

EC FEED HYGIENE REGULATION (183/2005)

*This question and answer (Q&A) guidance note provides advice on the requirements of the **EC Feed Hygiene Regulation (183/2005)**¹. The guidance has been updated to take into account latest developments and in response to stakeholder comments. A list of definitions is provided at Annex A.*

It should be borne in mind that interpretation of legislation contained within this document is only in the form of opinions and ultimately only the courts can give an authoritative interpretation of the law.

Legislative Background

The Feed Hygiene Regulation was one of a number of animal feed measures proposed in the European Commission's White Paper on Food Safety of January 2000. It contains a number of provisions aimed at improving feed safety. This includes rules to improve the operational standards of feed businesses, and traceability measures to ensure that in the case of a feed contamination incident, feeds can be easily traced and recalled if necessary. The Regulation also requires the approval and/or registration of feed business establishments.

EC Regulations are directly applicable in all Member States. However, in order to give them effect in the UK, it is necessary to introduce certain national rules. For EC Regulation 183/2005, national enforcement powers (e.g. penalties and offences) and procedures for application for approval and registration have been introduced in ***The Feed (Hygiene and Enforcement) (Wales) Regulations 2005 (WSI 2005 No.3368 (W.265))***, which came into force on 1 January 2006. These Regulations can be viewed online at:

<http://www.opsi.gov.uk/legislation/wales/wsi2005/20053368e.htm>

Separate but parallel Regulations were also made in England, Scotland and Northern Ireland. These Regulations also came into force on 1 January 2006.

A copy of Regulation 183/2005 and other animal feed legislation can be downloaded from the Agency's website at:

<http://www.food.gov.uk/foodindustry/farmingfood/animalfeed/>

Alternatively, for further information you can contact:

**General Enforcement Branch
Food Standards Agency Wales
11th Floor Southgate House
Wood Street
Cardiff
CF10 1EW**

**Or by e-mail to: andrew.morris@foodstandards.gsi.gov.uk
Direct line: 029 20678960 Fax: 029 20678918**

In Great Britain feed legislation is enforced, primarily by trading standards departments of local authorities. In Northern Ireland, enforcement is carried out by the Department of Agriculture and Rural Development (DARD). If a feed business operator has a specific query on approval and/or registration they should contact their enforcement authority for further advice.

¹ The EC Feed Hygiene Regulation (183/2005) of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene.

Approval and Registration

Q1. Who is covered?

A1. Virtually all feed businesses² that make, market or use animal feed, including manufacturers of compound feeds, feed materials, feed additives and premixtures, and importers and sellers of these products require approval and/or registration. Also covered are transporters of feed (e.g. haulage companies), storers of feed, food and biofuel companies selling co-products for use as feed and pet food manufacturers. Livestock farms, fish farms and arable farms growing and using or selling crops for feed use are also within the scope of the Regulation.

Q2. What is the difference between approval and registration?

A2. Approval requires a prior inspection visit by the enforcement authority before a feed business establishment is allowed to operate. Registration involves the placing of premises on a list with follow-up checks. Generally establishments subject to approval are those which carry out certain higher risk activities such as the manufacture and marketing of certain feed additives or premixtures of feed additives. A list of approval activities can be downloaded from the link directly below. The vast majority of feed business establishments (including most farms) are subject to the registration requirement.

Q3. How does a new business make an application for approval and/or registration?

A3. EC Regulation 183/2005 requires feed business operators to notify the relevant enforcement authority of any establishment under their control active in any stage of production, processing, storage, transport or distribution of feed in a form required by the enforcement authority with a view to applying for approval and/or registration. A model application document and list of approval and/or registration activities can be found on the Food Standards Agency's (FSA) website at:

<http://www.food.gov.uk/foodindustry/guidancenotes/hygguid/approvregfeedguidance>

Q4. Is it possible to amend an approval or registration?

A4. Yes. For example, this might be where a new activity is to be carried out. In this case a new application should be completed. This will need to include similar details as in the original application on the identity of the establishment. However, the new activity should be indicated in section 3 of the application.

Q5. Is there a fee for registration or approval?

A5. There are no fees for registering establishments. However, there is a fee chargeable by the enforcement authority for premises applying for approval for the first time and for an amendment to an approval. The Feed (Hygiene and Enforcement) Regulations 2005 set out the provisions on approval fees (Regulation 14 – Schedule 2).

Q6. Who do I register with for the mixing of medicated feed or the use of specified feed additives (e.g. coccidiostats, histomonostats and non-antibiotic growth promoters)?

A6. Farmers mixing medicated feedingstuffs must register with, and be approved by, the Animal Medicines Inspectorate (AMI) of the Veterinary Medicines Directorate (VMD).

For details on how to apply for approval contact the AMI at the following address:

Animal Medicines Inspectorate, Stoneleigh Park, Warwickshire, CV8 2LZ
Tel: 024 7684 9260 fax: 024 7684 9261 e-mail: enquiries@ami.gov.uk

² Feed businesses are defined 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.' (This definition is from the EC Regulation on Feed and Food Law (178/2002).

Veterinary Medicines Guidance Note number 22 provides guidelines on the manufacture of medicated feedingstuffs and feedingstuffs incorporating specified feed additives and can be obtained from the VMD at the following address and weblink:

Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS

Email: Telephone +44 (0)1932 336911 Fax: +44 (0)1932 336618

http://www.vmd.gov.uk/General/VMR/vmg_notes07/VMGNote22.pdf

Q7. Does the Regulation apply to biofuel companies?

A7. Companies that market co-products from biofuel production for animal feed use are subject to the requirements of Regulation 183/2005. This means that they are subject to registration and must apply the principles of a Hazard Analysis Critical Control Points (HACCP) system and Annex II of the Regulation – see Q16

Q8. Do the provisions apply to all food producers which provide material for animal feed, despite the fact that the material will undergo some further processing, e.g. pet food use, fishmeal producers?

A8. Yes. The provisions of Regulation 183/2005 apply despite the overlap with certain areas of the Animal By-products legislation

Q9. Do shipping companies need to be registered? If so, where would registration take place?

A9. Whether or not a shipping company requires registration depends on whether the company undertakes the activities characteristic of a feed business. If a company has several premises at which feed activities are undertaken, then a separate application will need to be made to each enforcement authority in which the premises are located.

Q10. Are hauliers subject to the requirements of the Regulation?

A10. A business which transports feed is a feed business for the purposes of Regulation 183/2005. Where companies have depots at which feed transport activities take place, those individual depots should register with each local authority in which the depots are located.

Q11. How will intermediaries, that act solely as traders without ever holding the product in their facilities, be affected?

A11. They will need to apply for approval or registration. However, there are special conditions that apply to intermediaries that act solely as traders without ever holding the product in their facilities. For example, those applying for approval will not be subject to prior on-site visits (Article 17(1) of the Feed Hygiene Regulation refers). To qualify for this exemption, the intermediary must make a declaration that they meet the requirements laid down in Article 17(2) of the Regulation.

Q12. Are some activities exempt from the approval/registration requirements?

A12. Yes. The following activities are outside the scope of the Feed Hygiene Regulation:

- the private domestic production of feed for food-producing animals kept for private domestic consumption and for animals not kept for food production;
- the feeding of food-producing animals kept for private domestic consumption;
- the feeding of animals not kept for food production;
- the direct supply of small quantities of primary production of feed at local level by a producer to local farms for use on those farms;
- the activities mentioned in Article 1(2)(c) of EC Regulation 852/2004 are described as “the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the consumer”.

Article 2(1)(b) defines “primary products” as “products of the soil, of stock farming, of hunting and fishing”;

- the retailing of pet food.

(EC Regulation 183/2005 does not define ‘small quantities’. However, a working definition of primary production of feed is less than 20 tonnes per annum).

(“Local” and “localised” is being interpreted as “sales within the supplying establishment’s own county *plus* the greater of either the neighbouring county or counties or 30 miles/50 kilometres from the boundary of the supplying establishment’s county”).

Q13. Is there a published list of approved premises?

A13. Yes. There is a legal requirement under Regulation 183/2005 for the competent authorities of Member States to provide a national list of UK approved establishments to the Commission and for the Commission to publish such lists for the first time in November 2007 and thereafter each year by 30 November. The list of approved establishments was posted to the Agency’s website and also sent to the Commission. It can be accessed from both the links below:

<http://www.food.gov.uk/multimedia/pdfs/ukfeedapproved.pdf>

<http://www.vmd.gov.uk/Industry/AMI/ApprovedPremises.pdf>

Q14. Where can a list of registered premises be found?

A14. EC Regulation 183/2005 also requires the competent authority of Member States to ‘record in a national list or lists the establishments they have registered’ and to ‘make available to the public, the lists of registered establishments’. The Agency carried out a feasibility study and it was considered that a central list of registered establishments should not be drawn up as such a list would be very resource intensive for enforcement authorities and the Agency. To meet the provision of making the lists publicly available, enforcement authorities have been advised to hold this information on a local basis, and if possible publish such details on their websites and/or provide online contact details from whom, in the authority, enquirers can obtain this information.

Q15. Can a feed business label its feeds with the approval number allocated by the Animal Medicines Inspectorate (AMI), rather than the approval or registration number issued by a local authority?

A15. The requirement to include AMI numbers on labels of feeds predates the EC approval number requirement. Previous advice was that where an establishment has an AMI number and a local authority number, only the AMI number needs to be included on the label.

Conditions of EC Regulation 183/2005

Q16. What are the main requirements of the Regulation?

A16. The Regulation contains various operational requirements that feed businesses must comply with. The detailed requirements are mainly set out in Annexes I, II and III of the Regulation (see below) and include standards relating to facilities and equipment, personnel, quality control, storage and transport and record-keeping. Most feed businesses, except the majority of farms, were required to apply the principles of a HACCP system by January 2008.

Now that the Regulation is in force, enforcement authorities will be implementing an enforcement programme and will be carrying out visits to check compliance on farms.

Annex I - covers the requirements that primary producers (farms) have to follow. Operations should be managed to avoid hazards and to ensure that feed products produced and used are protected against contamination and spoilage.

Annex II – this applies to businesses operating other than at the level of primary production. It includes requirements relating to facilities and equipment, personnel, production, quality control, storage and transport and record-keeping.

In addition, feed businesses (except most farms) are required to apply the principles of a HACCP system.

Annex III - is a code on animal feeding practice, which all producers are obliged to follow when feeding animals that produce food products for human consumption.

Q17. What are the conditions in respect of food manufacturing companies?

A17. Businesses selling co-products such as other surplus food products from the food and drink industry for use as animal feed are subject to registration (co-products are products which have value in their own right as feed materials, e.g. soyabean meal, brewers' grains, wheat feed, bakery products). Businesses selling such products for use as animal feed must also comply with the requirements of Regulation 183/2005 – Q16 above refers.

Farms

Q18. What are the requirements that farms have to follow?

A18. Most livestock farms and arable farms that grow, use or sell crops for use as animal feed will need to comply with the requirements of Annex I of the Regulation. This requires that operators avoid hazards to ensure that feed produced and used is protected against contamination and spoilage. There are also certain record-keeping requirements that must be carried out. The majority of farms do not need to apply HACCP principles. However, farmers that mix feed containing additives and premixtures must follow more detailed requirements (see below).

Q19. What are the requirements that farmers have to follow who mix feed containing additives or premixtures such as Vitamin A and D and trace elements (copper, selenium, zinc etc)?

A19. This type of activity is considered higher risk compared with some other on-farm activities, therefore farmers must comply with Annex II of Regulation 183/2005 and adopt the principles of HACCP.

Q20. What are the requirements that farmers have to follow who mix feeds with complementary feeds containing additives?

A20. These types of farms must comply with the conditions set out in Annex I and III of Regulation 183/2005. They are not required to adopt the full principles of HACCP but should identify and adequately control feed hazards, to ensure that the objectives of the Regulation are met. In the UK, under previous legislation (Directive 95/69) the requirements applied to farms which mix feeds with complementary feeds containing certain additives. For these farms the requirements of Regulation 183/2005 applied from 1 January 2006.

Farms mixing feeds with non-antibiotic growth promoters, coccidiostats and histomonostats (including complementary feeds, containing these additives) are subject to approval by the Animal Medicines Inspectorate (AMI), which is part of the Veterinary Medicines Directorate. This reflects the position that previously applied under Directive 95/69.

The use of antibiotic growth promoters was banned from 1 January 2006.

Q21. What is required of farmers who store bought-in feed?

A21. A farmer who buys manufactured feed and stores it (with no mixing) before feeding it to livestock would be required to comply with Annexes I and III of Regulation 183/2005. The activity carried out is considered to be lower risk as no mixing of additives is involved. This is also the case if the feed is a compound feed containing additives.

Q22. Do these new requirements apply to farms that top dress feeds?

A22. Yes. The practice of 'top dressing' (i.e. spreading additives/premixtures or compound feeds containing additives on top of other feeds e.g. forage and cereals), which was not previously subject to registration, is now caught by the provisions of the Feed Hygiene

Regulation. This is because the Regulation covers feed businesses that 'carry out any operation of production, manufacture, processing, storage, transport or distribution of feed'.

Q23. Where can I obtain further guidance on feeding practices?

A23. The Advisory Committee on Animal Feedingstuffs Review of 'On-Farm Feeding Practices' report (available from the link below) includes information on identifying hazards and minimising risks in the use of feed at farm level;

<http://www.food.gov.uk/multimedia/pdfs/farm.pdf>

Industry Code of Practice for On-Farm Feeding. This Code applies to farmers and covers all aspects of on farm feeding, including on farm mixing. A copy of this code can be found at:

http://www.redtractor.org.uk/download/rt_code_farm_feeding.pdf

Q24. What are the requirements for primary producers under the Food Hygiene Regulation (852/2004)?

A24. The Q&A relating to food hygiene for farmers and growers can be found on the following area of the FSA website:

<http://www.food.gov.uk/foodindustry/regulation/hygleg/hygleginfo/primprodqanda/>

Pet food and feed for other non-food producing animals

Q25. What is the status of the wholesaling of pet foods?

A25. As laid down in Article 2(2)(e) of Regulation 183/2005, the provisions of this Regulation do not apply to the retailing of pet food. However, all other activities relating to the distribution and storage of pet foods fall within the scope of the Regulation, and therefore feed businesses carrying out such activities are subject to registration. There types of businesses must also comply with the relevant requirements of the Regulation.

Q26. Does the Regulation cover the manufacture of horse feeds?

A26. Yes, the manufacture of feeds for horses is within the scope of Regulation 183/2005; however, there are two exemptions relevant to consideration of activities related to horse feeds. The Regulation does not apply to: a) the feeding of animals not kept for food production (Article 2(2)(c)), and b) the retailing of pet food (Article 2(2)(e)).

Q27. How does the Regulation affect establishments keeping horses?

A27. Whilst the Regulation does not apply to the feeding of animals not kept for food production (Article 2(2)(c)), in some circumstances it may be obvious that horses are being kept for human consumption and therefore fall within the scope of the Regulation. For example, an establishment rearing horses with the intention of selling them for the human food market or where the horse passport, required under the Horse Passports (England) Regulations 2004³ had been completed to indicate a horse was available for human consumption. These types of establishments would be subject to approval or registration under the Feed Hygiene Regulation.

Q28. How does the Regulation affect the product dog chews?

A28. Generally establishments making, packing and storing pet foods, etc. would need to apply for registration. However, the position with regard to dog chews is slightly different as follows:

Solid raw hide chews are not sold to contribute to the nutritional needs of a pet and not considered a feedingstuff. By comparison, if the chew consists of chopped or ground hide together with binder then they do have a nutritional value and therefore would be caught by the Feed Hygiene Regulation- this means that businesses making, storing or packing such chews would require registration.

³ Equivalent legislation applies in England, Scotland and Northern Ireland

Q29. What is the position for a company that markets food products for humans, which is then re-branded for pets (e.g. dog treats)?

A29. If a company is manufacturing and/or putting pet foods into circulation, it would be subject to registration under Regulation 183/2005.

Q30. Does the Regulation cover the retailing of food for ornamental fish?

A30. Where ornamental fish are clearly kept for ornament only and will never enter the human food chain, then the retailing of feed for such fish is outside the Regulation.

Q31. Where can I find further information about pet food?

A31. A background note on pet food can be found on the Agency's website at:

<http://www.food.gov.uk/multimedia/pdfs/petfood.pdf>

Importing feed from non-EU countries (third countries)

Q32. How does the Regulation affect imports from non-EU countries?

A32. At present there is no requirement for non-EU countries to register or be approved in the EU. However, feed businesses can import feed products only from those non-EU countries that have a representative 'established in the European Community'. Article 23 of Regulation 183/2005 sets out the conditions relating to imports from non-EU countries and Article 24 provides details of the interim measures in place. This is a continuation of the arrangements that applied under previous legislation (Article 6 of Directive 98/51/EC). These representatives are required to submit to the competent authority (in the UK this is the FSA and in Northern Ireland it is DARD), declarations as to the activities carried out on the manufacturing establishment. This is to ensure that imported additives, premixtures and feedingstuffs containing additives comply with the same quality control standards that apply in Member States.

It should be noted that these are only interim arrangements. Regulation 183/2005 envisages that all non-EU countries and establishments exporting feed to the EU are entered into a Community list. We await further information from the European Commission regarding progress on this area of work.

Community and national Guides to Good Practice

Q33. Where do I find the Guidelines for the development of national voluntary Guides to Good Hygiene Practice?

A33. Article 20 of Regulation 183/2005 provides for the development, dissemination and use of national Guides to Good Practice. (This Article also covers Community Guides – see Q34 below).

In March 2007, the Agency carried out a public consultation on draft guidelines for the development and assessment of national Guides to good practice drawn up by industry. The revised Guidelines were published on the Agency's website at:

<http://www.food.gov.uk/multimedia/pdfs/feednvgaugust07.pdf>

Guides submitted will be considered by an assessment panel to ensure that they are suitable and practicable guides to compliance with the legislation.

Q34. What is the position with regard to Community guides as referred to in Article 22 of the Regulation?

A34. Such guides must be drawn up by, or in consultation with, representatives of the European feed sectors. To date three Community Guides to good practice have been developed in accordance with Article 22 of Regulation 183/2005. These Guides may be used on a voluntary basis by feed business operators as an aid to compliance with the requirements of the Regulation.

The Guides, which cover compound feed manufacture, feed additive/premixture manufacture, and pet food manufacture, have been published in the 'C' series of the Official Journal of the European Union and can be found on the European Commissions website at:

http://ec.europa.eu/food/food/animalnutrition/feedhygiene/guide_goodpractice_en.print.htm

Feed Additives

Q35. Is Propcorn classed as an additive?

A35. This product is either an additive or premixture on the basis that it has a preservative effect and it contains propionic acid which is an authorised feed additive.

Q36. Where can I find a list of authorised feed additives?

A36. The list of authorised feed additives can be found by way of the Community Register of Feed Additives, which can be found via the following link:

http://ec.europa.eu/comm/food/food/animalnutrition/feedadditives/registeradditives_en.htm

Q37. Is there any guidance on the legislation that applies to the marketing and use of feed additives, and the authorisation process?

A37. Yes. The Agency has issued guidance in question and answer form which is available to view on the link below:

<http://www.food.gov.uk/multimedia/faq/animalfeedaddfaq/>

**General Enforcement Branch Wales
August 2008**

CERTAIN DEFINITIONS

Competent authority: authority of a Member State or of a third country designated to carry out official controls - EC Regulation 183/2005 on Feed Hygiene, Article 3(e). Examples in the UK include the Food Standards Agency, local authorities and the Department of Agriculture and Rural Development in Northern Ireland.

Complementary feed: mixtures of feedingstuffs which have a high content of certain substances but which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs - Council Directive 79/373/EEC on the marketing of compound feedingstuffs, Article 2(e).

Compound feed: organic or inorganic substances in mixtures, whether or not containing additives, for oral animal feeding in the form of complete feedingstuffs or complementary feedingstuffs - Council Directive 79/373/EEC on the marketing of compound feedingstuffs, Article 2(b).

Establishment: any unit of a feed business - EC Regulation 183/2005 on Feed Hygiene, Article 3(d).

Feed additive: substances, micro-organisms or preparations, other than feed materials and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions: (a) favourably affecting the characteristics of feed, (b) favourably affecting the characteristics of animal products, (c) favourably affecting the colour of ornamental fish and birds, (d) satisfying the nutritional needs of animals, (e) favourably affecting the environmental consequences of animal production, (f) favourably affecting animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or (g) having a coccidiostatic or histomonostatic effect - EC Regulation 1831/2003 on additives for use in animal nutrition, Article 2(a).

Feed business operator: the natural or legal person responsible for ensuring that the requirements of the present Regulation are met within the feed business under their control - EC Regulation 183/2005 on Feed Hygiene, Article 3(b).

Feed hygiene: the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use - EC Regulation 183/2005 on Feed Hygiene, Article 3(a).

Feed (or 'Feedingstuff'): means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals - EC Regulation 178/2002 on the general principles of food and feed law, Article 3(4).

HACCP (Hazard Analysis and Critical Control Points): HACCP is a system of food safety management based on the prevention of food safety problems. It provides a documented, structured approach to ensuring food safety and places a requirement on businesses to identify, manage and control hazards inherent in their handling and production process, and is a risk based system. The general principles of HACCP are outlined in Article 6 of EC Regulation 183/2005 on Feed Hygiene.

Premixture: a mixture of feed additives, or a mixture of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals - EC Regulation 1831/2003, Article 2(e).

(Additives include vitamins, trace elements (e.g. copper), and preservatives. Premixtures of additives should be labelled as such. They should not be confused with other more commonly used animal feeds containing additives such as 'complementary feedingstuffs' or 'mineral feedingstuffs' which also should be clearly labelled as such).

Third country establishment: any unit of a feed business located outside the EU.