

EUROPEAN PARLIAMENT AND COUNCIL REGULATION 183/2005 OF 12 JANUARY 2005 LAYING DOWN REQUIREMENTS FOR FEED HYGIENE

GUIDANCE FOR STAKEHOLDERS

This question-and-answer guidance note provides advice on the interpretation and implementation of certain aspects of EC Regulation 183/2005 laying down the requirements for feed hygiene. It has been compiled both in response to specific questions asked by enforcement authority and feed industry stakeholders, and has been updated to take account of the current position.

This guidance note is intended for the use of enforcement authority and feed industry stakeholders, including importers, feed manufacturers, merchants and on-farm growers and users of feed, as well as producers of feed for pets and other non-food-producing animals. All feed businesses covered by EC Regulation 183/2005 must comply with all those provisions which apply to their activity. There are no exceptions for small and medium-sized enterprises.

This guidance note cannot cover every situation and stakeholders may need to consider the legislation itself to see how it applies in their particular circumstances. However, this guidance note should help stakeholders comply with the law. Businesses with specific queries may wish to seek the advice of their local enforcement authority, which in Northern Ireland will be the Department of Agriculture and Rural Development (DARD).

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, and contains a number of provisions aimed at improving feed safety. These include rules to improve the operational standards of feed businesses and traceability measures to ensure that in the case of a feed contamination incident feed products can be easily traced and recalled if necessary. The Regulation also requires the registration and/or approval of feed business establishments.

EC Regulations are directly applicable in all Member States, but in order to give them effect in the UK it was necessary to introduce certain national rules. For EC Regulation 183/2005, national enforcement powers (e.g. penalties and offences) and procedures for application for registration and approval were introduced in the The Feed (Hygiene and Enforcement) Regulations (Northern Ireland) 2005 (S.R. 2005 No. 546), which came into force on 1 January 2006. (There is separate but parallel legislation in England, Scotland, and Wales.)

The Regulations can be found online at <http://www.legislation.gov.uk/browse/ni> (enter the year and number of the measure in the search box at the top of the page).

A copy of Regulation 183/2005 can be found online at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_035/l_03520050208en00010022.pdf

Details of other animal feed legislation can be found on the Food Standards Agency's website at: <http://www.food.gov.uk/foodindustry/farmingfood/animalfeed/animalfeedlegislation>

Further Information

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QUESTIONS AND ANSWERS

Approval and Registration

1. *Who is covered by the Feed Hygiene Regulation?*

Virtually all feed businesses 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 to be registered and/or approved. The Regulation also applies to those who transport (e.g. haulage companies) or store feed, to biofuel and food businesses selling co-products or surplus food for use as feed, to pet food manufacturers, and to feed for creatures living freely in the wild and wild game intended for human consumption. Livestock farms, fish farms and arable farms growing and using or selling crops for feed use are also within the scope of the Regulation.

There are some feed-related activities to which the Regulation does not apply. These exemptions are listed at question 12 below.

2. *What is the difference between approval and registration?*

Approval requires a prior inspection visit by the enforcement authority before a feed business establishment is allowed to operate. Registration involves the placing of establishments on a list with follow-up checks. The vast majority of feed business establishments, including most farms, are subject to the registration requirement. The requirement for approval applies to those establishments which carry out certain higher risk activities such as the manufacture and marketing of certain feed additives or premixtures of feed additives, or the production of feed containing specified feed additives.

3. *How does a business apply for approval and/or registration?*

Regulation 183/2005 requires feed business operators to notify the relevant enforcement authority of any establishment under their control active in any stage of the production, processing, storage, transport or distribution of feed, with a view to applying for approval and/or registration. A model application document for this purpose, which has a list of approval and registration activities annexed to it, can be found on the Food Standards Agency's (FSA) website at <http://www.food.gov.uk/multimedia/pdfs/feedhygmodelform.pdf>

4. *Is it possible to amend an approval or registration?*

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

5. *Is there a fee for registration or approval?*

There are no fees for the registration of establishments. However, there is a fee chargeable by the enforcement authority for establishments applying for approval for the first time, and for an amendment to an existing approval. The provisions on approval fees are set out in regulation 14 and Schedule 2 of the Feed (Hygiene and Enforcement) (Northern Ireland) Regulations 2005.

6. *What about the mixing of medicated feed or the use of specified feed additives (e.g. coccidiostats, histomonostats and non-antibiotic growth promoters)?*

In Northern Ireland, feed businesses mixing medicated feeds must be approved by DARD. Its contact details are as follows:

DARD Quality Assurance Branch
Room 115
Magnet House
81-93 York Street
Belfast BT15 1AB
Telephone: +44 (0)2890 547194
Email gab.admin@dardni.gov.uk

Veterinary Medicines Guidance Note number 17 provides guidance on the manufacture of medicated feeds and feeds which incorporate specified feed additives. It can be obtained from the VMD either at the address above or online at: <http://www.vmd.defra.gov.uk/pdf/vmgn/VMGNote17.pdf>

7. *Does the Regulation apply to biofuel companies?*

Biofuel-producing businesses that market co-products for animal feed use are subject to the requirements of Regulation 183/2005. This means that they must register and must apply the principles of a Hazard Analysis Critical Control Points (HACCP) system and Annex II of the Regulation -- see question 16 for further information.

8. *Does the Regulation apply to all businesses which provide material for animal feed, even though some of it may undergo further processing (e.g. for use in pet food or fishmeal)?*

Yes. The provisions of Regulation 183/2005 apply irrespective of any overlap with certain areas of the Animal By-Products legislation for which Defra is responsible.

9. *Do shipping companies need to register? If so, where?*

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

10. *Are hauliers subject to the requirements of the Regulation?*

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

11. *Does the Regulation also apply to intermediaries, who act solely as traders without ever holding the product in their facilities?*

Intermediaries also need to apply for approval or registration. However, there are special conditions applicable to intermediaries who 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 (see Article 17(1) of Regulation 183/2005). To qualify for this exemption, the intermediary must make a declaration that it meets the requirements laid down in Article 17(2) of the Regulation.

12. *Are some activities exempt from the approval and registration requirements?*

Yes. The following activities are outside the scope of Regulation 183/2005:

- 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 Regulation 852/2004 on food hygiene, 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) of this Regulation defines “primary products” as “products of the soil, of stock farming, of hunting and fishing”; and
- the retailing of pet food.

Regulation 183/2005 does not define “small quantities”. However, a working definition of primary production of feed is less than 20 tonnes per annum.

For consistency with the interpretation of “local” adopted by the Food Standards Agency in the context of food hygiene legislation, this term should be taken to mean “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”. This is to make allowance for the imbalance between closely spaced urban authorities and widely spaced remote populations, as well as those on the boundaries or bordered by the sea.

13. *Is there a published list of approved establishment?*

Yes. There is a legal requirement under Regulation 183/2005 for the competent authorities of Member States to provide a national list of approved establishments to the Commission and for the Commission to publish such lists by 30 November each year. The list of UK approved establishments is both posted to the Agency's website and sent to the Commission, and can be found online at: <http://www.food.gov.uk/multimedia/pdfs/ukfeedapproved.pdf>

14. *Where can a list of registered establishments be found?*

Regulation 183/2005 also requires Member States' competent authorities 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 list is compiled by the Food Standards Agency based on data it receives from local authorities in Great Britain and the Department of Agriculture and Rural Development in Northern Ireland, but is not published on the Agency's website. However, information on how to obtain details of registered feed business establishments can be found at <http://www.food.gov.uk/enforcement/sectorrules/feedapprove/feedpremisesregister>

15. *Can a feed business label its products with the approval number allocated by the VMD's Inspections and Investigations Team rather than the approval or registration number issued by a local authority?*

In Northern Ireland, all approval numbers are issued by DARD.

Conditions of EC Regulation 183/2005

16. *Other than registration and approval, what are the main requirements of the Regulation?*

The Regulation contains various operational requirements with which feed businesses must comply. The detailed requirements are mainly set out in Annexes I, II and III of the Regulation, and include standards relating to facilities and equipment, personnel, quality control, storage and transport, and record-keeping.

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 applies to businesses operating other than at the level of primary production, and 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 practices, which all producers are obliged to follow when feeding food-producing animals -- i.e., animals that produce food (milk, meat and eggs) for human consumption.

17. *What about businesses producing food and drink for human consumption?*

Businesses which supply co-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. soya bean meal, brewers' grains, wheat feed, bakery products.) Such businesses must comply with the appropriate requirements of Regulation 183/2005 -- question 16 above refers.

Food businesses (including food retailers) which supply surplus food products (such as out-of-date or off-specification products) into the animal feed chain are also subject to the requirements of Regulation 183/2005.

Farms

18. *What are the requirements for farms?*

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 met. The majority of farms do not need to apply HACCP principles. However, farmers who mix feed containing additives and premixtures must follow more detailed requirements -- see questions 19 and 20.

19. *What are the requirements for farmers who mix feed containing additives such as Vitamin A and D and trace elements such as copper and zinc, or premixtures of such additives?*

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

20. *What are the requirements for farmers who mix feeds with complementary feed containing additives?*

These types of farms must comply with the conditions set out in Annexes 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.

Farms mixing feeds with non-antibiotic growth promoters, coccidiostats and histomonostats (including complementary feeds containing these additives) are subject to approval by DARD in Northern Ireland.

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

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

A farmer who buys manufactured feed and stores it (without mixing it) 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 low risk, as no mixing of additives is involved. This is also the case with bought-in compound feed containing additives.

22. *Do these requirements apply to farms that top dress feeds?*

Yes. The practice of “top dressing” (i.e. spreading compound feeds containing additives on top of other feeds such as forage and cereals), is caught by the provisions of Regulation 183/2005. This is because the Regulation covers feed businesses that “carry out any operation of production, manufacture, processing, storage, transport or distribution of feed”.

23. *Where can I obtain further guidance on feeding practices?*

The Advisory Committee on Animal Feedingstuffs report *Review of On-Farm Feeding Practices*, published in September 2003, includes information on identifying hazards and minimising risks in the use of feed at farm level. It is available online at <http://www.food.gov.uk/multimedia/pdfs/farm.pdf>

The *Industry Code of Practice for On-Farm Feeding*, which applies to farmers and covers all aspects of on-farm feeding, including on-farm mixing, was revised in April 2010 and is available at http://assurance.redtractor.org.uk/resources/000/556/445/Industry_Feed_Code_of_practice_April_2010.pdf

24. *What are the requirements for primary producers under Regulation 852/2004 on food hygiene?*

The Q&A relating to food hygiene for farmers and growers can be found on the Food Standards Agency’s website at <http://www.food.gov.uk/foodindustry/regulation/hygleq/hygleqinfo/primprodqanda/>

Pet Food and Feed for Other Non-Food-Producing Animals

25. *Does the Regulation cover the wholesaling of pet foods?*

Article 2(2)(e) of Regulation 183/2005 states that its provisions do not apply to the retailing of pet food. However, all other activities relating to the production, distribution and storage of pet food fall within the scope of the Regulation, and feed businesses carrying out such activities are therefore subject to registration. These businesses must also comply with the relevant requirements of the Regulation.

26. *How does the Regulation affect products such as dog chews?*

In general, establishments making, packing and storing pet food need to apply for registration. However, the position with regard to dog chews is slightly different, as solid rawhide chews are not sold to contribute to the nutritional needs of a pet and so are not considered to be a feedingstuff. By comparison, however, a chew which consists of chopped or ground hide together with a binder does have a nutritional value and is therefore caught by the Regulation. This means that businesses making, storing or packing such chews do require registration.

27. *What about a company marketing food products for human consumption which are then re-branded for pets (e.g. dog treats)?*

Any company manufacturing and/or putting into circulation feed for pets, including companies which supply products knowing that they will be used for feed, is subject to registration under Regulation 183/2005.

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

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

29. *Where can I find further information about pet food?*

There is a background note about feed legislation as it applies to pet food on the Agency's website at <http://www.food.gov.uk/multimedia/pdfs/petfood.pdf>

Importing feed from non-EU Countries (Third Countries)

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

Feed businesses within the EU can import feed products only from feed business establishments in 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. These interim measures are 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 Food Standards Agency), declarations as to the activities carried out by the manufacturing establishment in the non-EU country. This is to ensure that imported additives, premixtures and feed products which contain additives comply with the same quality control standards that apply in Member States.

It should be noted that (a) the non-EU countries Iceland, Liechtenstein and Norway have adopted Regulation 183/2005 and for its purposes therefore count as EU countries; and that (b) these are only interim arrangements. Regulation 183/2005

envisages that all non-EU countries and establishments exporting feed to the EU will be entered into a Community list, but as yet further information from the European Commission regarding progress on this area of work is still awaited.

EU and National Guides to Good Practice

31. *Are there any published guides to Good Hygiene Practice?*

Article 20 of Regulation 183/2005 provides for the development, dissemination and use of national and EU Guides to Good Practice.

The Food Standards Agency undertook a public consultation in March 2007 on guidelines for the development and assessment of national guides to good practice, and the finalised Guidelines were published on the Agency's website at <http://www.food.gov.uk/multimedia/pdfs/feednvgaugust07.pdf> Any further guides which may be submitted in future will be considered to ensure that they are suitable and practicable guides to compliance with the legislation.

To date, three EU Guides (originally called Community Guides) have been developed by, or in consultation with, representatives of the European feed sectors, and may be used on a voluntary basis by feed business operators as an aid to compliance with the requirements of the Regulation. These Guides -- which cover the manufacture of compound feed, feed additives and premixtures, and pet food -- were published in the "C" series of the *Official Journal* of the European Union and can be found on the European Commission's website at http://ec.europa.eu/food/food/animalnutrition/feedhygiene/guide_goodpractice_en.htm

Feed Additives

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

The list of authorised feed additives is published as the Community Register of Feed Additives and is frequently updated. It can be found online at http://ec.europa.eu/comm/food/food/animalnutrition/feedadditives/registeradditives_en.htm

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

Yes. The Agency has published guidance in question and answer form which is available at <http://www.food.gov.uk/multimedia/faq/animalfeedaddfaq/>

LIST OF CERTAIN DEFINITIONS USED IN THIS GUIDANCE

Competent authority: authority of a Member State or of a third country designated to carry out official controls -- Article 3(e) of Regulation 183/2005 on feed hygiene. In Northern Ireland, these are the Food Standards Agency and the Department of Agriculture and Rural Development in Northern Ireland.

Complementary feed: compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed -- Article 3(2)(j) of Regulation 767/2009 on the placing on the market and use of feed.

Complete feed: compound feed which, by reason of its composition, is sufficient for a daily ration -- Article 3(2)(i) of Regulation 767/2009 on the placing on the market and use of feed.

Compound feed: a mixture of at least two feed materials, whether or not containing feed additives, for oral animal feeding in the form of complete or complementary feed -- Article 3(2)(h) of Regulation 767/2009 on the placing on the market and the use of feed.

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

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 -- Article 2(a) of Regulation 1831/2003 on additives for use in animal nutrition.

Feed business: 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 -- Article 3(5) of Regulation 178/2002 on the general principles of food law.

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

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 -- Article 3(a) of Regulation 183/2005 on feed hygiene.

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

Feed materials: products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures -- Article 3(2)(g) of Regulation 767/2009 on the placing on the market and use of feed.

HACCP (Hazard Analysis and Critical Control Points): a system of feed safety management based on the prevention of feed safety problems. It provides a documented, structured approach to ensuring feed 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 -- Article 6 of 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 -- Article 2(e) of Regulation 1831/2003 on feed additives.

(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.