animal origin they must, in addition to the Feed Hygiene Regulation, also implement the appropriate requirements laid down in this specific Regulation;
- The TSE Regulation: they must comply with any restrictions and requirements specifically laid down in that Regulation and related implementing legislation, concerning the possible feed uses of certain products of animal origin.

## 4. PRIMARY PRODUCTION

#### 4.1. General considerations

The Feed Hygiene Regulation also covers the primary production of feed. Primary production of feed is defined in Article 3(f) of the Feed Hygiene Regulation as 'the production of agricultural products, including in particular growing, harvesting, milking, rearing of animals (prior to their slaughter) or fishing resulting exclusively in products which do not undergo any other operation following their harvest, collection or capture, apart from simple physical treatment'.

The rules applicable to primary production of feed are laid down in Annex I, Part A of the Feed Hygiene Regulation. As mentioned above, the requirements of the Animal by-products and TSE Regulations also apply to feed business operators handling and/or feeding feed of animal origin to animals.

The requirements laid down in Annex I of the Feed Hygiene Regulation apply to the operations carried out by feed business operators as referred to in Article 5(1) of that Regulation. This provision covers operations at the level of primary production of feed and the following associated operations:

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

Primary production (and associated operations) refers to activities at the farm or at a similar level and includes inter alia:

- Production, rearing or growing of plant products such as grains, fruits, vegetables and herbs as well as their transport within and storage and handling of products (without substantially changing their nature) at the farm and their further transport to an establishment;
- Rearing of animals for slaughter or production of products of animals origin at farm level;

- Production, rearing, growing and gathering of insects;
- Some drying techniques of primary products such as algae and roughages and/or cereals for example, grown and harvested on the same farm.

Such drying operations are considered as normal routine operations at the level of primary production of feed in accordance with Article 5(1) of the Feed Hygiene Regulation.

However, certain drying operations carried out on the farm are likely to alter the products and/or to introduce new hazards to feed e.g. direct drying of primary products with a fuel source which can cause hazardous contamination (such as with dioxins). This operation cannot be considered as a normal routine operation at the level of primary production nor as an operation associated with primary production and is therefore to be considered as an operation referred to in Article 5(2) of the Feed Hygiene Regulation.

## Remarks on primary production:

- General rules on primary production are laid down in Annex I to the Feed Hygiene Regulation.
- Good animal feeding practices: are laid down in Annex III to the Feed Hygiene Regulation.
- Specific requirements of the feeding of farmed animals with feed of animal origin, registrations and permitted use of derogated animal by-products: are laid down in Annex IV (feed ban) to the TSE Regulation and Articles 11(1) and 14(d)(i) of the Animal-by-products Regulation.

## 4.2. 'Small quantities' of primary production as referred to in Article 2.2(d) of the Feed Hygiene Regulation

The Feed Hygiene Regulation does not apply to the direct supply of small quantities of primary production of feed at local level by the producer to local farms for use on those farms.

Pursuant to Article 2(3) of the Feed Hygiene Regulation, it is up to the Member States whether or not to further define the concept of 'small quantities', and to lay down under national law the rules and guidance necessary to ensure the safety of the feed (risk based approach).

Member States have regulated this issue in different ways in accordance with the principles of proportionality and subsidiarity under their local conditions and needs.

A non-exhaustive list of rules and criteria under national law established by some Member States in respect of 'small quantities' as referred to in Article 2(2)(d) of the Feed Hygiene Regulation can be found in Annex I of this document.

In addition, competent authorities may grant, in accordance with Article 20(4)(d) of Regulation (EU) No 142/2011, a derogation from the notification obligation under the Animal by-products Regulation to operators selling on the local market or in local retail establishments, small amounts of locally produced pet food.

## 4.3. Activities at farm level not considered as primary production

In addition to the primary production of feed, some feed business operators also mix feed for the exclusive requirements of their own holdings when using additives or premixtures of additives with the exception of silage additives'. Article 5(2) of the Feed Hygiene Regulation covers this activity and the rules applicable to such operation are laid down in Annex II of that Regulation. The requirement of implementing relevant procedures based on the HACCP principles following Article 6 of the Feed Hygiene Regulation also applies to these farmers. In some Member States, these feed business operators are referred to as 'HACCP-farmers'.

## 5. ACTIVITIES EXCLUDED FROM THE SCOPE OF THE FEED HYGIENE REGULATION

Article 2(2) of the Feed Hygiene Regulation excludes:

- (a) the private domestic production of feed:
  - (i) for food-producing animals kept for private domestic consumption (e.g. eggs of laying hens reared in private premises which will be used for private consumption);
  - (ii) for animals not kept for food production (e.g. production of feed for a private pet animal or for fur animals) (16);
- (b) the feeding of food-producing animals kept for private domestic consumption or for the direct supply, by the producer, of small quantities of primary products (e.g. eggs, milk, meat) to the final consumer or to local retail establishments directly supplying the final consumer;
- (c) the feeding of animals not kept for food production;
- (d) the direct supply of small quantities of primary production of feed at local level by the producer to local farms for use on those farms (17);
- (e) the retailing of pet food.

Article 2(3) of the Feed Hygiene Regulation, states that Member States may establish national rules and guidance governing the activities excluded from the scope of the Feed Hygiene Regulation, which ensure the achievement of the objectives of the Regulation.

## Remarks on activities excluded from the scope of the Feed Hygiene Regulation:

Article 15 of Regulation (EC) No 178/2002, states that feed shall not be placed on the market or fed to any food or non-food producing animal (18) if it is unsafe.

## 6. THE REGISTRATION AND APPROVAL OF ESTABLISHMENTS

## 6.1. The registration of establishments

Article 9(2) of the Feed Hygiene Regulation requires each establishment under control of a feed business operator and which is active in any of the stages of production, processing, storage, transport or distribution of feed, to be registered with the competent authority.

As mentioned in recital 17 of the Feed Hygiene Regulation, this requirement aims at ensuring traceability from manufacturer to final user and at facilitating the implementation of effective official controls.

'Registration' allows in particular:

- the national competent authorities to know where establishments are located and which activities are carried out, so as to perform official controls whenever judged necessary in accordance with Article 31 (19) of Regulation (EC) No 882/2004 which establishes the general rules on official controls, and
- to make the feed businesses operators aware of the requirements of the relevant EU and national legislation.

<sup>(16)</sup> Competent authorities may grant certain derogation from the prohibition of feeding certain Category 2 materials and certain catering waste to fur animals in accordance with Article 18 of the Animal by-products Regulation.

<sup>(17)</sup> See Chapter 4.2. of this Guidance document.

<sup>(18)</sup> Article 4(1) of Regulation (EC) No 767/2009 establishes that the requirements set out in Article 15 of Regulation (EC) No 178/2002 shall apply mutatis mutandis, to feed for non-food producing animals.

<sup>(19)</sup> Article 146 of Regulation (EU) 2017/625 which repeals with effect from 14 December 2019 Regulation (EC) No 882/2004.

Registration is a procedure whereby the competent authorities are informed about (at least) the name and address of the establishments and the relevant activities carried out. In any case, each Member State will define its own procedures for the registration of the establishments according to Article 9 of the Feed Hygiene Regulation. Practicalities can be arranged by Member States (e.g. one single list referring to each activity or two or more separate lists).

Registration under the Feed Hygiene Regulation and registration under other EU legislation related to the feed sector may be combined provided that the relevant rules for each registration system are complied with and that the competent authority decides to operate this combined registration system.

According to Article 19(7) of the Feed Hygiene Regulation, Member States shall make available to the public the lists of establishments registered in accordance with Article 9. Available information in the Member States can be found in Annex II of this document.

## 6.1.1. Registration of traders

Certain businesses are specialised in trading feed ('brokers'). While they may arrange for the movement of feed between suppliers or to establishments, they do not necessarily handle the feed or even store it on their premises (which may effectively be an office).

Provided they meet the definition of 'feed business operator', the registration requirement also applies. An 'approval' may also be required for some traders' establishments, when necessary (20).

#### 6.1.2. Feed businesses and internet sales

Certain businesses offer feed for sale via the internet. Although such trade is not specifically referred to in the Feed Hygiene Regulation, such businesses fall within the definition of a feed business and the relevant requirements of feed law are applicable to them, including the registration requirement.

Concerning the retail internet sales of pet food directly to pet owners, these sales should be considered as being within the scope of 'retailing of pet food' as provided for in Article 2(2)(e) of the Feed Hygiene Regulation. In other words, with regard to pet food sold on internet by retail, the Feed Hygiene Regulation does not apply.

## 6.2. The approval of establishments

Article 10(1) of the Feed Hygiene Regulation requires certain establishments to be approved by the competent authority where such establishments carry out specific activities which can present a higher risk. In that case, such activities may not be performed without prior approval.

Those activities are specified in Article 10(1) of the Regulation, which refers to operations concerning certain types of feed.

Additional approval requirement may be laid down by Member States in accordance with Article(2) of the Regulation and by a Commission Regulation in accordance with Article 10(3) of the same Regulation.

Approval requires a verification of the structural/operational conditions stipulated by the law by an on-site visit before the feed business is authorised to place its products on the market.

## 6.2.1. Establishments subject to approval

The approval requirement laid down in Article 10(1) of the Feed Hygiene Regulation concerns establishments which carry out the following activities:

— manufacturing and/or placing on the market of feed additives covered by Regulation (EC) No 1831/2003 and referred to in Chapter 1 of Annex IV to the Feed Hygiene Regulation;

<sup>(20)</sup> See Chapter 6.2. of this Guidance document.

- manufacturing and/or placing on the market of premixtures prepared using feed additives referred to in Chapter 2 of Annex IV to the Feed Hygiene Regulation;
- 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 the Feed Hygiene Regulation;

#### Note

For the purposes of conciseness and clarity, a consolidated version of Annex IV of the Feed Hygiene Regulation, can be found in Annex III of this Guidance document, in which references to products formerly covered by Directive 82/471/EEC (which has been repealed), as well as references to antibiotics as growth promotors are omitted, since these references to these products in Annex IV are no longer relevant to the legislation in force.

In addition, the Feed Hygiene Regulation requires feed business operators to ensure that establishments under their control and covered by that Regulation are approved by the competent authority under certain other circumstances:

Annex II of the Feed Hygiene Regulation requires that establishments shall also be subject to approval when carrying out one or more of the following activities to place on the market products for use in feed (21):

- processing of crude vegetable oil, except those under the scope of Regulation (EC) No 852/2004 (<sup>22</sup>);
- oleochemical manufacturing of fatty acids;
- manufacturing of biodiesel;
- fat blending;

and,

- as referred to in Article 1 of Regulation (EC) No 141/2007 (23), establishments manufacturing and/or placing on the market feed additives of the category 'coccidiostats and histomonostats';
- as referred to in Article 6 of Regulation (EU) 2015/786 (24), establishments which carry out a detoxification process;
- as referred to in Article 8 of Regulation (EC) No 767/2009, establishments producing feed for a particular nutritional purpose exceeding 100 times the relevant fixed maximum content of certain feed additives.

Article 19(6) of the Feed Hygiene Regulation states that the Commission should compile and make available to the public the lists of establishments approved in the Member States in accordance with Article 13 of the Regulation. The information can be found on the Commission's web page concerning 'Animal Feed' (25).

<sup>(21)</sup> Commission Regulation (EU) No 225/2012 of 15 March 2012 amending Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof (OJ L 77, 16.3.2012, p. 1).

(22) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

<sup>(</sup>OJ L 226, 25.6.2004, p. 3).

<sup>(23)</sup> Commission Regulation (EC) No 141/2007 of 14 February 2007 concerning a requirement for approval in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council for feed business establishments manufacturing or placing on the market feed additives of the category 'coccidiostats and histomonostats' (OJ L 43, 15.12.2007, p. 9).

<sup>(24)</sup> 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 (OJ L 125, 21.5.2015, p. 10).

<sup>(25)</sup> https://ec.europa.eu/food/safety/animal-feed/feed-hygiene/approved-establishments\_en

## 6.2.2. The approval of establishments under national law

Article 10(2) of the Feed Hygiene Regulation allows Member States to require the approval of feed establishments for which Union law does not require approval.

This could be the case of manufacturers of medicated feedingstuffs as referred to in Article 4(1)(a) of Council Directive 90/167/EEC which are approved in some Member States according to Article 10(2) of the Feed Hygiene Regulation.

## 7. THE BEGINNING OF THE FEED CHAIN

The feed chain is very complex, especially when considering the many sources of feed materials. Feed-borne incidents, i.e. past cases of contamination of feed having adversely affected the safety of the feed and food chain, have also demonstrated the particular importance of defining where the feed chain starts in order to ensure product safety and full traceability.

In addition, in recent years the use of former foodstuffs as feed has progressively gained momentum, in an attempt to curb food loss and waste and to make efficient use of food that is safe but cannot be redistributed for human consumption via food banks. In this regard, the Commission has established an action plan to reduce food waste as an integral part of the Communication on the Circular Economy (<sup>26</sup>), which among other objectives, aims to facilitate valorisation of food no longer intended for human consumption for its use in animal nutrition.

Depending on the particular situation in each Member State, different approaches to the registration of establishments have been adopted, in order to apply Article 9(2) of the Feed Hygiene Regulation, for those supplying only part of their production to the feed chain, but whose main activity is not in the feed area (such as mining, chemical or food industries), which led to different conclusions as to the inclusion of those establishments within the scope of the Feed Hygiene Regulation.

Consequently, operators have reported significant burdens, which might hinder or even prevent them from dispatching food no longer intended for human consumption to the feed sector, such as, double registration as a food and feed business operator or the lack of harmonisation of the requirements for registration of food business operators as feed business operators.

Clarification is then required to improve and harmonise the implementation of the Feed Hygiene Regulation having regard to the different experiences across the Member States and to the importance for the competent authorities to have a full knowledge of all the links of the feed chain, while encouraging a practical approach. Such clarification is necessary in order to determine the scope of Article 5(6) ( $^{27}$ ) of the Feed Hygiene Regulation. While it is clear that farmers must source and use feed from establishments that are registered and/or approved in accordance with the Feed Hygiene Regulation, the qualification of other operators as 'feed business operators' needs some guidance.

An essential objective of the Feed Hygiene Regulation is to ensure the safety of the products and their traceability. From this standpoint the following main criteria may be considered in order to identify whether or not an establishment should be registered according to the Feed Hygiene Regulation and whether a product may enter into the feed chain or not, taking into account the relevant regulatory context:

— The definition of 'feed' laid down in Article 3(4) of Regulation (EC) No 178/2002, which refers to any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. The criterion of the intention to use the substance or product for oral feeding to animals is therefore decisive for a qualification as 'feed'. Therefore, the operator's intention when supplying a product is a basic criterion to be considered in order to determine whether the Feed Hygiene Regulation's requirements should apply.

<sup>(26) &#</sup>x27;Closing the loop — an EU action plan for the Circular Economy' (COM (2015)614 final).

<sup>(27)</sup> Article 5(6) of the Feed Hygiene Regulation establishes that 'feed business operators and farmers shall only source and use feed from establishments which are registered and/or approved in accordance with this Regulation'.

- The legal status of the product, in accordance with the classification laid down in the relevant EU legislation. Such legal status may be for instance: food, by-product from animal or non-animal origin, feed or waste, as developed in the Guidelines for the feed use of food no longer intended for human consumption.
- The information accompanying the products supplied by the operator when placed on the market (e.g. on the label or commercial document).
- The type of establishment which manufactured the product and from which it originates and the establishment to which the product is supplied: for example, animal by-products or former foodstuffs processing plants, and feed establishments and farms.

In order to avoid unnecessary administrative burdens both on the operators and competent authorities in the Member States, in some particular cases, it could be accepted that some feed business operators source products (28) from establishments which are registered (and/or approved if required) in accordance with Regulation (EC) No 852/2004 and/or Regulation (EC) No 853/2004 and/or the Animal by-products Regulation.

The feed business operator, who is responsible for all feed safety requirements, must ensure that a re-categorisation of the product (29) to a feed material is subject to compliance to all relevant provisions of feed legislation, as referred to in Article 4(1) of the Feed Hygiene Regulation, including not only feed hygiene rules but also requirements concerning in particular residue limits of contaminants and concerning labelling.

Also, feed business operators who carry out operations which are not covered by Article 5(1) of the Feed Hygiene Regulation must put in place, implement and maintain a permanent written procedure or procedures based on the HACCP principles, as laid down in Article 6 of the Feed Hygiene Regulation.

In addition, during the re-categorisation of a product (30) into a feed material, the feed business operator must be especially aware of all existing requirements and restrictions foreseen in the Animal by-products and TSE Regulations (including the feed ban).

In any case, competent authorities in the Member States may decide, after an evaluation of the specific activities concerned, whether registration of the operators according to the Feed Hygiene Regulation is required. Registration strengthens Member State's national systems of official controls.

## 7.1. By-products and food no longer intended for human consumption from the food and drink industry with intended uses as feed material

7.1.1. By-products according to Directive 2008/98/EC on waste (31) and repealing certain Directives (known as the Waste Framework Directive-WFD)

A major use for by-products from the food and drink sector is animal feed. The production processes in numerous sectors (e.g. oilseed crushing or production of sugar, starch and malt) generate materials that are subsequently used as feed. The use of these materials of non-animal origin as feed is consistent with the goal of a circular economy and in particular the waste hierarchy as enshrined in Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. The WFD introduces provisions in order to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste by reducing overall impacts of resource use and improving the efficiency of such use.

Materials which are not produced deliberately in a production process are a production residue and may or may not be waste. A production residue can be considered as a by-product and not waste only if a production residue meets the cumulative conditions set out in Article 5(1) of the WFD, i.e. it is produced as an integral part of the production process and its further use in animal feed is lawful and certain, without further processing outside of the production process of that material. These by-products that will be used in animal feed are therefore feed materials.

<sup>(28)</sup> Which are not considered yet as 'feed' at that stage.

<sup>(29)</sup> Which are not considered yet as 'feed' at that stage.

<sup>(30)</sup> Which is not considered yet as 'feed' at that stage.

<sup>(31)</sup> As amended by Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste (OJ L 150, 14.6.2018, p. 109).

In addition, the WFD explicitly distinguishes between disposal and recovery, with recovery (including recycling) having priority over disposal in the waste hierarchy (Article 4 WFD) and the recovered product ceasing to be waste (if the conditions of Article 6 WFD are met).

Animal by-products, including processed products covered by Regulation (EC) No 1069/2009 (except those which are destined for incineration, landfilling or use in a biogas or composting plant), are excluded from the scope of the WFD to the extent that they are covered by other Union legislation (Article 2 WFD).

On the interpretation of the WFD, detailed guidance can be found in the following EC publications:

- Guidance on the interpretation of key provisions of Directive 2008/98/EC on waste (32) and
- Communication from the Commission to the Council and the European Parliament on the Interpretative Communication on waste and by-products (33).

It is important that operators placing products on the market to enter the feed chain should clearly identify those products as intended for feed use since products that are considered as 'waste' cannot re-enter the feed chain at a later stage.

## 7.1.2. Main legal obligations

As regards the main legal obligations of feed business operators, Article 4(1) of the Feed Hygiene Regulation establishes that 'Feed business operators shall ensure that all stages of production, processing and distribution under their control are carried out in accordance with Community legislation, national law compatible therewith, and good practice. They shall ensure in particular that they satisfy the relevant hygiene requirements laid down in this Regulation'.

As mentioned before, many types of by-products and food no longer intended for human consumption can be used along the feed chain by feed business operators when appropriate. Feed business operators must ensure that their activities and the by-products and foods no longer intended for human consumption which are placed on the market, apart from being in accordance with the Feed Hygiene Regulation, must also be in accordance with other relevant legislation, such as:

- Regulation (EC) No 178/2002 (General Food Law);
- Regulation (EC) No 767/2009 on the placing on the market and use of feed;
- Directive 2002/32/EC on undesirable substances in animal feed (34);
- with the Animal by-products Regulation and Regulation (EU) No 142/2011 (implementing the Animal by-products Regulation), and
- the TSE Regulation.

Therefore, labelling requirements and commercial documents during transport must comply with the above legislation, when relevant.

## 7.1.3. Food no longer intended for human consumption

The WFD has been amended by Directive (EU) 2018/851 of the European Parliament and of the Council amending Directive 2008/98/EC on waste. It foresees that substances that do not consist of or contain animal by-products and that are destined to be used as feed are excluded from the scope of the WFD to the extent that they are covered by other Union legislation, such as Regulation (EC) No 767/2009.

<sup>(32)</sup> http://ec.europa.eu/environment/waste/framework/guidance.htm

<sup>(33)</sup> http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52007DC0059

<sup>(34)</sup> Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

As to the use of food no longer intended for human consumption, further and detailed guidance can be drawn from the Guidelines for the feed use of food no longer intended for human consumption, the purpose of which is to facilitate the feed use of certain food no longer intended for human consumption, with and without products of animal origin. Those guidelines should assist the national and local competent authorities and the operators in the food chain in applying the relevant EU legislation.

In particular, Chapter 3.2.2. of the Guidelines for the feed use of food no longer intended for human consumption describes the measures to increase the use of food of non-animal origin no longer intended for human consumption as feed and, among others, proposes that food retailers may not need to be registered under Feed Hygiene Regulation in certain circumstances.

Particular attention should also be paid to Chapter 1.3 of the above-mentioned Guidelines, Figure 1: 'Flow chart from food to feed' (35), where it is detailed when a product may be directly supplied to a feed business or in the case of products of animal origin is subject first to the conditions of Animal by-products Regulation.

General provisions governing feed materials are listed in Part A of the Annex of Regulation (EU) No 68/2013. Many examples of by-products and residues from the industry are listed in Part C of that Annex, in particular under chapter 13 thereof.

The list of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited according to Annex III of Regulation (EC) No 767/2009 must also be taken into consideration.

## 7.2. Examples of operators that may or may not be registered under the Feed Hygiene Regulation

According to their activities and establishments involved, some operators may have to be registered or not according to the Feed Hygiene Regulation, as follows:

7.2.1. Non-food operators supplying directly or indirectly part of their production to the feed chain, but whose main activity is not in the feed area

## Examples:

- Chemical industry: production of iron sulphate, organic acids, sodium or calcium hydroxide to produce salts of fatty acids
- Bioethanol production: distillers solids, grain protein
- Pharmaceutical industry
- Quarry/Mining: minerals
- (a) Certain producers or suppliers may not always be aware that their products or raw materials could enter indirectly into the feed chain after its sale. Thus, it may or may not be their intention to place feed on the market. This is particularly relevant for activities and/or establishments, which normally have little association with the feed sector and may market a minimum part of their products (36) usually through intermediate operators who could, among other options, channel those products to the feed chain for the production of additives and/or feed materials. For example:
  - The first supplier of certain products (37) (e.g. a quarry) need not be regarded as a feed business operator and therefore, competent authorities need not require registration. The feed chain would start when the product is intended to be used for the production of feed. For example with the intermediate operator placing the products on the market to the attention of producers of feed additives, who must both be registered according to the Feed Hygiene Regulation.

<sup>(35)</sup> Arising from the amendments by Directive (EU) 2018/851, referred to in the first paragraph of section 7.1.3, the special conditions referred to in the flow chart are no longer relevant.

<sup>(36)</sup> Which are not considered yet as 'feed' at that stage.

<sup>(37)</sup> Which are not considered yet as 'feed' at that stage.

- The supplier of certain chemical products (38) (e.g. calcium hydroxide and butyric acid) which at a later stage could be used in producing feed additives/feed materials (e.g. calcium butyrate) obtained by their chemical reaction need not be regarded as a feed business operator and therefore, competent authorities need not require registration. The feed chain would start when the product is intended to be used for the production of feed additives/feed materials, this is, with the producer of the feed additive/feed material, which must be registered according to the Feed Hygiene Regulation.
- (b) However, if the first supplier places on the market products with the intention to be used as feed, including:
  - feed additives (according to Regulation (EC) No 1831/2003),
  - and/or feed materials (according to Regulation (EC) No 767/2009),

then, the supplier must be registered as a feed business operator according to the Feed Hygiene Regulation.

7.2.2. Food establishments supplying part of their production to the feed chain, but whose main activity is not in the feed area

In these cases, it may or may not be the intention of the food business to produce feed, but as a portion of its activity (small in most of the cases but with some exceptions such as food establishments extracting vegetable oil) by-products of animal and non-animal origin are produced which are frequently used in the feed industry. Also certain food that is not intended for human consumption can be supplied to the feed chain (39).

Subsequently, taking into account these criteria and to a greater or lesser extent, the following types of situations can be observed:

(a) Food establishments (including retailers) supplying animal by-products (including food of animal origin no longer intended for human consumption) to animal by-products/former food processing plants (40) which will process them into feed materials (41)

Examples include products from:

- Slaughterhouses/cutting plants/meat processing plants
- Fish cutting plants
- Food processing industries (confectionery, pasta or pizza industry): products containing animal by-products such
  as eggs, milk, meat or fish and/or food no longer intended for human consumption containing those animal
  by-products
- Retailers such as butchers and fishmongers
- Supermarkets

In this case, when the food establishments supply products (42) for further treatment to animal by-products processing plants, the food establishment need not be regarded as a feed business operator and therefore, competent authorities need not require registration according to the Feed Hygiene Regulation. The feed chain would start then with the animal by-products and/or former food processing plant which produces the feed materials and which should be registered according to the Feed Hygiene Regulation.

(38) Which are not considered yet as 'feed' at that stage.

(40) Approved according Article 24 of the Animal by-products Regulation.

<sup>(29)</sup> See Guidelines for the feed use of food no longer intended for human consumption. Provisions on the restriction of products of animal origin in animal nutrition can be found in Animal by-products Regulation and Commission Regulation (EU) No 142/2011. Feed ban provisions are laid down in Article 7 and Annex IV of the TSE Regulation.

<sup>(41)</sup> Conditions for use must be consulted in Chapter 4 of Commission Notice — Guidelines for the feed use of food no longer intended for human consumption.

<sup>(42)</sup> Which are not considered yet as 'feed' at that stage.

(b) Food establishments (including retailers) supplying food of non-animal origin no longer intended for human consumption to processing plants which will process them into feed materials (43)

## Examples:

- Food processing industries (e.g. frozen vegetables industry, canning industry, beverage industry): food no longer intended for human consumption
- Bakeries: bread (not containing products of animal origin)
- Supermarkets and other retail shops: vegetables, fruits, etc.

In this case, when the food establishment (including retailers) supplies products (44) for further treatment to processing plants, the food establishment need not be regarded as a feed business operator and therefore, competent authorities need not require registration according to the Feed Hygiene Regulation. The feed chain may start with the processing plant which produces the feed materials and which should be registered according to the Feed Hygiene Regulation.

(c) Food establishments (other than retailers) supplying animal by-products and/or derived products including former foodstuffs of animal origin to feed business operators (other than animal by-products processing plants) (45)

## Examples:

 A derogation applicable to dairy industry: milk, milk-based products and certain milk-derived products set out in part II of Section 4 of Chapter II of Annex X to Regulation (EU) No 142/2011

In this case, when food establishments supply animal by-products to feed business operators directly to be used as feed materials, the food business operators should be registered as feed business operators according to the Feed Hygiene Regulation in addition to the registration according to the Animal by-products Regulation (46).

If the feed business operator to which the by-products are supplied is a pet food producer, it must also be approved according to the Animal by-products Regulation.

(d) Food establishments (other than retailers) supplying by-products and food of non-animal origin no longer intended for human consumption (47) to feed business operators other than processing plants

## Examples:

- Milling industry: bran, wheat bran
- Sugar industry: sugar beet pulp
- Chips industry: potato peelings
- Brewery: brewers grains
- Distillery: wet distillers grains (WDG) and distiller's dried grains with solubles (DDGS)
- Juice factory: orange pulp

<sup>(43)</sup> Conditions for use must be consulted in Chapter 3 of Commission Notice — Guidelines for the feed use of food no longer intended for human consumption.

<sup>(44)</sup> Which are not considered yet as 'feed' at that stage.

<sup>(45)</sup> Conditions for use must be consulted in Chapter 4 of Commission Notice — Guidelines for the feed use of food no longer intended for human consumption.

<sup>(46)</sup> In accordance with derogations set out in Part II of section 4 of Annex X to Regulation (EU) No 142/2011 if authorised by competent authorities.

<sup>(47)</sup> Conditions for use must be consulted in Chapter 3 of Commission Notice — Guidelines for the feed use of food no longer intended for human consumption.

In this case, the food establishment should be regarded as a feed business operator and should be registered according to the Feed Hygiene Regulation where the products are intended to be used for oral feeding to animals.

(e) Feed business operators other than processing plants sourcing small amounts of food (including food no longer intended for human consumption) of non-animal origin from food retailers

Examples:

— Artisanal feed producers which source food of non-animal origin from local food retailers

The food retailer registered or approved according to Regulation (EC) No 852/2004, which places on the market food as such, in compliance with the provisions of food law, to a feed business operator who collects the food for transformation into feed or directly transforms it into feed, need not be regarded as a feed business operator and therefore, competent authorities need not require registration according to the Feed Hygiene Regulation. The feed chain would start then with the feed business operator who will use the raw materials as such and produces the final compound feed and who should be registered then according to the Feed Hygiene Regulation.

Thus, for example, feed business operators such as small artisanal local pet food producers (producing dog biscuits) could also purchase certain foods from food retailers with the intention for use as feed materials. These food retailers place on the market goods for food purposes which in this case are then intended to be used as feed materials by the feed business operator, always taking into account existing provisions and restrictions foreseen in the legislation, as safety and traceability can be assured and competent authorities can easily have full knowledge of all the providers.

— Farmers sourcing food of non-animal origin no longer intended for human consumption from local food retailers

Article 5(6) of the Feed Hygiene Regulation provides that a farmer shall only source and use feed from establishments which are registered and/or approved in accordance with the Feed Hygiene Regulation. Therefore, in the case where food retailers sell the product as feed, they should be regarded as feed business operators and be registered according to the Feed Hygiene Regulation, as it must be considered that they are supplying a feed material (former foodstuff) directly to be used for oral feeding to animals on the farm.

- 7.2.3. Animal by-products processing plants and other processing plants supplying feed to feed business operators Examples:
- Production of processed animal protein (PAP), animal fat, etc....
- Production of feed materials from food no longer intended for human consumption (bread, cookies, bakery industry, pasta, etc.)
- Processing a feed material from another feed material: production of silage from orange pulp

In this case, animal by-products processing plants and former foodstuffs processing plants supplying feed materials to feed business operators should be registered according to the Feed Hygiene Regulation.

## $8. \ \ \textbf{FREQUENTLY ASKED QUESTIONS} - \textbf{FEED BUSINESS OPERATORS}$

#### **Question 1**

I have a farm with cattle. I produce my own feed with the cereals that I harvest from my own land. I also use products containing additives on the production of that feed. Do I need to comply with the requirements in Annex II of Regulation (EC) No 183/2005?

#### **ANSWER**

Many feed products contain additives and it is important to focus on how the product is marketed. All feedingstuffs must be marketed according to Regulation (EC) No 767/2009 or Regulation (EC) No 1831/2003.

When using products marketed as 'additive' or 'premixtures' farmers must comply with Annex II of the Feed Hygiene Regulation, with the exception of use of 'silage additives' or 'premixtures of silage additives'.

The use of 'complementary feedingstuffs' does not require complying with Annex II of the Feed Hygiene Regulation.

Borderline between premixtures and complementary feedingstuffs is defined in Article 8(1) — content of additives — of Regulation (EC) No 767/2009 of 13 July 2009 on the placing on the market and use of feed.

'Without prejudice to the conditions of use provided for in the relevant legal act authorising the respective feed additive, feed materials and complementary feed shall not contain levels of feed additives that are higher than 100 times the relevant fixed maximum content in complete feed or five times in case of coccidiostats and histomonostats.'

## Question 2

'I have a farm with cattle. I produce my own feed with the cereals that I harvest in my own land. I also use additives/premixtures on the production of that feed. Should I register my farm or not? What annexes should I comply with? Should I ask for approval according Regulation (EC) No 183/2005?'

#### **ANSWER**

Farms manufacturing feed for the feeding of their animals must be registered according to the Feed Hygiene Regulation and in this case comply with Annex I, Annex II and Annex III of the Feed Hygiene Regulation.

When producing feed material and compound feed (complementary feed or complete feed) at primary level, Annex I and Good Agriculture Practice shall apply. If the farm uses feed additives (other than silage additives) or premixtures in the production of feed for the use on their own farm, Annex II and HACCP systems shall apply.

Farmers shall also comply with the provisions set out in Annex III when feeding food-producing animals.

Those farms that produce 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 of the Feed Hygiene Regulation shall ensure they are approved by the competent authorities.

## Question 3

'I am a fisherman who produces fish baits for local fishermen around my village. Am I a feed business operator?'

## ANSWER

Fishing baits designed to be scattered to attract fish to an area (often known as ground bait) are considered to fall within the definition of feed as covered by Regulation (EC) No 178/2002.

Therefore, producers of these ground baits must be considered as feed business operators and be registered in accordance with the Feed Hygiene Regulation. However, in the cases of a 'private domestic production' of ground baits to be used for fish for private domestic consumption, the producers are exempted from the requirement of registration according to Article 2(2)(a) of the Feed Hygiene Regulation.

However, fish baits intended to be attached onto a fish hook whose purpose is therefore not to meet the nutritional needs of an animal should not be considered as animal feed.

This is also consistent with Union legislation, considering the reference made in Article 18 of the Animal by-products Regulation to maggots and worms for fishing bait in a context of animal feeding (48) and provisions of Chapter III of Annex X to Regulation (EU) No 142/2011.

## **Question 4**

'I am the owner of a rendering plant. I buy products from food business operators to produce feed materials which I then sell to compound feed producers. However, my suppliers label the products I buy as waste. Is this an acceptable labelling from my supplier?'

## **ANSWER**

No. Animal by-products mixed with waste and labelled as waste may not be used for feeding farmed animals. Animal by-products may only be used in accordance with the animal by-products legislation for the production of certain technical products or disposed of as waste.

A food establishment (such as a slaughterhouse) may supply only Category 3 animal by-products to an animal by-products processing plant for the production of feed for farmed animals. In this case, the Waste Framework Directive does not apply.

Therefore, these products of animal origin should be labelled according to requirements of Annex VIII of Regulation (EC) No 142/2011 and Annex V of Regulation (EC) No 999/2001.

Annex II of the Feed Hygiene Regulation, Section 'PRODUCTION', point 8 also establishes that 'The labelling of the products shall clearly indicate whether they are intended for feed or other purposes. If a certain batch of a product is declared not intended for feed use, this declaration shall not be subsequently altered by an operator at a later stage of the chain.'

With respect to the safety and integrity of the food chain, food no longer intended for human consumption placed on the market as waste should be excluded from entering the feed chain (49). Thus, feed business operators cannot use these products when producing feed in their establishments.

## Question 5

I have a feed business company. According to the advice of the competent authorities in my country, I am obliged to buy products from feed or food producers companies which are registered or approved under Regulation (EC) No 183/2005. However, when I buy some products from a company in another Member State, and I require the evidence that this company is registered under that Regulation, they tell me that it is not necessary because at national level they are already registered according to Regulation (EC) No 1069/2009 (Animal by-products Regulation).'

#### **ANSWER**

Registration and/or approval under both Regulations shall apply. Practicalities can be arranged by Member States (e.g. one single registration/approval number or not, one single list referring to either acts or 2 separate lists).

Registration under other EU legislation related to the feed sector and registration under the Feed Hygiene Regulation may be combined provided that the relevant rules for each registration system are complied with and the competent authority decides to operate this combined registration system.

## Question 6

T am a feed business producing raw pet food (50). Pet food may contain products such as raw meat (including offal, bones and fats) or fruits and vegetables, vegetables oils, olive oils etc.

<sup>(48)</sup> Summary Report Standing Committee PAFF 17-18 December 2009 — Point 6. AOB

<sup>(49)</sup> Summary Report Standing Committee PAFF 19/20 May 2014 — Point A.06.

<sup>(50)</sup> See detailed explanation in Chapter 4.3 of Guidelines for the feed use of food no longer intended for human consumption.

On the other hand, as a feed business operator, I must be registered (or approved) according to Regulation (EC) No 183/2005 as every feed producer, for food and non-food producing animals. Should I be registered according to Regulation (EC) No 1069/09 (art. 24) or Regulation (EC) No 183/2005?'

#### ANSWER

Registration and/or approval under both Regulations shall apply.

You should be approved according to Article 24(1)(e) of the Animal by-products Regulation and registered according to Article 9 of the Feed Hygiene Regulation.

As pet food producer you should also pay your attention to requirements on traceability set out in Article 21 and 22, own checks set out in Article 28 and to HACCP plan set out in Article 29 of the Animal by-products Regulation.

Practicalities can be arranged by Member States (e.g. one single registration/approval number or not, one single list referring to either acts or two separate lists). All the activities that the feed business operators carry out must be detailed and it must be assured that the establishment complies with the requirements laid down in the Feed Hygiene Regulation.

## Question 7

'I have an internet business. I import pet food and sell directly to the pet owners. Shall I be considered as covered by the concept of "retailing" as referred to in Article 2(2)(e) of Regulation (EC) No 183/2005?'

#### ANSWER

In absence of any specific provisions on internet sales with regard to feed hygiene, there is no reason to consider internet sales as being outside the scope of retail of pet food as provided in Article 2(2)(e) of the Feed Hygiene Regulation. It is merely one of many business models where feed is equally handled and stored at the point of sale or delivery to the final users. In other words, with regard to pet food sold on the internet directly to the final user (pet owner), the Feed Hygiene Regulation is not directly applicable.

It is not the qualification of a retailer according to the different stages of the business activities ('retailer of pet food' or 'importer') that matters for the application of the Feed Hygiene Regulation, but the activity itself. Article 2(1)(c) of the Feed Hygiene Regulation explicitly provides that this Regulation shall apply to imports and exports of feed from and to third countries. Therefore, even if someone is retailing pet food, activity which is excluded from the scope of the Feed Hygiene Regulation according to its Article 2(2)(e), he still has to comply with the Feed Hygiene Regulation with regard to the imports of pet food.

However, the exclusion of the scope of the Feed Hygiene Regulation does not imply that other requirements such as feed labelling for example, do not have to apply to the feed placed in the market.

On the other hand, if the activity of internet sales includes selling feed not only to final users but selling feed to other establishments, the Feed Hygiene Regulation shall apply.

Pet food may be imported in the Union only if the consignment complies with all provisions of the animal by-products legislation.

## **Question 8**

I have a pet shop and I am selling pet food. But at the same time I am also selling small quantities of feed for food producing species such as rabbits or chickens for consumers that have grown these animals for their private domestic consumption. As the retailing of pet food is excluded from the scope of Regulation (EC) No 183/2005, I think that I do not need to be registered'.

#### **ANSWER**

Effectively, retailing of pet food is out of the scope of the Feed Hygiene Regulation. However, rabbits and chickens for example cannot be considered pets, the retail of this feed is not excluded from the scope of the Feed Hygiene Regulation, therefore, the pet shop, for this activity, should be at least registered according to Article 9(2).

#### Question 9

'I am a veterinarian running an animal hospital. At the same time I am also offering to my customers special products for animal nutrition. Do I need to be registered according to the Feed Hygiene Regulation?'

## **ANSWER**

The production and/or sale of feed for food producing animals and the production of pet food fall within the scope of the Feed Hygiene Regulation and for these activities the veterinary surgery or clinic must be registered or, if applicable, authorised according to the Feed Hygiene Regulation.

The sale of pet food would be regarded as a retailing activity and would therefore fall out of the scope of the Feed Hygiene Regulation. However, rabbits and chickens for example cannot be considered pets. The retail of such feed is not excluded from the scope of the Feed Hygiene Regulation, therefore, this activity must be registered or, if applicable, approved according to the Feed Hygiene Regulation.

## 9. FREQUENTLY ASKED QUESTIONS — COMPETENT AUTHORITIES

#### **Question 10**

'How should Article 10(1)(b) of Regulation (EC) No 183/2005 — approval for premixtures productions (51) be interpreted?'

#### ANSWER

Article 10(1)(b) of the Feed Hygiene Regulation reads as follows:

Feed business operators shall ensure that establishments under their control and covered by this Regulation are approved by the competent authorities, where ... manufacturing and/or placing on the market of premixtures prepared using feed additives referred to in Chapter 2 of Annex IV to this Regulation.'

Therefore, there are three types of situations:

- a feed business operator manufactures and places on the market premixtures;
- a feed business operator places on the market premixtures;
- a feed business operator manufactures premixtures.

The last case is only relevant if the producer of premixtures works by order of another feed business operator or the producer only uses the premixtures in its own establishment. The production of premixtures for internal use is particularly relevant for such additives which can be used for the production of compound feed only in form of a premixture.

In conclusion, all producers of premixtures containing additives mentioned in Annex IV Chapter 2 for their own use as well as for placing on the market need an approval for this operation.

## Question 11

'Pet food given to food banks. During recent years, donation by supermarkets of pet food to food banks to assist people in difficult situations and owning pets has increased. Food banks are intermediaries for the distribution of those products which are normally sold at a symbolic price to the concerned people. Donations concern many different products without any link between them (different size, different brand, etc.). Shall this activity fall under the scope of Regulation (EC) No 183/2005 and also traceability should be required in the cases of pet food donation by a supermarket to a food bank?'

<sup>(51)</sup> Point A.09 of summary report of the Standing Comittee on Plants, Animals, Food and Feed held in Brussels on 15 September 2014-16 September 2014 (section animal nutrition)

#### **ANSWER**

According to Article 2(2)(e), the Feed Hygiene Regulation does not apply to the retailing of pet food.

It could be considered that delivery of pet food from supermarkets (and other retailers) to food banks remains a retail activity under national law and therefore excluded from the scope of the Feed Hygiene Regulation.

However, pursuant to Article 2(3) of the Feed Hygiene Regulation, Member States may establish rules and guidance on the activities excluded from the scope of the Feed Hygiene Regulation.

The general traceability requirements set out in Article 18 of Regulation (EC) No 178/2002 (GFL) (52) nevertheless apply with respect to all activities related to, amongst others, all stages of distribution of feed, including the distribution of pet food from supermarkets to food banks. The latter provision only provides the goal to be achieved and not the means; as such it provides sufficient flexibility for a practical approach. In this way, in order to meet traceability requirements, organisations taking part in this form of distribution need to keep records of where they source the pet food, and if they provide pet food to another organisation, they must also document to whom the pet food has been distributed. Traceability should not be a problem for pre-packed pet food but consideration may have to be given by Member States to pet food sold in bulk.

Further information can be found in the Guidance on the implementation of articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law (53).

In the case of pet food other than processed pet food which reaches the end point in the manufacturing chain of animal by-products in accordance with Article 3(b) and (c) of Regulation (EC) No 142/2011, the food bank must be subject to approval in accordance with Article 24(1)(i) or (j) of Regulation (EC) No 1069/2009.

## Question 12

'How can the registration of interim storage of pet food be considered under the Feed Hygiene Regulation?'

## ANSWER

Article 2, paragraph 2(e) of the Feed Hygiene Regulation lays down that: 'the Regulation shall not apply to: ... the retailing of pet food'.

Since interim storage could be considered as retail establishments in the broader sense of the definition in Article 3(7) of Regulation (EC) No 178/2002, one might conclude that interim storage of pet food are generally excluded from the scope of the Feed Hygiene Regulation and are therefore not the subject of registration by the competent authorities.

However, with regard to interim storage of pet food, the Feed Hygiene Regulation lays down requirements which must be considered, as storage operations fall within the scope of the Feed Hygiene Regulation, e.g.:

 Section 'STORAGE AND TRANSPORT' of Annex II contains requirements regarding storage for feed, and interim storage of pet food are therefore establishments handling products which are considered feed and shall not operate unless the competent authority has registered them;

Interim storage within wholesale operations which are physically limited to transport and storage, must be registered. When wholesale activities include more than storage and transport (for instance re-wrapping), the interim storage of pet food requires establishments to be registered in accordance with Article 9(2).

<sup>(52)</sup> Article 5(1) of Regulation (EC) No 767/2009 establishes that the requirements set out in Article 18 and 20 of Regulation (EC) No 178/2002 and Article 4(1) of Regulation (EC) No 183/2005 shall apply mutatis mutandis to feed for non-food producing animals.

<sup>(53)</sup> DG SANTE Web Page: Food Law General Requirements. http://ec.europa.eu/food/safety/general\_food\_law/general\_requirements\_en

However, in the light of Article 2, paragraph 2(e), interim storage premises of pet food operated by retail outlets not covered by the Feed Hygiene Regulation are not subject to registration while they may be subject to the provisions of Article 24(1)(i) or (j) of Regulation (EC) No 1069/2009.

### **Question 14**

Tam the owner of a warehouse facility that stores for third parties additives listed in Annex IV, chapter 1, and premixtures containing additives listed in Annex IV chapter 2 of Regulation (EC) No 183/2005. Should I be approved according to Article 10 of Regulation (EC) No 183/2005?'

#### **ANSWER**

No. Article 10(1)(a) of the Feed Hygiene Regulation requires that establishments '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' and 'premixtures prepared using feed additives referred to in Chapter 2 of Annex IV to this Regulation' shall be subject to approval. But the activity of 'placing on the market' is the responsibility of the owner of the products (manufacturer and/or intermediary). The owner of the products shall therefore be approved according to Article 10(1)(a) and the warehouse facilities shall be registered according to Article 9(2) of the Feed Hygiene Regulation.

In the same way, transport companies which only transport the products shall be registered according to Article 9(2) of the Feed Hygiene Regulation. Requirement for approval is not necessary.

#### 10. GUIDES TO GOOD PRACTICE

The development, dissemination and use of both national and Community guides to good practice must be encouraged. However, these guides may be used on a voluntary basis by the feed business operators.

Guidelines for the development of Community guides to good practice (54) have been prepared together with the Member States.

These Community guides to good practice were developed in accordance with Article 22 of the Feed Hygiene Regulation. Their contents are practicable throughout the EU for the sector to which they refer and are suitable as guides for compliance with the hygiene and HACCP requirements of the Feed Hygiene Regulation.

## 10.1. EU guides (55)

The Standing Committee on the Food Chain and Animal Health assessed the following Community guides to good practice:

— Title: Community guide to good practice for the EU industrial compound feed and premixtures manufacturing sector for food-producing animals (56) — European Feed Manufacturers Guide

Author: FEFAC — Fédération Européenne des Fabricants d'Aliments Composés (57) (Europäischer Verband der Mischfutterindustrie, European Feed Manufacturers' Federation)

— Title: Community guide to good practice for feed additive and premixture operators (58)

Author: FAMI-QS — European Association for Feed Additives and Premixtures Quality System (59)

— Title: Guide to good practice for the manufacture of safe pet foods (60)

Author: European Pet Food Industry Federation (61)

<sup>(54)</sup> http://ec.europa.eu/food/safety/docs/animal-feed-guides-good-practice-guidelines\_good\_practice\_en.pdf

<sup>(55)</sup> http://ec.europa.eu/food/safety/animal-feed/feed-hygiene/guides-good-practice/index\_en.htm

<sup>(56)</sup> Commission notice on Community guides to good practice (2016/C 418/02) (OJ C 418, 12.11.2016, p. 2).

<sup>(57)</sup> http://www.fefac.org/

<sup>(58)</sup> Notice on community guides to good practice (2007/C 64/04) (OJ C 64, 20.3.2007, p. 17).

<sup>(59)</sup> http://www.fami-qs.org/

<sup>(60)</sup> Commission notice on Community guides to good practice (2018/C 128/03) (OJ C 128, 11.4.2018, p. 3).

<sup>(61)</sup> http://www.fediaf.org/

— Title: European Guide to good practice for the industrial manufacture of safe feed materials (62
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#### Author:

- Starch Europe (63)
- The EU Oil and Proteinmeal Industry (FEDIOL) (64)
- The European Biodiesel Board (EEB) (65)
- In cooperation with the European Feed Ingredients Safety Certification (EFISC) (66).

## Sector reference documents:

- The manufacturing of safe feed materials from starch processing
- The manufacturing of safe feed materials from oilseed crushing and vegetable oil refining
- The manufacturing of safe feed materials from biodiesel processing
- Salmonella auditor checklist
- Fact Sheet Salmonella
- Title: European Guide to Good Hygiene Practices for the collection, storage, trading and transport of cereals, oilseeds, protein crops, other plant products and products derived thereof (67)

## Author:

- European association of cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agro supply trade (COCERAL) (68)
- European agri-cooperatives (COGECA) (69)
- European association of professional portside storekeepers for agribulk commodities within the European Union (UNISTOCK) (70)

The Standing Committee on the Food Chain and Animal Health periodically review the guides in cooperation with the stakeholders and other interested parties.

## 10.2. National Guides

A Register for National Guides to Good Practice (71) has been set up by the Commission to make them available to Member States and feed and food business operators.

<sup>(62)</sup> Commission notice on Community guides to good practice (2016/C 418/02) (OJ C 418, 12.11.2016, p. 2).

<sup>(63)</sup> http://www.starch.eu/

<sup>(64)</sup> http://www.fediol.eu/

<sup>(65)</sup> http://www.ebb-eu.org/

<sup>(66)</sup> http://www.efisc.eu/

<sup>(67)</sup> Commission notice on Community guides to good practice (2016/C 418/02) (OJ C 418, 12.11.2016, p. 2).

<sup>(68)</sup> http://www.coceral.com/

<sup>(69)</sup> http://www.copa-cogeca.be/

<sup>(70)</sup> http://www.unistock.be/

<sup>(71)</sup> http://ec.europa.eu/food/safety/docs/animal-feed-guides-good-practice-biosafety\_food-hygiene\_legis\_guidance\_good-practice\_regnat.pdf

#### ANNEX I

# Non-exhaustive list of rules and criteria under national law established by some Member States (¹) in respect of small quantities as referred to in Article 2, paragraph 2(d) of the Feed Hygiene Regulation

#### EU MEMBER STATES

#### 1. AUSTRIA

'Small quantities at regional farm level' means the deliveries of 3 metric tons from a farm to another farm within a radius of 15 km. No registration is required.

Futtermittelgebührentarif 2017 (FMT 2017) (2) — Feed tariff rate 2017 — FMT 2017.

#### 2. CROATIA

'Small quantities' means those agricultural products produced on agricultural holdings which are registered in the ARKOD system (3) with less than 5 hectares of agricultural land and/or have no more than one valuable livestock unit (4).

Pravilnik o registraciji poljoprivrednika koji posluju s hranom za životinje - Regulation on Registration of farmers who operate with feed (OG 24/16) (5).

## 3. **DENMARK**

'Small quantities' means the direct supply up to 5 tons of primary products per year to local farms for use on those farms within a radius of 50 km from the place of production.

Bekendtgørelse nr. 935 af 27. juni 2018 om foder og foderstofvirksomheder, § 11 - Danish Order No 935 of 27 June 2018 on feed and feed business establishments, § 11

#### 4. ESTONIA

'Small quantities' means a yearly primary production of feed up to 5 tons with the intention to be sold, or any other form of transfer, whether free of charge or not, from the primary producer to an agricultural producer within the territory of Estonia.

Peatükk 3, § 6 (10) Söödaseadus1 (vastu võetud 11.01.2007 RT I 2007, 6, 32) (6) - Chapter 3, § 6 (10) Feed Act (Passed 11.01.2007 RT I 2007, 6, 32) (7)

Vastu võetud 25.04.2007 nr 64; RTL 2007, 37, 641 - Sööda esmatoodangu väikesed kogused ning nende turuleviimise nõuded - Regulation No 64 of the Minister of Agriculture of 25 April 2007; RTL 2007, 37, 641 — Small quantities of primary production of feed and requirements for placing them on market (8).

## 5. **FINLAND**

'Small quantities' means the primary products obtained by feed business operators who are exempted of the obligation of notification (for registration as primary producers) as they only supply exclusively and directly to local farms (or similar operators) from a place of production with a surface area up to 3 hectares.

Rehulaki 8.2.2008/86 (9) - Feed Act 86/2008, amendments up to 565/2014 included (10) (section 18, par. 1).

Maa- ja metsätalousministeriön asetus rehualan toiminnanharjoittamisesta 548/2012 ( $^{11}$ ) - Decree of the Ministry of Agriculture and Forestry on the pursuit of activities in the animal feed sector 548/2012, amendments up to 960/2014 included ( $^{12}$ ) (section 5, par. 2).

- (1) And Norway as EEA Country
- (2) http://www.baes.gv.at/amtliche-nachrichten/gebuehrentarife/futtermittelgesetz/
- (3) The national system of recording of agricultural land
- (4) An animal or group of animals of the same species that weigh no more than 500 kg.
- (5) http://narodne-novine.nn.hr/clanci/sluzbeni/2016\_03\_24\_723.html
- (6) https://www.riigiteataja.ee/akt/101092015029
- (7) https://www.riigiteataja.ee/en/eli/ee/503092015007/consolide
- (8) https://www.riigiteataja.ee/akt/12823160
- (\*) http://www.finlex.fi/fi/laki/ajantasa/2008/20080086?search%5Btype%5D=pika&search%5Bpika%5D=2008%2F86
- (10) http://www.finlex.fi/fi/laki/kaannokset/2008/en20080086.pdf
- (11) http://www.finlex.fi/fi/laki/smur/2012/20120548?search%5Btype%5D=pika&search%5Bpika%5D=548%2F2012
- (12) http://www.finlex.fi/fi/laki/kaannokset/2012/en20120548.pdf

#### **GERMANY** 6.

'Small quantities' means the direct supply of feed from the feed primary producer (with a production up to 5 hectares/ year) at local level (within a 50 km radius from the place of production).

Leitfaden zur Registrierung von Futtermittelunternehmen (seite 12) - Guidance on the registration of feed business operators (page 12) (13).

#### 7. **ITALY**

'Small quantities' means the direct supply, under request of the final user, of primary products obtained in the same farm and located in the same province or neighbouring provinces.

Circolare esplicativa Nazionale del 28 dicembre 2005 numero di protocollo n.45950-P-I8da9/1 - National explanatory notice of 28 December 2005 protocol number n.45950-P-I8da9/1 (14).

#### **LATVIA** 8.

'Small quantities' means the trade of feed primary products (sale, sale or delivery whether free of charge or not) up to ten tons per calendar year.

Ministru kabineta noteikumi Nr.865 – 2009 gada 4.augustā (prot. Nr.51 40.§) Higiēnas prasības dzīvnieku barības primārajai ražošanai un tiešajām piegādēm mazos daudzumos - Regulation of Cabinet of Ministers of Latvia Number 865, in force from 4 August 2009, Hygiene Requirements for feed at primary production and the direct supply of small quantities.

#### **SLOVENIA** 9

'Small quantities' means any quantity of feed of plant origin from the primary production produced in an agricultural holding which is delivered to another agricultural holding as final user within the territory of the Republic of Slovenia.

Člen 2(6) Pravilnik o registraciji in odobritvi obratov nosilcev dejavnosti na področju krme (Uradni list Republike Slovenije, št. 50/15, 67/65) - Article 2(6) of the Rules on the registration and approval of establishments of feed business operators (Official Journal of the Republic of Slovenia 50/15, 67/65) (15).

#### **SWEDEN** 10.

'Small quantities' means the direct supply up to 10 tons of dry matter of primary products per year to local within a 50 km radius from the place of production.

Kapitel 4 (§1) Statens jordbruksverks föreskrifter och allmänna råd om foder - State Board of Agriculture regulations and general advice on feed, Chapter 4 (§1).

#### 11. **UNITED KINGDOM**

United Kingdom has not introduced legislation to determine small quantities of feed in respect of the provisions of Article 2, paragraph 2(d) in Regulation (EC) No 183/2005. However, as a general guide, enforcement authorities use a working definition of small quantities of primary production of feed as being less than 20 tonnes per year.

## OTHER EEA COUNTRIES

#### **NORWAY**

'Small quantities' means the direct supply up to 15 tons of primary products per year to local farms within 30 km from the place of production.

Forskrift om fôrhygiene, § 3. Unntak for små mengder landdyrfôr til lokale mottakere - Regulation on feed hygiene, § 3. Exception for small quantities of feed to local farmers (16).

<sup>(13)</sup> http://www.bvl.bund.de/SharedDocs/Downloads/02 Futtermittel/fm Leitfaden Registrierung Betriebe.pdf? blob= publicationFile&v=3

<sup>(14)</sup> http://www.salute.gov.it/imgs/C\_17\_pubblicazioni\_1198\_allegato.pdf (15) http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV7397

<sup>(16)</sup> https://lovdata.no/dokument/SF/forskrift/2010-01-14-39?q=fôrhygiene

#### ANNEX II

## Lists of establishments registered in accordance with Article 9 of the Feed Hygiene Regulation

#### EU MEMBER STATES

#### 1. AUSTRIA

https://www.baes.gv.at/amtliche-nachrichten/kundmachungen/futtermittelgesetz/

#### 2. **BELGIUM**

http://www.favv-afsca.fgov.be/productionanimale/alimentation/agrementsautorisations/

## 3. BULGARIA

http://www.babh.government.bg/en/Object/site\_register/index/

## 4. CROATIA

http://www.veterinarstvo.hr/default.aspx?id=12

#### CYPRUS

http://www.moa.gov.cy/moa/da/da.nsf/All/B5CA788BBB54A58BC22581E800448B77?OpenDocument

## 6. CZECH REPUBLIC

http://eagri.cz/public/app/srs\_pub/eu183/index.php?search=advanced

## 7. **DENMARK**

https://www.foedevarestyrelsen.dk/Leksikon/Sider/Lister-over-registrerede-fodervirksomheder.aspx

## 8. ESTONIA

https://jvis.agri.ee/jvis/avalik.html#/kaitlemisettevotedparing

## 9. **FINLAND**

https://www.evira.fi/en/animals/feed/

#### 10. FRANCE

https://www.economie.gouv.fr/dgccrf/profil-entreprise/exploitants-enregistres-secteur-alimentation-animale

## 11. **GERMANY**

 $https://www.bvl.bund.de/DE/02\_Futtermittel/03\_AntragstellerUnternehmen/01\_Zulassungs\_Registrierungspflicht/02\_Futtermittelbetriebe\_Verzeichnis/fm\_FMBetriebeVerzeichnis\_node.html$ 

#### 12. GREECE

http://www.minagric.gr/index.php/en/farmer-menu-2/livestock-menu/feedingstuffs-menu

## 13. HUNGARY

http://portal.nebih.gov.hu/-/takarmany-listak

## 14. IRELAND

http://www.agriculture.gov.ie/agri-foodindustry/feedingstuffs/listsoffbos-registeredandapproved/

#### 15. ITALY

http://www.salute.gov.it/portale/temi/p2 6.jsp?lingua=italiano&id=1572&area=sanitaAnimale&menu=mangimi

## 16. LITHUANIA

http://www.vic.lt:8101/pls/seklos/rpu.sel

## 17. LUXEMBOURG

http://www.securite-alimentaire.public.lu/professionnel/aliments\_animaux/index.html

## 18. LATVIA

http://www.pvd.gov.lv/?sadala=615#jump

#### 19. **MALTA**

http://agriculture.gov.mt/en/vrd/Documents/2017/animalNutritionSection/Register % 20 of % 20 Maltese % 20 Feed % 20 Businesses % 20 v.120917.pdf

## 20. THE NETHERLANDS

https://english.nvwa.nl/topics/approved-establishments/animal-feed-sector

#### 21. POLAND

https://pasze.wetgiw.gov.pl/demo/index.php? mode=2&search\_mode=1&lng=&protect=952b2f6e4c267ed40ecee2abc7a0737e

## 22. PORTUGAL

http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=201155&cboui=201155

#### 23. ROMANIA

http://www.ansvsa.ro/unitati-nutritie-animala/

#### 24. SLOVAKIA

http://www.uksup.sk/okvz-register/

## 25. SLOVENIA

http://www.uvhvvr.gov.si/en/registers\_and\_lists/feed/list\_of\_feed\_establishments/

#### 26. SPAIN

http://www.mapama.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/registro\_general\_establecimientos.aspx

## 27. SWEDEN

http://www.jordbruksverket.se/swedishboardofagriculture/engelskasidor/animals/feedandanimalbyproducts.4.3a2bcf1b1244c6487a480004440.html

## 28. UNITED KINGDOM

https://www.food.gov.uk/enforcement/sectorrules/feedapprove/feedpremisesregister

## OTHER EEA COUNTRIES

#### 1. NORWAY

https://www.mattilsynet.no/om\_mattilsynet/godkjente\_produkter\_og\_virksomheter/forvarer/approved\_and\_registered\_feed\_companiespdf.9258-438/binary/Approved%20and%20registered%20feed%20companies.pdf

#### ANNEX III

# Based on Annex IV of the Feed Hygiene Regulation concerning approval of feed business establishments (ref. Article 10 of the Feed Hygiene Regulation)

#### **CHAPTER 1**

Additives authorised pursuant to Regulation (EC) No 1831/2003:

- Nutritional additives: all additives in the group,
- Zootechnical additives: all additives in the group,
- Technological additives: additives covered by Annex I(1)(b) ('anti- oxidants') of Regulation (EC) No 1831/2003: only those with a fixed maximum content,
- Sensory additives: additives covered by Annex I(2)(a) ('colorants') of Regulation (EC) No 1831/2003: carotenoids and xantophylls.

#### **CHAPTER 2**

Additives authorised under Regulation (EC) No 1831/2003:

- Zootechnical additives: additives covered by Annex I(4)(d) ('other zootechnical additives') of Regulation (EC) No 1831/2003
- Coccidiostats and histomonostats: all additives,
- Nutritional additives:
  - additives covered by Annex I(3)(a) (Vitamins, provitamins and chemically well-defined substances having a similar effect) of Regulation (EC) No 1831/2003: A and D,
  - additives covered by Annex I(3)(b) ('compounds of trace elements') of Regulation (EC) No 1831/2003: Cu and Se.

## **CHAPTER 3**

Additives authorised under Regulation (EC) No 1831/2003:

- Zootechnical additives: additives covered by Annex I(4)(d) ('other zootechnical additives') of Regulation (EC) No 1831/2003
- Coccidiostats and histomonostats: all additives.