

Controls on Animal By-Products

Guidance on Regulation (EC) 1069/2009 and accompanying implementing Regulation (EC) 142/2011, enforced in England by the Animal By-Products (Enforcement) (England) Regulations 2011

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1. Introduction

Regulation (EC) 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and its accompanying implementing Regulation (EC) 142/2011 applies from 4 March 2011.

In England these Regulations are administered and enforced by the Animal By-Products (Enforcement) (England) Regulations 2011.

These guidance notes have been produced by the Department for Environment, Food and Rural Affairs (Defra) to provide informal advice on how to comply with the legal requirements of the EU legislation and our domestic Animal By-Products (Enforcement) (England) Regulations 2011, which administer and enforce the EU Regulations. The Regulations are wide reaching and cover a number of diverse sectors. This guidance explains the different categories of animal by-products, how they should be used or disposed of, and where this can safely be done. It also explains which animal by-products fall outside the Regulations.

It is ultimately the responsibility of individual businesses to ensure their compliance with the law. Compliance with the advice on good practice is not required by law. Businesses with specific queries may want to seek the advice of their local enforcement agency, which will normally be the trading standards/environmental health department of the local authority.

2. Intended audience

This guidance is applicable to any person/business generating, using, disposing of, storing, handling or transporting animal by-products.

3. Regional coverage

This guidance is applicable in England only. Devolved administrations in the UK will be preparing parallel domestic legislation and will provide their own guidance.

4. Purpose and legal status

This guidance provides advice on complying with the requirements of Regulation (EC) 1069/2009 and its implementing Regulation (EC) 142/2011. EU Regulations are directly applicable in all EU Member States and their provisions must be complied with.

The Animal By-Products (Enforcement) (England) Regulations 2011 is the national legislation in England which administers and enforces the EU Regulations. It provides for offences for failure to comply with the EU Regulations and is enforced by local authorities. The national legislation also provides for certain derogations and national rules which the EU rules permit Member States to exercise.

Regulation (EC) 1069/2009, and the accompanying implementing rules, will replace Regulation (EC) 1774/2002. The Animal By-Products (Enforcement) (England) Regulations 2011 will replace the Animal By-Products Regulations 2005 (SI 2347/2005) in England.

The Trade and Animal Related Products (TARP) Regulations 2011 will enforce the import and intra-EU trade aspects of the EU Regulations. Please see Section 17 for further details.

This guidance is intended to accompany these various Regulations.

5. Regulatory background

Animal by-products can present a risk to human and animal health, in particular in relation to Transmissible Spongiform Encephalopathies (TSEs), dioxin contamination, and exotic diseases such as Classical Swine Fever and Foot and Mouth Disease.

Regulation (EC) 1069/2009 and its corresponding implementing Regulation (EC) 142/2011 revokes and replaces Regulation (EC) 1774/2002. It is the consequence of a long and comprehensive review carried out by the EU Commission to assess the operation of EU-wide controls on animal by-products.

An initial report was submitted by the Commission with Member States to the European Parliament and Council in 2005. This stated that although the legislation was working well and generally met its overall objectives, there were areas where changes needed to be considered. These included updating the legislation and providing legal certainty, and simplifying the legislation and thus reducing the burden on business. Consequently, the Commission consulted extensively, including all Member States, with a view to recasting Regulation (EC) 1774/2002 in order to meet better regulation principles, to improve and make the measures more effective and efficient, and reduce the unnecessary burden for operators whilst ensuring protection of public and animal health and food safety were not undermined.

The new Regulation (EC) 1069/2009, with its implementing Regulation (EC) 142/2011, continues to have a very wide scope covering all animal products including meat, fish, milk and eggs when they are not intended for human consumption and other products of animal origin including hides, feathers, wool, bones, horns, and hoofs. It also covers carcasses of fallen stock on farms, pet animals, and wild animals where they are suspected of being diseased. It continues to regulate the use of animal by-products for example as feed (including petfood), fertiliser or for technical products and lays down rules for their transformation through composting and biogas and their disposal via rendering and incineration. It also continues to prevent catering waste from being fed to livestock.

However, to take on board the concerns identified during the review Regulation (EC) 1069/2009 now also:

- Gives greater clarity on the scope of the Regulation, more clearly defining when products are no longer considered to be animal by-products and therefore exempt from the controls of the Regulation;

- Improves the categorisation of animal by-products in line with the risk they pose (category 1 is highest risk and category 3 lowest risk);
- Removes duplication of approval for certain premises; and
- Provides further derogations for Member States to use.

The Regulations will have an impact upon any person or business generating, using, disposing of, storing, handling or transporting animal by-products.

This regime links into a package of regulatory regimes such as the TSE Regulations, and food hygiene controls that also provide for requirements in relation to animal by-products.

6. Overview of changes in the new Regulations

While the overall framework of animal by-products controls remains broadly in line with previous legislation, the new Regulations will provide greater legal certainty, simplify some requirements, and reduce burdens on operators. They also take into account advancements in science and technology, and revise the categorisation of some animal by-products according to the risk they pose. The main areas of change to note will be:

(a) Introduction of animal by-products end point

The Regulation introduces the concept of an "**end point**" in the manufacturing of animal by-products, after which the processed products are no longer subject to the Regulation- as some potential risks have been eliminated- e.g. by heat or chemical substances. Instead, the general rules on product safety apply. Removing certain finished products such as cosmetic products, medical devices and in vitro diagnostic kits from the scope of the Regulation reduces burdens on operators e.g. with respect to labelling and record-keeping.

(b) Food chain safety

The distinction between foodstuffs and animal by-products is clarified by confirming that operators need to make an irreversible decision if products are destined for purposes other than human consumption. This means that once a product has become an animal by-product, it must not re-enter the food chain.

(c) Changes to categories of certain animal by-products

Certain animal by-products, which so far have been classified by default as category 2 material but which have been proven to pose no major risks, are reclassified as belonging to category 3, so as to allow their use for certain feeding purposes. This includes blood from young ruminants, and ruminants which have passed a TSE test; day old chicks; and invertebrates.

It should be noted that ruminant-derived blood cannot be sourced for the production of blood products and bloodmeal for use as restricted proteins in

feeding non-ruminant farm animals under the TSE Regulations 2010. However, dead-in-shell chicks have been moved up from category 3 to category 2. In addition, spoiled material has been clarified as category 3 material with restricted permissible disposal options (e.g. it can't go for use in petfood). For any other animal by-product not listed under one of the three categories, the classification by default as category 2 material is maintained for precautionary reasons.

(d) Plants handling animal by-products

Any plant that *handles* animal by-products will now have to be approved or registered. This is a change from establishments being approved by activity rather than type of establishment. If your plant handles animal by-products you should contact your local Animal Health office who will explain the requirements.

(e) Registration and approval of plants

There have been some changes to the requirements for registration and approval of operators handling animal by-products. For instance technical plants which were previously approved by Animal Health will in future only need to be registered, reducing burdens on operators.

Some transporters of animal by-products will need to be registered for the first time. This requirement has been introduced in order to strengthen traceability. See section 12 for further details.

(f) Home composting exception

Normally when animal by-products and catering waste are composted or anaerobically digested this must be done in a plant which meets the plant hygiene standards and treatment requirements set out in the legislation and which has been approved for the purpose by Animal Health.

Previously we had a home composting exception which allowed the composting of catering waste on the premises of origin without the need to be approved by Animal Health. Primarily, this allowed domestic householders to compost their kitchen waste in their garden, but the exception could also be used by schools, universities, hospitals or other premises provided the resultant compost was kept on-site. We have now widened this exception to include anaerobic digestion and to permit use of the compost off-site in certain situations where there is no risk of livestock gaining access to it. This will be beneficial particularly to community composting and anaerobic projects who may be able to run small community or neighbourhood schemes without requiring full approval from Animal Health.

(g) Wild game animal by-products

Approved Game Handling Establishments (AGHEs) will now need to dispose of animal by-products generated in their premises in line with the Regulations.

AGHEs should contact their local Animal Health office for a list of registered waste collectors.

(h) Derogations and areas of national discretion

The Regulations allow for Member States to have the option of taking advantage of various derogations from the main animal by-products controls and areas of national discretion. Some of these continue previous derogations, such as the use of animal by-products for feeding at hunt kennels, some expand previous derogations, such as it now being permissible where there is no health risk to feed carcasses of zoo animals to other carnivorous zoo animals, and some are new, such as the introduction of a concept of 'small quantities' of animal by-products which have greater options for disposal than previously, the possibility of spreading eggshells to land under national rules, and the use of animal by-products in biodynamic agriculture.

These derogations and areas for national discretion are discussed in detail in sections 14 and 15 of this Guidance.

7. Definition of “animal by-products”

Animal by-products are defined in Article 3 of Regulation (EC) 1069/2009 as 'entire bodies or parts of animals, products of animal origin or other products obtained from animals that are **not intended for human consumption**'. This includes catering waste, used cooking oil, former foodstuffs, butcher and slaughterhouse waste, blood, feathers, wool, hides and skins, fallen stock, pet animals, zoo and circus animals, hunt trophies, manure, ova, embryos and semen not intended for breeding purposes.

8. Categories of “animal by-products”

Under Regulation (EC) 1069/2009 animal by-products can fall into one of three categories.

(a) Category 1 Material

Category 1 material is defined in Article 8. Category 1 material is the highest risk, and consists principally of material that is considered a TSE risk, such as Specified Risk Material (those parts of an animal considered most likely to harbour a disease such as BSE, e.g. bovine spinal cord). Pet animals, zoo and circus animals and experimental animals are also classified as category 1 material due to the level of veterinary drugs and residues they are likely to contain and due to the fact that adequate diagnoses of the exact cause of death of exotic animals can be difficult to achieve. Several are known to harbour TSEs and may carry other diseases. Likewise, wild animals may be classified as category 1 material when they are suspected of carrying a disease communicable to humans or animals. Catering waste from means of international transport (i.e. which has come from outside the EU) is also category 1.

(b) Category 2 Material

Category 2 material is also high risk material and is defined in Article 9. Category 2 material includes fallen stock, manure and digestive content. Category 2 is also the default status of any animal by-product not defined in Regulation (EC) 1069/2009 as either category 1 or category 3 material.

(c) Category 3 Material

Article 10 of Regulation (EC) 1069/2009 defines category 3 animal by-products. Category 3 materials are low risk materials. Category 3 material includes parts of animals that has been passed fit for human consumption in a slaughterhouse but which are not intended for consumption, either because they are not parts of animals that we normally eat (hides, hair, feathers, bones etc) or for commercial reasons. Category 3 material also includes former foodstuffs (waste from food factories and retail premises such as butchers and supermarkets).

Catering waste, including domestic kitchen waste is category 3 material, though it is only in the scope of the Regulations in certain situations, to prevent it from being fed to livestock (which is banned under the Regulation) or such as when it is intended for composting or anaerobic digestion.

9. Restrictions on use

Article 11 of Regulation (EC) 1069/2009 sets out restrictions on use relating to feeding of animal by-products and bans intra-species recycling (feeding material derived from a species to a creature of the same species) and the feeding of catering waste to farmed animals.

Article 11 also prohibits the feeding to farmed animals of herbage from land to which organic fertilisers or soil improvers have been applied within unless grazing restrictions have been observed. In England the grazing ban is 8 weeks for pigs and 3 weeks for all other farmed animals.

10. Disposal and use of animal by-products

(a) Disposal and use of category 1 material

Article 12 of Regulation (EC) 1069/2009 sets out the disposal routes for category 1 material. As the highest risk material, generally speaking this material must be destroyed by incineration, or by rendering followed by incineration. These are the only options for TSE suspects. Other category 1 material is also permitted to be pressure-rendered and disposed of in an authorised landfill site.

International catering waste may be disposed directly in an authorised landfill site.

In principle the Regulation allows for category 1 material to be used as a fuel for combustion though the European Commission is yet to formulate rules for this.

Category 1 material can also be used for the manufacture of derived products as specified by the Regulation, such as medical devices.

(b) Disposal and use of category 2 material

Article 13 of Regulation (EC) 1069/2009 sets out the disposal routes for category 2 material. The basic options of incineration and rendering followed by incineration are permitted, as with category 1 material. All category 2 material can also be pressure-rendered and disposed of in an authorised landfill site. Use as fuel for combustion is foreseen in the Regulation once the Commission formulates rules for this. Category 2 material can also be used for the manufacture of derived products as specified by the Regulation, such as medical devices.

However there are also other uses for category 2 material which do not apply to category 1 material. Category 2 material can be pressure-rendered and then used for the production of organic fertilisers and soil improvers. It can also be pressure-rendered and used in an approved composting or anaerobic digestion plant.

A very limited number of category 2 materials (manure, digestive tract content, milk and milk-based products and colostrum) may be applied directly to land without processing provided there is no risk of transmitting a disease.

There is also an option for ensiling of category 2 fish under national rules. However, currently in the UK we have no agreed rules to permit this.

(c) Disposal and use of category 3 material

Article 14 of Regulation (EC) 1069/2009 sets out the use and disposal routes for category 3 material. As low-risk material, there are a much wider range of options for use and disposal of category 3 material compared to higher risk material.

Category 3 material can like category 1 and category 2 material be incinerated, or rendered followed by incineration. Category 3 material can also be rendered followed by disposal in an authorised landfill (unlike higher category material this does not have to be pressure rendering). Use as fuel for combustion is foreseen in the Regulation once the Commission formulates rules for this. Category 3 material can also be used for the manufacture of derived products as specified by the Regulation, such as medical devices.

Category 3 material can be rendered for the production of petfood and organic fertilisers or soil improvers. Rendered category 3 material can also be used in the production of animal feedingstuffs, though TSE related restrictions on the feeding of processed animal protein severely restrict this.

Category 3 material can be used directly in approved composting or anaerobic digestion plants, and in the production of raw petfood.

Certain category 3 material (raw milk, colostrum and products derived from these) can be applied directly to land provided there is no risk of transmitting a disease. Shells from shellfish and eggshells may be applied to land in accordance with national rules.

There is also an option for ensiling of category 3 fish under national rules. However, currently in the UK we have no agreed rules to permit this.

11. Requirements for collection, identification and transport

Article 21 of Regulation (EC)1069/2009 sets out the requirements for collection and identification of animal by-products. Detailed implementing rules are contained in Annex VIII of Regulation (EC) 142/2011.

Animal by-products must be collected, identified and disposed of without undue delay, in order to prevent risks arising to public and animal health. What constitutes 'undue delay' will depend on a case-by-case assessment depending on the type of animal by-products involved but for instance a farmer may have his fallen stock collected every few days and a retail shop may have a weekly return of out of date food.

Animal by-products must be transported in sealed new packaging or covered leak-proof containers or vehicles in accordance with Section I of Annex VIII. Containers must be dedicated to the use of specific categories of animal by-products and where they are not they must be cleaned and disinfected after each use in order to prevent cross contamination.

Animal by-products must be identified in accordance with Chapter II of Annex VIII. They must be collected and identified by category. Mixtures of different categories of animal by-products must be treated as the higher or highest risk of the mixed materials e.g. if category 3 material is mixed with category 2 material, all the material must be disposed of as category 2 material.

Category 3 material must be labelled as 'not for human consumption'. Category 2 material must be labelled 'not for animal consumption' (unless it is specifically intended for feeding under the derogation in Article 18(1) of Regulation (EC) 1069/2009 for feeding to animals such as zoo and circus animals). Category 1 material must be labelled as 'for disposal only'. Specific types of animal by-products such as collagen, blood products or raw petfood may require further labelling in accordance with Chapter II of Annex VIII of Regulation (EC) 142/2011.

During transportation a commercial document, or in certain circumstances, a health certificate must accompany the animal by-products, in accordance with Chapter III of Annex VIII. The commercial document must record the date on which the material is taken from the premises; a description of the material;

the quantity of the material, in weight or volume; the place of origin of the material; the name and address of the transporter; the name and address of the receiver and its approval or registration number if appropriate; and the approval or registration number of the plant of origin if appropriate.

Annex VIII provides a model commercial document which may be used but it is not mandatory to do so provided all the required information is recorded.

Records and related commercial documents or health certificates must be retained for at least two years.

12. Registration and approval

Generally speaking if you are a plant handling animal by-products, you will need to be approved or registered.

(a) Registration

Registration must take place in accordance with Article 23 of Regulation (EC) 1069/2009. They must comply with the requirements of Article 20 and Annex IX Chapter IV of Regulation (EC) 142/2011.

Registration generally applies to low-risk operations such as technical plants. You may also need to be registered if you transport animal by-products commercially. Your local Animal Health Office will be able to tell you if your operation or establishment requires a registration to handle animal by-products.

Food premises which are already registered or approved under food hygiene legislation Regulation (EC) 852/2004 or Regulation (EC) 853/2004 do not need to be further registered by Animal Health.

Registration entails notifying Animal Health of the nature of your operation, the category of the animal by-products you will be using, and what you are doing with them.

Registered plants and operations will be added to a database of registered and approved plants and operations which will be publicly available.

(b) Approval

Approval of plants must take place in accordance with Article 24 of Regulation (EC) 1069/2009.

Approved plants will generally be plants that are receiving animal by-products for any of the uses outlined in Articles 12-14 of Regulation (EC) 1069/2009. You do not need an approval under animal by-products legislation if your operation is already approved under food hygiene legislation. Your local Animal Health Office will be able to tell you if your operation or establishment requires an approval to handle animal by-products.

The main types of plants that require approval, and a brief outline of the requirements they need to meet follows.

13. Types or premises handling animal by-products

(a) Rendering Plants

Rendering plants can take all categories of animal by-products. They must be approved in accordance with Article 24 of Regulation (EC) 1069/2009 and operators must meet the general hygiene requirements in Article 25.

Operators must also meet the processing standards and plant requirements set out in Article 8, Article 9 and Annex IV of Regulation (EC) 142/2011. These include the general plant conditions in Chapter I Section 1; the waste water treatment requirements in Chapter I Section 2; the separation requirements for category 1 and 2 plants in accordance with Chapter I Section 3; and category 3 plants must comply with the processing requirements in Chapter I Section 4. There are also additional hygiene and processing requirements set out in Chapter II with specific processing requirements for category 1, 2 and 3 material as specified. Plants must be approved to use one of the processing methods 1 to 7 as set out in Chapter III as appropriate.

Animal Health guidance on rendering, petfood and feedingstuffs, organic fertilisers and soil improvers will be available shortly.

(b) Incinerators

Most incinerators are approved under the Waste Incineration Directive (Directive 2000/76/EC) and will be regulated by the Environment Agency or Local Authority depending on throughput.

Incinerators which incinerate only animal carcasses and nothing else (such as on-farm incinerators for the disposal of fallen stock) are exempt from the Waste Incineration Directive and are instead regulated by Regulation (EC) 1069/2009. Incinerators must be approved in accordance with Article 24 of Regulation (EC) 1069/2009.

All incineration plants must comply with Article 6 and Annex III of Regulation (EC) 142/2011, in particular the hygiene conditions set out in Chapter I Section 1, the operating conditions in Chapter I Section 2, residue disposal requirements in Chapter I Section 3, temperature measurement requirements in Chapter I Section IV and requirements for dealing with abnormal operating conditions in Chapter I Section 5. In addition high capacity plants must meet the specific operating conditions in chapter II Section 1 and water discharge requirements of Chapter II Section 2 and low capacity plants the requirements of Chapter III.

Animal Health guidance on incineration will be available shortly.

(c) Composting and Anaerobic Digestion (Biogas) Plants

Composting and anaerobic digestion (biogas) plants can only treat category 3 animal by-products, category 2 animal by-products if they have been pressure rendered, and certain specified category 2 materials such as manure, digestive contract, milk and milk products. Composting plants must produce a finished product that is recognised as a compost by the Environment Agency, and must be able to demonstrate that most of the heat in the treatment phase is generated by biological activity (i.e. operators cannot simply 'cook' the material to meet the temperature standards). Anaerobic digestion must take place for the production and collection of biogas.

Composting and biogas plants must be approved in accordance with Article 24 of Regulation (EC) 1069/2009. Plants must comply with the requirements of Article 10 and Annex V of Regulation (EC) 142/2011, these include the general plant requirements in Chapter I, the hygiene requirements in Chapter II, the transformation parameters in Chapter III Section 1 and the microbiological sampling requirements in Chapter III Section 3.

Animal Health guidance on composting and biogas plants will be available shortly.

(d) Petfood Plants

Petfood plants can only use certain category 3 animal by-products.

Plants manufacturing petfood must be approved in accordance with Article 24 of Regulation (EC) 1069/2009 and Article 19 of Regulation (EC) 142/2011. Petfood must be placed on the market in accordance with Article 35 of Regulation (EC) 1069/2009.

Plants must meet the requirements of Annex IX Chapter I of Regulation (EC) 142/2011 and the general requirements set out in Annex XIII chapter I. Specific requirements for raw petfood, processed petfood and dog chews including end points (after which the petfood is no longer controlled by the Regulations) are set out in Annex XIII Chapter II. Annex XIII Chapter III sets down the rules for flavouring innards for the manufacture of petfood. Raw petfood from retail shops for supplying the consumer on the spot and derived from animals slaughtered on farm for domestic consumption are out of scope (Article 2.2(i) and (j) of Regulation (EC) 1069/2009).

Animal Health guidance on petfood plants will be available shortly.

(e) Intermediate Plants (plants handling animal by-products after their collection)

Intermediate plants must be approved in accordance with Article 24 of Regulation (EC) 1069/2009 and Article 19 of Regulation (EC) 142/2011 and operators must meet the general hygiene requirements in Article 25 of Regulation (EC) 1069/2009. Intermediate plants must comply with the general

requirements in Annex IX Chapter II of Regulation (EC) 142/2011 and the hygiene requirements in Annex IX Chapter II Section 2.

(f) Storage Plants

Storage plants must be approved in accordance with Article 24 of Regulation (EC) 1069/2009 and Article 19 of Regulation (EC) 142/2011. Storage plants receiving raw products must comply with the general requirements in Chapter II of Annex IX. Storage plants receiving derived products must comply with Chapter III of Annex IX.

(g) Technical Plants

Technical plants must be registered in accordance with Article 23 of Regulation (EC) 1069/2009. Technical plants must meet the conditions for registered operators in Article 20 and Chapter IV of Annex IX of Regulation (EC) 142/2011.

(h) Alternative Methods

Alternative methods for the treatment of animal by-products are new technologies or methods of disposing of animal by-products. Several of them, such as biodiesel and alkaline hydrolysis, were originally introduced under previous legislation. The Regulation also makes provision for the introduction of new technologies or methods in the future with rules for the authorisation of such operations.

Alternative methods must be approved in accordance with Article 24 of Regulation (EC) 1069/2009. Existing alternative methods for treatment of animal by-products are set out in Annex IV Chapter IV Section 1 of Regulation (EC) 142/2011.

Applications for authorisation of alternative methods must be carried out in accordance with Article 20 of Regulation (EC) 1069/2009 and Article 16 and Annex VII of Regulation (EC) 142/2011.

14. Derogations

Articles 16, 17, 18 and 19 of Regulation (EC) 1069/2009 allow for Member States to permit derogations from the basic framework of animal by-products controls in certain specified areas. The following guidance examines the derogations that are available to Member States, whether the UK intends to take advantage of them, what controls we would put in place, and where we are not planning to take advantage of them, the reasons we are not doing so.

(a) Use of animal by-products in research and other specific purposes: Article 16(b) and Article 17

The UK intends to take advantage of this derogation and may authorise the use of animal by-products in research establishments and for specific

purposes such as exhibitions, artistic activities and for diagnostic or educational purposes, under conditions which ensure the control of risks to public and animal health.

Requirements for samples for research and other purposes (except in the case of use of low risk material for educational purposes for which a general duty of care to ensure safe use and disposal applies) are set out in Article 11 and Annex VI Chapter I Section 1 of Regulation 142/2011. Record keeping requirements are set out in Article 17 and Annex VIII Chapter IV Section 1.

Except in the case of use of low risk material for educational purposes, if you wish to use animal by-products for these purposes, you will need to be registered. Please contact Animal Health for further information.

Animal by-products must still be disposed of in accordance with the Regulation.

(b) Use of category 2 and category 3 material for feeding to various animals: Article 16(c) and Article 18(1)

The Regulation allows for derogations for the feeding of category 2 and category 3 materials to various animals:

- i. Zoo animals
- ii. Circus animals
- iii. Reptiles/birds of prey other than zoo or circus animals
- iv. Fur animals
- v. Wild animals
- vi. Dogs from recognised kennels or packs of hounds
- vii. Dogs and cats in shelters
- viii. Maggots and worms for fishing bait

Most of these derogations were already available under previous legislation. The UK does not intend to use the derogation for fur animals because fur farming is banned in the UK. The derogation for feeding to wild animals will apply except in the case of feeding wild boar where there is a potential risk to animal health. We intend to make provisions for the feeding of dogs and cats in shelters, which was not an available derogation under previous legislation. As with feeding at hunt kennels and recognised packs of hounds, this would require registration with Animal Health. The derogation for the use as bait has been expanded to include worms as well as maggots.

In most instances if you wish to use any of these derogations you will need to be registered to do so with Animal Health. Feeding must be carried out in accordance with the conditions in Article 13 and Annex VI Chapter II of Regulation (EC) 142/2011. Record keeping requirements are set out in Article 17 and Annex VIII Chapter IV Section 1 and Section 2.

Animal Health guidance on feeding of category 2 and category 3 material will be available shortly.

(c) Feeding of category 1 material to zoo animals and necrophagous birds: Article 16(c) and Article 18(2)

The UK intends to take advantage of this derogation with respect to zoo animals and permit zoo animals carcasses to be fed to other zoo animals in certain circumstances where there is no risk of disease transmission and the level of veterinary residues in the carcass would not pose an animal health risk. This must be done in accordance with Article 14 and Annex VI Chapter II Section 4 of Regulation (EC) 142/2011. Record keeping requirements are set out in Article 17 and Annex VIII Chapter IV Section 1 and Section 2.

(d) Burial of dead pet animals and horses: Article 16(d) and Article 19(1)(a)

The UK intends to take advantage of this derogation and the burial of pets remains permissible. Previously, horses could be buried where they were pets but not in other circumstances. Regulation (EC) 1069/2009 now widens this and Article 19(1)(a) provides a derogation for the burial of all equidae. Burial should take place in accordance with Article 15 and Annex VI Chapter III Section 1 of Regulation (EC) 142/2011. Article 17 and Annex VIII Chapter IV Section 6 set out record keeping requirements.

(e) Burial/burning or disposal by other means in remote areas of category 1 material (e.g. entire bodies of dead animals containing SRM), category 2 material and category 3 material: Article 16(d) and Article 19(1)(b)

The UK intends to take advantage of this derogation. Dead animals such as fallen stock can be buried or burned in areas designated as remote in our domestic legislation. The remote areas in England are Lundy Island and the Scilly Isles. Disposal should be carried out in accordance with Article 15 and Annex VI Chapter III of Regulation (EC) 142/2011. Article 17 and Annex VIII Chapter IV Section 6 set out record keeping requirements.

(f) Burial/burning or disposal by other means of fallen stock where access is practically impossible for category 1 material (e.g. entire bodies of dead animals containing SRM), category 2 material and category 3 material: Article 16(d) and Article 19(1)(c)

The UK intends to take advantage of this derogation. Burial/burning or disposal by other means will be permitted for fallen stock where access is practically impossible or where access would only be possible under circumstances, related to geographical or climatic reasons or due to a natural disaster, which would pose a risk to the health and safety of the personnel carrying out the collection or where access would necessitate the use of disproportionate means of collection. This will be limited to unusual situations such as where an animal has fallen down a ravine or a cliff or has been trapped in a bog and retrieval of the body for disposal by rendering or incineration is not possible. Disposal should be carried out in accordance with

Article 15 and Annex VI Chapter III of Regulation (EC) 142/2011. Article 17 and Annex VIII Chapter IV Section 6 set out record keeping requirements.

Animal Health guidance on burial of fallen stock will be available shortly.

(g) Disposal of small quantities of category 3 animal by-products: Article 16(d) and Article 19(1)(d)

The UK intends to take advantage of this derogation. Small quantities of former foodstuffs (retail and factory waste) may be disposed of by landfill. This would increase the disposal options available for industry and has the potential to reduce costs significantly. Disposal must be carried out in accordance with Annex VI Chapter IV of Regulation (EC) 142/2011. Article 17 and Annex VIII Chapter IV Section 1 set out record keeping requirements.

‘Small quantities’ are defined as up to 20kg of former foodstuffs per week.

(h) Authorising the disposal by burning or burial on site of Category 1 material (except that under Article 8(a)(i)) in a notifiable disease outbreak: Article 16(d) and Article 19(1)(e)

The UK intends to take advantage of this derogation. In the case of a notifiable disease outbreak in some instances disposal of fallen stock by burning or burial on site may be the most sensible option, and this can be done if Animal Health authorise it. This derogation already existed in previous legislation.

Annex VI, Chapter III, Section I of the Regulation (EC) 142/2011 sets out the conditions that apply to disposal. Article 17 and Annex VIII, Chapter IV, Section 6 set out record keeping requirements.

(i) Authorising the disposal by burning or burial on site of bees and apiculture by-products: Article 16(d) and Article 19(f)

The UK intends to take advantage of this derogation. Disposal of bees and apiculture by-products on site by burial or burning may be carried out in accordance with an authorisation from Animal Health. This derogation already existed in previous legislation.

Annex IX, Section III, Chapter III of the draft Implementing Regulation allows Member States to decide conditions to ensure burning or burial does not endanger human or animal health or the environment. Article 17 and Annex VIII Chapter IV Section 6 set out record keeping requirements.

(j) Allowing animal by-products to be disposed of or used in accordance with alternative methods: Article 16(e)

The UK intends to take advantage of this derogation. This derogation permits the use of alternative methods for disposal of animal by-products so there is a

framework for the approval of new technologies if they arise. This derogation already existed in previous legislation.

Alternative methods must be authorised by the procedure set out in Article 20. Existing alternative methods are set out in Annex IV Chapter IV Section 2 of Regulation (EC) 142/2011. Article 17 and Annex VIII Chapter IV Section 1 set out record keeping requirements.

(k) Allowing category 2 and category 3 materials to be used for biodynamic preparations to be applied to land: Article 16(f)

The UK intends to take advantage of this derogation provided it is carried out in accordance with Regulation (EC) 834/2007 on organic production and labelling of organic products. Biodynamic agriculture is a method of organic farming which takes a holistic approach to farm management and uses preparations derived from animal by-products for use in fertilisers. This derogation permits the use of category 2 and category 3 animal by-products in biodynamic preparations as referred to in Article 12(1)(c) of Regulation (EC) 834/2007.

(l) Allowing category 3 material to be fed to pets: Article 16(g)

The UK intends to take advantage of this derogation subject to certain conditions.

Category 3 animal by-products may be supplied as raw material for feeding to pets provided:

- It is category 3 material which is fit but not intended for human consumption
- It is kept separate in the abattoir/cutting plant from other category 3 material which does not fit this description
- At the abattoir/cutting plant it should be kept in a clean, safe place at an appropriate temperature (i.e. chilled or frozen) up until the point of sale
- The end user must ensure that it is stored safely away from food and kept chilled/frozen prior to feeding.

Failure to keep such material separate as above will be in breach of the conditions of the derogation.

(m) Allowing category 2 and 3 material from surgical intervention to be disposed of on farm: Article 16(h)

The UK intends to take advantage of this derogation subject to certain conditions. Material arising from amputations (e.g. tails), castrations and hoof clippings can be buried. However we do not intend to apply the derogation to foetuses or placenta, which must be disposed of in accordance with the Regulation (sent for rendering or incineration).

15. Areas of national discretion

Regulation (EC) 1069/2009 also permits Member States to exercise discretion in a number of areas if they choose to. This section discusses the various areas of discretion available and the approach that the UK intends to take.

(a) Option to require pressure sterilisation before category 1 and category 2 material is disposed of as waste by incineration or recovered/disposed of by co-incineration: Article 12(a) and (b) and Article 13(a) and (b)

The UK does not intend to apply this measure. This was not a requirement prior to Regulation (EC) 1069/2009 and we see no need to restrict industry by requiring pressure sterilisation of this material.

(b) Option to allow certain category 2 material to be composted or transformed into biogas: Article 13(e)(ii)

The UK intends to take advantage of this measure. Category 2 materials that can go for composting or anaerobic digestion are manure, digestive tract and its content, milk, milk-based products, colostrum, eggs and egg products. Most of these were already able to go for composting or anaerobic digestion under previous legislation, but this list has now been expanded to include milk-based products, eggs and egg products. The UK will permit these uses provided we are satisfied there is no risk of spreading a serious transmissible disease.

Composting and biogas plants must be approved in accordance with Article 24 of Regulation (EC) 1069/2009. Plants must comply with the requirements of Article 10 and Annex V of Regulation (EC) 142/2011 Article 17 and Annex VIII Chapter IV Section 1 set out the record keeping requirements.

(c) Option to allow category 2 and category 3 material to be applied to land without processing: Article 13(f) and Article 14(l)

The UK intends to take advantage of these measures. Certain materials may be spread direct to land without treatment. These materials are manure, digestive tract content separated from the digestive tract, milk, milk-based products and colostrum. Most of these materials were already permitted to be spread to land untreated under previous legislation, but this list has now been expanded to include milk-based products.

These materials can be applied to land as organic fertilisers or soil improvers and as such the grazing ban will apply (except for spreading of manure and digestive tract content). The grazing ban prohibits access by livestock to land to which organic fertilisers and soil improvers have been applied, and is 8 weeks for pigs and 3 weeks for all other livestock. The UK will permit these uses provided we are satisfied there is no risk of spreading a serious transmissible disease. If there is suspicion or confirmation of a notifiable disease spreading of this material may be restricted or prohibited.

Article 17 and Annex VIII Chapter IV Section 4 of Regulation (EC) 142/2011 set out the record keeping requirements.

(d) Option to set conditions to allow shellfish shells to be spread to land: Article 14(h)

The UK does not intend to take advantage of this measure. The UK has been working with industry to come up with rules for removal of soft tissues from shellfish. Shells that are flesh-free are out of scope of the Regulation and could therefore be applied to land, subject to any environmental controls that may also apply. Shells with the flesh intact remain category 3 material and must be disposed of accordingly.

(e) Option to set conditions to allow eggshells to be applied to land: Article 14(h)

The UK intends to take advantage of this measure under conditions to ensure microbiological safety. Operators wishing to apply eggshells to land without prior heat treatment will need to be registered and comply with the following conditions:

- I. The eggs can be traced back to egg laying flocks which have been sampled by the operator and the Competent Authority under the requirements of the Salmonella National Control Programme (NCP) in laying flocks in the UK (or equivalent NCPs in countries other than UK); and
- II. the eggs were laid by flocks which were negative for the Salmonella serovars for which a Community target for their reduction is set out in Regulation (EC) 1168/2006 and according to the testing protocol laid out in the Salmonella National Control Programme during the laying phase of the flocks and the flocks or the eggs produced by the flocks are not subject to any restrictions imposed under national or EU legislation; and
- III. the eggshells have undergone a technical process to ensure that the egg residue in the end product has been reduced to at least 4%.
- IV. The spreading of eggshells without prior heat processing to land will be reviewed and may be banned following suspicion or confirmation of an outbreak of notifiable disease and/or reportable infection.

Article 17 and Annex VIII Chapter IV Section 4 of Regulation (EC) 142/2011 set out the record keeping requirements.

(f) Option to set conditions on the use of organic fertilisers and soil improvers: Article 32

The UK intends to take advantage of this measure. Organic fertilisers and soil improvers derived from processed animal protein must be mixed before they are applied to land (e.g. with wood shavings) in order to ensure that they are not attractive or palatable to farmed animals. They must comply with the requirements set out in Annex XI of Regulation (EC) 142/2011. They must be placed on the market in accordance with Article 32 of Regulation (EC) 1069/2009. Article 17 and Annex VIII Chapter IV Section 4 of Regulation (EC) 142/2011 set out the record keeping requirements.

Animal Health guidance on organic fertilisers and soil improvers will be available shortly.

(g) Option to allow disposal of former foodstuffs and processed petfood to landfill: Article 7 of Regulation (EC) 142/2011

The UK intends to take advantage of this measure. This was already permissible as a transitional measure under previous legislation. The UK will allow this to continue as a permanent measure. This must be done in accordance with Article 7 of Regulation (EC) 142/2011. Article 17 and Annex VIII Chapter IV Section 1 set out the record keeping requirements.

(h) Option to authorise the supply of colostrum from one farm to another: Annex X Chapter II Section IV Part II Paragraph 4 of Regulation (EC) 142/2011

The UK intends to take advantage of this measure, subject to an authorisation, and provided that the colostrum comes from bovine animals from bovine TB free herds. This will allow farmers to move raw colostrum between farms e.g. to feed an orphan calf. Raw colostrum from animals in TB restricted herds cannot be supplied under this derogation.

(i) Option to authorise the placing of the market of unprocessed wool under conditions to prevent the transmission of health risks: Annex XIII Chapter VII of Regulation (EC) 142/2011

The UK intends to take advantage of this measure. This will permit operators to handle unprocessed wool by a simple registration with Animal Health and with addition guidance on safe handling. Article 17 and Annex VIII Chapter IV Section 1 of Regulation (EC) 142/2011 set out the record keeping requirements.

16. Offences and penalties under the Regulations

EU Regulations are directly applicable in all Member States and it is an offence to fail to comply with them. Animal by-products must be handled,

identified, transported and used or disposed of in accordance with the requirements of the legislation.

Most operators will be operating under an approval or a registration from Animal Health. Animal Health are the main inspection body for premises handling animal by-products and are responsible for approving plants and can suspend or withdraw the approval if operators are not complying with the conditions of the Regulation or of the approval, or where there is a risk to public or animal health. Other enforcement action such as serving notices or prosecutions will usually be carried out by local authorities.

(a) Notices

Where an offence has been committed, an inspector may serve a notice on any person in possession or control of any animal by-product requiring that the animal by-products are disposed of as may be specified in the notice (and if necessary specify how to store it pending disposal); or serve a notice on the occupier of any premises prohibiting animal by-products being brought on to the premises, or only permitting this in a way specified in the notice.

Generally speaking the local authority as the main enforcement body will serve the notice, but notices may also be served by Animal Health.

(b) Suspension and/or withdrawal of approval

Alternatively, where an operator is operating under an approval and commits an offence, Animal Health also have the power to suspend that approval until such a point as the operator can demonstrate that they can satisfactorily comply with the law again. For instance, a plant may fail to treat animal by-products in accordance with the Regulations and Animal Health may decide it is necessary to suspend the approval of the plant until the material in question has been disposed of in accordance with the legislation and the plant fully decontaminated.

In some situations such as a very serious breach of the Regulations or where an operator has been persistently unable to comply with the law, Animal Health also has the power to withdraw the approval of the plant altogether. Once a plant has had its approval withdrawn, it may no longer handle or receive animal by-products.

(c) Prosecution

Serious breaches that are considered to be a threat to public and/or animal health may also be punishable by prosecution. The penalties available are, on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment not exceeding three months, or both; or on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years, or both.

17. Imports of animal by-products

The requirements for the importation into the EU of animal by-products from third countries (outside of the EU) in Regulation (EC) 1069/2009 and the Implementing Regulation (EC) 142/2011 update and consolidate previous import controls and are to be enforced in England by the Trade and Animal Related Products Regulations 2011. The import requirements in the new Regulations have not changed dramatically from those currently in place, but it is worth highlighting a few key changes (which tend to be de-regulatory allowing industry to make greater use of animal by-products with less Government intervention):

- Commission Regulation (EC) No 2007/2006 will be repealed and its provisions incorporated with only relatively small changes, including widening the definition of intermediate products;
- Commission Regulation (EC) No 878/2004/EC as amended will also be repealed and its provisions incorporated and will still require that the competent authorities (in Member States) authorise the import of specific animal by-products but under less prescriptive conditions;
- there has been a re-assessment of the risk attributed to certain animal by-products, which has reclassified some animal by-products from category 2 to 3, where the risk is low, increasing the scope for their use;
- industry will be now able to make greater use of some category 1 materials in certain circumstances e.g. for intermediate products and untreated and treated blood products;
- rules have been included for the import of animal by-products for research and diagnostic samples, trade samples (e.g. for machine testing) and display items (e.g. for artistic activities). Competent authorities (in Members States) will need take account of these rules when authorising the import of these products and industry will need to adhere to them. For example, trade samples and display items will have to enter the EU through a Border Inspection Post and undergo veterinary checks.

More information on the main changes can be found on the import of animal products pages of the Defra website.

18. Exports of animal by-products

Information on the export of animal by-products can be found on the export of animal products pages of the Defra website.

19. Frequently asked questions

Q1: I am a farmer with fallen stock – what rules do I need to follow?

A: When livestock dies on your farm, unless you have an on-farm incinerator the carcass must be disposed of at an approved site, which may be a:

- knacker
- hunt kennel
- maggot farm
- incinerator
- renderer

You can make private arrangements to dispose of your fallen stock at an approved destination, or you can make the arrangements through the National Fallen Stock Scheme. You can find out how to do this by contacting the National Fallen Stock Company either via their website or by phone on 0845 0548888.

If you want to make your own arrangements, the Animal Health Office (AHO) in your area will provide a list of approved knackers, hunt kennels, maggot farms, incinerators or renderers. You can find contact details for your local AHO on the Defra website.

You must contact your local Animal Health Office immediately if you think an animal has died of a notifiable disease.

Ban on burial or burning fallen stock in the open: The burial or burning or disposal by other means of fallen stock in the open is banned due to the risk of spreading disease through residues in the soil, groundwater or air pollution. This ban also covers animal by-products, including afterbirth and stillborn animals. In the UK, the only exceptions to the ban are:

- in remote areas – in England these are the Scilly Isles and Lundy Island
- in areas where access is difficult, for instance where an animal has fallen into a ravine or become trapped in a bog and cannot be reached. You may need to contact your Local Authority so that they can assess the site before you can bury or burn fallen stock.
- during outbreaks of notifiable disease, if there is a lack of capacity at rendering plants and incinerators, or if transporting carcasses would spread disease

Q2: I am a horse owner, what rules do I need to follow when a horse dies?

A: Regulation (EC) 1069/2009 provides a derogation in Article 19(a) permitting the burial of horses. If you wish to do so, you may bury your horse,

following your local authority and Environment Agency guidelines. These are likely to require horse burial sites to:

- be at least 250 metres away from any well borehole or spring that supplies water
- be at least 30 metres from any other spring or watercourse, and at least 10 metres from a field drain
- have at least 1 metre of subsoil below the bottom of the burial pit, allowing a hole deep enough for at least 1 metre of soil to cover the carcass
- be free of water at the bottom of the hole, when first dug.

You may also dispose of your pet horse at a pet crematorium, or if you are a member of NFSCo you can use their collection service for your horse.

Q3: I run a retail, catering or food manufacturing business, what rules do I have to follow for disposing of my waste?

A: Animal by-products arising from catering, retail, wholesale, manufacturing and distribution premises, convenience stores, food markets, butchers & bakers premises will generally fall into one of three categories- 1) raw meat & fish, 2) foodstuffs no longer intended for human consumption, or 3) catering waste.

1.1 Raw Meat & Fish includes

- uncooked meat, raw fish or seafood in coating (e.g. breadcrumbs or batter) or in a sauce
- cured meat, such as bacon
- raw meat (including sausages, burgers etc), poultry, fish & seafood in packs or loose.

NOTE: You cannot cook raw meat or raw fish to change its status to a cooked product.

1.2 Foodstuffs no longer intended for human consumption are defined as 'products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise'.

1.3 'Catering waste' is defined as 'all waste food including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens'.

All of the above food wastes become animal by-products when they are no longer intended for human consumption. An indication of such intent could be when produce is removed from sale because it has passed its sell by date or use by date, or because it is damaged, soiled or contaminated to an extent that it is no longer appropriate to display it for sale. Premises with waste food

to dispose of can do so in a number of ways, depending on which category (above) it falls into:

B: ALL animal by-products food waste can be:

- disposed of in a rendering plant
- disposed of in an incinerator plant
- transformed in an approved technical plant
- transformed in approved composting or biogas plant
- treated in approved alkaline hydrolysis plant
- used as a raw material in an approved pet food plant
- used to feed animals in zoos

Foodstuffs no longer intended for human consumption (not including raw meat, fish, seafood), and all catering waste can be disposed of to landfill.

C: Certain food waste can be recycled for feeding to farm animals

BUT NOT FROM CATERING PREMISES OR ANY FORM OF CATERING WASTE, even if it originates from vegetarian restaurants and kitchens. Catering waste including Used Cooking Oil from catering establishments cannot be recycled for feeding to farm animals. Vegetarian restaurants/ kitchens (but not vegan) kitchens are included in this ban, as they may still use products of animal origin, such as dairy products.

THE FOLLOWING APPLIES TO ONLY CERTAIN FORMER FOODSTUFFS from premises such as bakers, supermarkets, retail stores, crisp manufacturers and confectioners (although not from kitchens and restaurants based on these premises).

Food items which can be recycled for use in farm animal feed include:

- baked goods (bread, cakes, pastry and biscuits), vegetables, pasta, chocolate, sweets, and other products, such as breakfast cereals, which may contain rennet or melted fat, milk, milk products, flavourings, egg, honey, and gelatine of non-ruminant origin (not from pigs or poultry) - provided these items don't constitute the main ingredient. They must not contain - and must not have been in contact with - raw eggs, meat, fish and products or preparations derived from, or incorporating, meat or fish.
- milk, milk products provided they are not included in final products for general sale as farm animal feed i.e. can only be distributed to keepers registered on the milk register administered by Animal Health.
- eggs and egg products can only be sent for farm animal feeding from food factories (or from rendering plants) and not from retail premises or supermarkets.

A FEED BUSINESS – If a retail food, supermarket, or manufacturing business supplies former foodstuffs for animal feed use, it becomes a feed business under the Feed Hygiene Regulations (Regulation (EC) No.

183/2005), which contain requirements for registration, allows only safe former foodstuffs to be used and requires measures and controls to prevent contamination of these former foodstuffs by meat or other ineligible products of animal origin. If you want to supply waste food for feeding to livestock, please contact your local authority for further guidance.

Detailed information will be in Animal Health guidance, available shortly.

NOTE: If you are a retail premises with only a small quantity of animal by-products to dispose of (under 20kg per week) you can now dispose of your raw meat/fish via normal waste routes, rather than by separate collection. Contact your local Trading Standards department for more information.

Q4. What are alternative methods?

Alternative methods are methods of processing animal by-products other than by the traditional rendering standards set out in Annex III Chapter III of Regulation (EC) 142/2011 (methods 1 to 7).

Some alternative methods are listed in Annex IV Chapter IV Section 2 and include use in biodiesel, alkaline hydrolysis and Brookes gasification plants. Alternative methods require approval by Animal Health in the same way as conventional processing plants, though obviously they will be operating to different standards.

Article 20 of Regulation 1069/2009 and Article 16 and Annex VII of Regulation (EC) 142/2011 also lay down provisions and a standard format for the introduction of new alternative methods that are not currently permitted by the Regulation, so that new technologies or treatment methods can be adopted. An operator who wishes to have an alternative method adopted for the treatment of animal by-products must in the first instance contact Defra as the competent authority to discuss how to progress the application.

20. Website links

For further information on the requirements above, please visit the Defra animal by-products webpage:

<http://ww2.defra.gov.uk/food-farm/byproducts/>

For more information relating to the import and export of animal by-products please visit the Defra import of animal products webpage:

<http://ww2.defra.gov.uk/food-farm/import-export/>

For more detailed guidance on permitted uses, and on conditions for storage, handling, transporting, and processing animal by-products, please visit the Animal Health website:

<http://www.defra.gov.uk/animalhealth/managing-disease/animalbyproducts/index.htm>

Locate your nearest Trading Standards Office at:
<http://www.tradingstandards.gov.uk/advice/index.cfm>

Businesses may also want to visit the 'Businesslink' website which has detailed guidance to assist businesses who need to comply with this and other related regulations:

<http://www.businesslink.gov.uk/bdotg/action/home>

The National Fallen Stock Website:

<http://www.nfsco.co.uk/>

Legislation

Regulation (EC) 1069/2009:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:300:0001:0033:EN:PDF>

Regulation (EC) 142/2011:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:054:0001:0254:EN:PDF>

The TSE (England) Regulations 2010:

<http://faolex.fao.org/docs/pdf/uk93745.pdf>