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Your ref:
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Dear Sir/Madam

ANIMAL BY-PRODUCTS (SCOTLAND) REGULATIONS 2003

In February I sought your views on the enforcing legislation necessary to give effect to the EU Animal By-Products Regulation (EC) No 1774/2002. I am grateful to those who submitted comments.

Although we originally envisaged that the enforcing legislation would come into force on 1 May 2003, in line with the provisions of the EU Regulation, we delayed introduction of the enforcing legislation to enable it to reflect the implementing and transitional measures. These measures were agreed in mid-April but were only published in the Official Journal on 13 and 14 May (OJ Nos. L117 and 118).

The enforcing legislation (**The Animal By-Products (Scotland) Regulations 2003, SSI No 2003/411**) for the EU Regulation and the implementing and transitional measures was made on 8 September and will come into force in **Scotland on 1 October 2003**. The Regulations can be obtained from our website (www.scotland.gov.uk). Enforcing legislation was introduced on 1 July in England and I understand parallel measures will be introduced in Wales and Northern Ireland next month.

The following paragraphs describe the major developments made since our consultation exercise began in February. Also enclosed is a detailed summary of the changes we have made to the draft Scottish Statutory Instrument circulated earlier this year.

Implementing and transitional measures

The EU Regulation aims to protect animal and public health by tightening the rules on the disposal and use of animal by-products (animal carcasses, parts of animal carcasses and products of animal origin which are not intended for human consumption). It is a wide-ranging Regulation which impacts on a number of different sectors.

During negotiations, it was recognised that some sectors may need additional time to comply with the requirements of the Regulation and that further measures may need to be introduced, for example to permit certain practices after a scientific opinion had been obtained. The Regulation therefore provided for the introduction of implementing and transitional measures.

After adoption of the EU Regulation, negotiations took place on a number of implementing and transitional measures. These negotiations resulted in a satisfactory outcome for the UK. We secured transitional measures in relation to –

- * the use of small (less than 50kg/hour) incinerators which do not burn specified risk material, until 31 December 2004
- * the use in animal feed of used cooking oils, until 31 October 2004
- * the separation at oleochemical plants which process tallow derived from Category 2 and 3 material, until 31 October 2005
- * the rendering of mammalian blood at atmospheric pressure, until 31 December 2004
- * the rendering standards for the production of mammalian meat and bone meal for use in petfood, until the feed restrictions are lifted
- * the collection and disposal of certain types of former foodstuffs from food manufacturing premises and retail outlets, until 31 December 2005
- * the feeding of processed animal protein from all fish to farmed fish, until 31 December 2003.

The transitional measures are intended to allow the relevant industries time to adapt to the requirements of the Regulation and the Commission has made it clear that they will not be renewed. It will therefore be important that the time is used to make the necessary changes and we will be discussing progress with the relevant sectors during the transition periods.

We have not given effect to two Commission Regulations ((EC) No. 809/2003 and 810/2003) which permit the use of national standards to treat manure and Category 3 material in composting and biogas plants, providing the controls were in place on 1 November 2002. As we did not have any national controls in place on 1 November 2002, we are not exercising these transitional measures.

A transitional measure to delay the application of the import provisions until 31 December was also adopted, to allow time for the relevant Annexes and import certificates to be reviewed. The trade, import and export provisions of the Regulation are to be dealt with through separate Regulations.

Permanent implementing measures were also agreed which introduce –

- * rules to permit the incineration of specified risk material in low capacity (less than 50 kg/hour) incinerators
- * suitable measures to apply in the limited circumstances in which burial and burning is permitted (remote areas and disease outbreaks)
- * from January 1, 2004, a derogation from the ban on intra-species recycling in Article 22 to allow the feeding to farmed fish of processed animal protein derived from wild fish, subject to suitable controls

- * clarification that only animal material trapped at the primary stage of the treatment of waste water (by a screen or mesh of no more than 6mm) must be treated as an animal by-product.

The transitional and permanent implementing measures are also given effect by the enforcing legislation. Some of the measures (primarily the permanent implementing measures) were adopted as Commission Regulations and are directly applicable in member States. The text of those measures is therefore not repeated in our enforcing Regulations and reference will need to be made to both the Commission Regulation and the enforcing legislation. However, because they do not apply to all member States, most of the transitional measures were adopted as Commission Decisions. As they are not directly applicable, the text of the Decisions needs to be reflected in the enforcing legislation and you will only need to refer to the text of the enforcing Regulations.

Responses to consultation

Copies of the comments received in response to consultation are available from the main Scottish Executive library at K Spur, Saughton House, Edinburgh EH11 3XD. Copies will be supplied on request but there will be an administrative charge to cover copying and postage. To enable requests to be dealt with efficiently and to avoid undue delay it would be appreciated if personal callers could give at least 24 hours notice of their requirements.

We consulted 195 individuals and organisations, but only a number of technical points were made and concerns were expressed about the increased costs of disposing of abattoir waste, particularly blood; the need for guidance on issues such as the new incinerator controls; and the need to permit ensiling and composting of fish waste. However, in general the responses to both consultation exercises focussed on four areas -

- (a) composting
- (b) fallen stock
- (c) the definition of the remote area in Scotland; and
- (d) former foodstuffs.

(a) Composting and biogas plants

The responses from those in favour of allowing the treatment of catering waste in biogas and composting plants had four common themes. These were :-

- the proposed controls were too prescriptive and would severely restrict the development of the composting industry preventing the UK from meeting its landfill and recycling targets;
- Enterobacteriaceae was not an appropriate indicator organism and the costs of the proposed laboratory testing requirements would be too high;
- the standards should not be applied to mechanical and biological treatment plants (MBT) when composting is used to stabilise the organic matter of material destined for landfill with a view to meeting the pre-treatment requirements of the Landfill Directive;

- the length of the proposed ban on grazing following the application of compost/digestate to land did not fit in with farming practice, particularly in relation to digestate from biogas plants.

On the other hand, concerns were expressed that -

- the standards proposed were not adequate to safeguard animal health; and
- compliance with a no-grazing period would be difficult or impossible to enforce and should not be relied on as part of the controls.

The controls will apply to MBT plants only if they are producing compost for land application or landfill cover. If they are simply treating the material to remove recyclables prior to landfill or incineration of the residual waste, they will not be controlled. Nevertheless, this is an issue that we shall keep under review. If it becomes apparent that the operation of such plants does pose a risk to animal health, we shall consider the need for suitable controls. The controls in the regulations are based on a thorough risk assessment of the animal and public health implications and, while recognising that it will be difficult to monitor compliance with the no-grazing period, it will be in farmers' own interests to respect this as their animals would be the first to suffer in the event of any pathogens being present. For practical reasons we have reduced the period from 2 months to 3 weeks for all livestock other than pigs. By ensuring that controls are fully applied at the composting or biogas plant, the risk from such material should be very low. On the other points, we have endeavoured to meet most of the concerns expressed and have amended the enforcing legislation accordingly. In particular, the amendments will permit adoption of a HACCP approach to ensure compliance with the requirements in certain cases. In such cases, there will need to be a robust and auditable sampling protocol as well as thorough monitoring and recording of critical control points. Full details are in the attached summary of changes.

(b) Fallen stock

Many concerns were expressed about the ban on the burial of fallen stock, largely in relation to the additional costs of disposal that some farmers will face and, in the case of the fish farming industry, the current lack of suitable disposal facilities. Questions were also raised about practical issues such as the disposal of small quantities of waste; fish mortalities and shells from shellfish; and road kills. Enforcement bodies expressed concern about the possibility of an increase in illegal disposal of fallen stock and the associated costs that they would face, as well as the increased costs of enforcing the ban.

We have been discussing these issues with interests with a view to finding practical solutions, and wrote to all livestock farmers asking them if they would be interested in subscribing to a national fallen stock collection service, to which the Executive would make a substantial financial contribution in the first year. The scheme is set to be introduced in January 2004.

c) Remote area definition

As announced by Mr Finnie on 28 August, the enforcing legislation defines those parts of the Scottish Highlands and Islands which are considered to be remote areas and in which the burial or open-burning of fallen stock is permitted, subject to certain safeguarded measures, provided access to the prescribed disposal routes (incineration or rendering) is not feasible.

(d) Former foodstuffs

The Regulation also bans the burial (including landfill) of other types of animal by-products, including former foodstuffs from food manufacturing premises and retail outlets. A number of respondents expressed concern about the practical implications of this requirement and the compliance costs and queried the justification for the ban. In the light of discussions with interested parties, we therefore successfully asked the European Commission for a transition period to allow certain types of former foodstuffs to continue to be disposed of to landfill. This allows the disposal of the following material to landfill until 31 December 2005 –

- (a) material from food manufacturing premises which is currently considered to be catering waste under the Animal By-Products Order 1999 (ie waste from the production of products which are not intended to be cooked before they are eaten);
- (b) former foodstuffs from retail outlets, providing that suitable measures are in place to ensure that raw meat is excluded from the foodstuffs.

It should be noted that the transition period does not apply to raw meat or waste from the production of products that require further cooking from food manufacturing premises as this material is already considered to be an animal by-product under the Animal By-Products Order 1999. Nor does the transition period apply to raw meat or fish from retail outlets.

The transition period maintains the status quo in respect of food manufacturing premises. However, some food manufacturers with very small quantities of material and retail outlets will need to make changes to their procedures in order to comply with the new requirements. A UK wide Task Force, has been established, with Scottish Executive input, comprising representatives of the relevant industries and the enforcement bodies, to develop an implementation plan which will include guidance on how the requirements can be applied in a proportionate manner. The Task Force will also be working with relevant organisations to ensure that by the end of 2005, these foodstuffs are no longer being sent to landfill but are treated in alternative outlets such as biogas, composting or rendering plants.

Feeding to livestock of former foodstuffs that do not contain meat

The Animal By-Products Order 1999, as amended, currently prohibits the feeding to ruminant animals, pigs and poultry of former foodstuffs which originate on premises where meat and other products of animal origin are handled. The aim is to prevent the feeding to livestock of any material that may contain or have been in contact with meat. We sought views on relaxing this requirement to allow the feeding of former foodstuffs which do not contain meat or most other products of animal origin, providing adequate measures are in place to ensure that there can be no contact with meat and other animal material at any stage, including the handling and collection of the waste.

The enforcing legislation does not contain an provision equivalent to that in the Animal By-Products Order 1999 although it does maintain the offence of feeding meat and other products of animal origin to ruminant animals, pigs or poultry, and of allowing them access to such material.

Enforcement of these requirements will be a matter for local authorities but we envisage that premises that intend to supply material such as vegetables, pastry, crisp or sweet waste for feeding to livestock would need to be able to demonstrate that they have measures in place which ensure that there is no possibility of the material being contaminated by meat or other products of animal origin. In practice, to demonstrate that this particular hazard is being addressed, they will need to operate full HACCP procedures. The presumption must be that small premises are unlikely to operate in this way. For other premises, one way of demonstrating that adequate measures are in place would be for the operator to be a member of the Feed Materials Assurance Scheme (FEMAS). FEMAS is a product certification scheme for producers and processors of feed materials who supply either feed compounders or on-farm mixers. It dovetails with the UKASTA Feed Assurance Scheme which certifies safe feed production and has independently audited procedures, traceability, record keeping and hazard analysis and control to ensure that surplus food products can be safely used. Certification to FEMAS is only achieved following a successful independent audit against the FEMAS core standard and sector guidance note (for surplus food products for businesses producing products such as biscuit meal, bakery products, confectionery waste, pasta, pastry, ice cream and other products no longer intended for use as human food). Further details can be found on the UKASTA website (www.ukasta.org.uk).

Implementation and enforcement

The Regulation will be enforced by the Meat Hygiene Service in licensed slaughterhouses and cutting plants and by local authorities elsewhere. The issuing of approvals will be the responsibility of the State Veterinary Service. Although the Scottish Environment Protection Agency has no direct enforcement role in relation to the Animal By-Products (Scotland) Regulation, it is responsible for the enforcement of environmental legislation which impacts on the disposal of animal by-products. To raise awareness of the provisions of the Regulations and to promote better liaison between the various enforcement bodies, we will run a training course for those bodies. We have also prepared guidance on some topics such as technical plants and collection of blood at abattoirs, and are preparing guidance on other issues such as incinerators and composting, to provide more detailed advice on the provisions of the Regulation and other relevant legislation; this is, or will be, available on our website (www.scotland.gov.uk).

Although the EU Regulation has applied since 1 May, the delay in the introduction of our enforcing legislation has meant that the Regulation has not been enforceable. In Scotland, this will be rectified from 1 October but we recognise that it will also take some time for the measures to bed in fully. We will be writing to local authorities in Scotland, asking that, where operators are facing **genuine** difficulties in finding a legitimate disposal route, local authorities take a proportionate approach to enforcement. However, we do expect local authorities to take enforcement action if an operator is not making every effort to comply. We will write in similar terms to SEPA, which is responsible for licensing landfill sites in Scotland.

Approvals

Applications for approval for operations which are not currently controlled under the Animal By-Products Order 1999 or the TSE (Scotland) Regulations 2002 (which replaced the SRM Regulations 1997) should be submitted to the local Animal Health Divisional Office who will arrange for any necessary inspections. We are currently preparing application forms and they will be available shortly on our website or from the Animal Health Divisional Offices.

Approvals and registrations which have already been issued under the above legislation will continue to have effect in most cases. However, to avoid doubt, and to allow time for the SVS to visit premises and review their approvals, we intend to issue a general approval allowing such premises to operate until their approval has been replaced or withdrawn.

It is necessary to ensure that producers of animal by-products are aware of which premises are approved to receive their animal by-products. We also need to provide the European Commission with a list of approved premises. We will therefore make publicly available the name and address of approved operations, the approval number, the type of approval (eg as a petfood, rendering or composting plant) and, where appropriate, the category and species of the material that the premises may receive. Other details relating to the business will remain confidential. Our ultimate aim is that an up to date list should be available on our website but it will take time to develop the necessary systems. Until then, confirmation that a particular premises is approved to receive certain types of animal by-products can be obtained from the relevant Animal Health Divisional Office. The Food Standards Agency (Scotland) is using this SSI to make consequential amendments to the Animal By-Product (Identification) Regulations 1995, which require the staining of high risk (Category 2) animal by-products, to bring them into line with the EU Animal By-Products Regulation. The amendments will also apply in Scotland from 1 October 2003.

Future work

(a) the marking of animal by-products and processed animal protein;

The Commission has sought advice from the Joint Research Centre of the European Commission on suitable markers for certain types of animal by-products and processed products. The JRC's advice has yet to be received but the Commission has tabled a proposal which would require the marking, with visual markers and smell, of Category 1 and 2 animal by-products and processed animal protein (meat and bone meal) and tallow derived from Category 1 and 2 material. It has also proposed that petfood from animals that have been treated with certain substances should be marked with charcoal. It is also considering requiring casein, technical gelatine and technical collagen derived from Category 3 material to be marked.

We have stressed to the Commission that the system of markers must be practicable and that sufficient time must be allowed for the introduction of any new markers. In the meantime, we do not intend to apply the requirement in the Regulation for markers to be used other than as already required by our existing legislation (ie for Specified Risk Material and high risk (Category 2) material).

(b) milk

A number of responses to consultation asked how the Regulation impacted on the disposal of milk that was not used for human consumption. Although milk can continue to be applied to land, subject to SEPA's controls, a strict interpretation of the Regulation is that milk should be rendered before it is fed to livestock. However, the Commission has acknowledged that this is inappropriate and has come forward with a proposal that would enable pasteurised milk to be fed to livestock without further treatment. We are discussing this, and other issues relating to the disposal of milk, with the dairy industry with the aim of obtaining workable solutions. Until these issues are resolved at EU level, we see no reason to require the prior processing of Category 3 milk and milk products that is to be fed to livestock.

(c) biscuit, pastry, pasta, sweet waste

There is some uncertainty about whether the Regulation applies to certain types of former foodstuffs. The Commission has issued a declaration to make it clear that it does not consider that the Regulation should apply to surplus food such as biscuits, pastry and bread which do not contain meat but may contain other products of animal origin such as butter, lard or milk. It has now come forward with a proposal to give effect to that declaration.

(d) organic fertilisers and definition of pasture land

The current definition of pasture land in the Regulation does not indicate the period during which there must be no grazing of the land to which organic fertilisers have been applied. The Commission had undertaken to consult the EU Scientific Steering Committee on this issue before making a proposal, but has now come forward with a proposal that suggests that the no-grazing period should be three weeks. We intend to press for the no-grazing period to be in line with our national legislation ie 2 months for land to which pigs will have access, and 3 weeks for land to which other livestock will have access.

The Commission's proposal also proposes various treatment standards for compost and biogas digestion residues. The Commission has not given a very clear explanation for these standards and whether they are additional to the existing processing standards for those plants, or whether they are alternatives. However, their initial explanation was that they were additional requirements. We are seeking further clarification and justification for these requirements.

In my letter of 7 February, I noted that we were intending to review the fertiliser controls in the TSE (Scotland) Regulations 2002. We are consulting SEAC, The Ministers' independent advisory body on TSEs, and hope to consult on these and other changes later in the year. At the same time we also intend to review the Rendering (Fluid Treatment) (Scotland) Order 2001 which prevents rendered ruminant blood from being used as fertiliser if it is in liquid form.

Relationship with environmental legislation

The relevant parts of the Commission are liaising to resolve a number of queries concerning the relationship between the Animal By-Products Regulation and the environmental controls in the Waste Framework Directive and the Waste Incineration Directive; this focuses primarily on animal carcasses from agricultural premises. However, in most cases environmental controls will continue to apply in addition to the controls in the Animal By-Products Regulation. For example, while an activity such as the land application of digestive tract contents or the composting of catering waste may be permitted by the Animal By-Products Regulation, environmental regulatory constraints and authorisations will still need to be complied with.

Yours faithfully

Martin Morgan
Animal Health & Welfare Division

CHANGES MADE TO THE ANIMAL BY-PRODUCTS (SCOTLAND) REGULATIONS 2003

These changes are presented in the same order as they appear in the final version of the Animal By-Products (Scotland) Regulations 2003 (SSI No 2003/411).

Scope of Regulations

1. The Regulations now give effect to the EU Animal By-Products Regulation as well as the relevant implementing and transitional measures. These are listed in regulation 2.

Possession or control

2. Regulations 4, 5 and 6 now make it clear that a person commits an offence if they have animal by-products in their possession or under their control and fail to dispose of them in the specified manner.

Processing standards

3. Articles 4 and 5 of the EU Regulation allow member States to require the processing of Category 1 and 2 material by method 1 (the pressure cooking standard) if the processed material is destined for incineration. However, we intend to permit any of methods 1-5 and regulations 4 and 5 now spell this out.

International catering waste

4. The controls on the transport and disposal of catering waste from international transport will be given effect by the Products of Animal Origin (Third Country Imports) (Scotland) Regulations, in line with the controls on other imported material. Regulation 4(2) therefore exempts catering waste from international transport from control under these Regulations.

Land application of manure, digestive tract contents, milk and colostrum

5. In regulation 5(2), we have clarified that the Scottish Ministers are the competent authority for the purposes of deciding whether manure, gut contents, milk and colostrum which are to be applied to land pose a risk of spreading any serious transmissible disease (Article 5(2) of the EU Regulation). We take the view that such a risk exists only during an outbreak of an OIE List A disease. This provision therefore spells out that land application is permitted as long as the Scottish Ministers have not imposed any restrictions relating to animal health in relation to that product (ie under notifiable disease legislation).

Mixing of animal by-products

6. Currently the mixing of Specified Risk Material with other animal by-products is not permitted, except at a rendering plant. We sought comments on whether we should allow the mixing of different categories of animal by-products. Although the comments made were limited, they generally supported the proposal to allow mixing. In particular, this will be important for those slaughterhouses which wish to mix blood with other by-products. Regulation 7 notes that where mammalian and non-mammalian material is mixed, it shall all be treated as mammalian material.

7. Because the EU Regulation already permits mixing of the different categories of animal by-product, providing the mixed material is treated as the highest risk category, there is no specific provision for this in the enforcing legislation. However, Schedule 4 makes consequential amendments to the TSE (Scotland) Regulations 2002 which will revoke the provisions in those Regulations which prevent the mixing of SRM with other animal by-products and replace them with a provision that requires mixed material to be treated as SRM. Although there is no requirement to record the quantities of the SRM and animal by-products that are mixed, we will monitor the operation of the mixing procedures and, if it appears necessary, will propose a record-keeping requirement as part of the amendments to the TSE Regulations which are planned for later this year.

8. We have maintained the provision (regulation 8) that permits the transport of different categories of animal by-products in containers that are not impervious (ie in compartmentalised vehicles) as long as all the material in the vehicle is rendered or otherwise disposed of as the higher risk category.

Controls on manure

9. Article 7 of the EU Regulation allows member States to decide not to apply to consignments of manure the requirement for transport to be in accordance with the provisions of Annex II and for consignments to be accompanied by a commercial document or health certificate. Regulation 8 makes it clear that we do not intend to apply those provisions to manure transported within the UK.

Access to animal by-products

10. In regulation 9(1) we have exempted milk and colostrum used on the farm of origin from the ban on feeding unprocessed animal by-products to livestock. Although ideally we would have exempted all Category 3 milk and colostrum from this provision, we are unable to do so because the EU Regulation requires milk other than that produced on the farm of use to be processed before feeding. In practice, we hope that enforcement bodies will note that the European Commission has proposed legislation to resolve this.

11. We have maintained the restriction in regulation 9(2) on allowing livestock and wild birds to have access to untreated animal by-products and catering waste, other than as specifically permitted (eg the feeding of birds of prey). However, regulation 9(5) now allows the secondary stage of a composting operation to be in the open (where wild birds might have access to it).

12. We have changed regulation 9(3) which bans the bringing of unprocessed animal by-products onto premises where livestock are kept. As a general principle, we do not want animal by-products to be brought onto premises where there are livestock. We do not therefore intend to approve operations to handle animal by-products (eg petfood plants, collection centres) if there are livestock on the same premises. However, a small number of existing premises (hunt kennels and petfood plants) have already been approved in this way and it would not be possible for them to make the changes necessary to comply. We therefore intend to allow existing premises (ie those operating on 1 November 2002) to continue, subject to there being suitable separation between the livestock and the animal by-products operation, but we will not approve any new premises which operate in this way. We have also provided for collection rounds to be able to bring by-products onto livestock premises, providing the by-products are not removed from the vehicle.

Definition of pasture land

13. The Regulation prohibits the use of material of animal origin on pasture land but does not provide a very helpful definition of pasture land. Our risk assessment on composting suggested that land to which compost derived from catering waste had been spread should not be grazed or cropped for two months after application. However, this will cause practical problems for biogas plants which wish to treat both manure and catering waste and return the treated residues to the farms that supplied the manure. In such cases it is not practicable to delay grazing for such a long time and the industry have pressed for a three week period. The risk assessment considered that a two month period was necessary because of the risk from pig diseases such as Classical Swine Fever and African Swine Fever. It was only considered necessary for Foot and Mouth Disease during an outbreak. We have therefore maintained the two month no-grazing ban in relation to pigs but reduced it to three weeks in relation to other farmed animals. We have specified that the land should not be grazed during those periods and that cropping is also banned during that period for feeding during that period. Thus zero-grazing would be prohibited but cutting for hay or silage production would be permitted during that period.

14. As explained earlier, the Commission has come forward with a proposal which, as currently drafted, would allow a 3 week no-grazing period for all livestock. We intend to press for the UK standards to be adopted but may need to revise those standards in the light of agreement at EU level.

Intra-species recycling of fish

15. Regulation 12 gives effect to Commission Regulation (EC) No 811/2003 which allows the feeding to farmed fish of processed animal protein derived from wild fish providing adequate separation is in place, the by-products are processed in accordance with the Regulation, and the processed material is suitably labelled. This provision takes effect from 1 January 2004, following the transition period provided for in Schedule 3, Part I, which allows the feeding of processed animal protein from farmed fish to continue until 31 December 2003. In practice, we understand that the industry does not feed farmed fish with processed animal protein from farmed fish.

Competent authority

16. As well as making it clear that the Scottish Ministers are the competent authority for the purposes of issuing approvals, regulation 13 also notes that the Scottish Ministers are the competent authority for a number of other functions which the Regulation requires the competent authority to perform. These include validating and checking plants. In other cases, an inspector will perform the relevant function (inspecting records). Other references to the competent authority have been inserted in the relevant regulations and Schedules.

Disposal of ash from incinerators

17. The permanent implementing measures which permit the incineration of Specified Risk Material in low capacity incinerators require the ash to be disposed of to a licensed landfill site. Regulation 14(3) provides for ash from high capacity incinerators which burn SRM to be disposed of in the same way. In both cases, the requirement is in line with our existing controls in the TSE (Scotland) Regulations 2002.

Composting and biogas plants

18. Regulation 15(1) clarifies that the provisions of paragraphs 1-11 of Annex VI to the Regulation (ie everything other than the processing standards) apply to the treatment of catering waste in a biogas or composting plant. These are **additional** to those in Schedule 1 of the enforcing legislation. Both sets of requirements also apply to plants which treat other animal by-products.

19. Regulation 15(2) provides for operators to choose to process catering waste to the EU standards as an alternative to the standards in Schedule 1 of the enforcing legislation.

20. Regulation 16 is the provision which allows for the domestic composting of catering waste providing the compost is used only on the premises. No changes have been made to this provision, although we have changed the way of presenting it.

Sampling requirements

21. The rendering industry has indicated that it is content with the sampling requirements in regulation 18.

22. We received a number of comments in relation to the sampling requirements at composting and biogas plants. These highlighted the cost implications and queried whether Enterobacteriaceae was a suitable indicator organism.

23. We recognise that there is considerable doubt about the suitability of Enterobacteriaceae as an indicator organism. The European Commission has therefore undertaken to seek a scientific opinion on the issue and, if necessary, propose changes to the testing requirements for animal by-products. Although in the meantime we must comply with the testing requirements in relation to most animal by-products, we do have the ability to introduce national rules in relation to the treatment of catering waste. For material derived from catering waste, we therefore propose to require testing for Salmonella only.

24. There was considerable concern about the proposed frequency of sampling. We also recognise that plants which adopt a HACCP approach may require more intensive sampling than those which are constructed in a way that ensures there can be no possibility of contamination of the treated or partially treated material. There may also be a need for more intensive sampling and testing during the initial validation of a plant, with a reduced frequency once it has been demonstrated to be operating satisfactorily. To allow for this to be dealt with on a site by site basis, regulation 19 therefore requires the operator to take a representative sample and for the frequency of sampling to be specified in the approval. We are preparing detailed guidance on how this might operate in practice.

25. Regulation 19(1) also requires the operator to take a representative sample of material after it has been treated to the time/temperature parameters. Providing the necessary heat treatment(s) have been completed, this could be during maturation or storage or, in a biogas plant, during the anaerobic digestion phase. Material cannot be removed from the premises until the results of testing are known.

26. Regulation 20(3) requires the operator to keep a record of the results of laboratory tests and to inform the Scottish Ministers from which batch a failed sample originated. The operator will therefore need to ensure that he or she has a system in place to link the microbiological testing results with the relevant batch of material.

Placing on the market

27. We were concerned that the record keeping requirement for consignments of compost and digestion residues did not really work. We have taken the view that our aim is to ensure that the no-grazing ban is respected, rather than to be able to trace a consignment back to source in the event of a problem. As such, we do not need a complete audit trail from the composting or biogas plant to the premises on which the compost or digestion residues are used, but can achieve our aims with a labelling requirement. This requires that if it is for use on agricultural land, the compost or digestion residues must be labelled or accompanied by documentation to draw the users attention to the grazing restrictions. To supplement this, we have retained the provision in regulation 39 which requires the farmer to keep records of application and grazing times but have deleted the requirement for the operator of the composting or biogas plant to keep records of all consignments. We will keep this issue under review and, if it becomes apparent that the lack of a record-keeping requirement for consignments is causing problems, will consider introducing a suitable provision.

Derogations

28. Regulation 28 exercises the derogation in Article 24 of the EU Regulation to allow the burial of dead pet animals.

29. In response to comments made during consultation, we have specified that burial and open-burning of animal by-products may be carried out only in remote areas of the Highlands and Islands of Scotland as detailed at Schedule 3.

30. We have also made consequential changes to regulations 29 and 30 to reflect the implementing measures in Commission Regulation (EC) No 811/2003 which specify how burial and burning of animal by-products must be carried out in the limited circumstances in which they are permitted (ie in remote areas and during outbreaks of serious notifiable disease where there is a lack of capacity at rendering plants or incinerators, or where transport would pose a health risk). These measures also require records to be kept of such burial or burning. Regulation 31 reflects the provision in the Commission Regulation which allows for the burial or burning of bees and apiculture products.

Record keeping

31. In regulation 35, we have maintained the provision which requires records to be kept of animal by-products and processed products which are disposed of on the premises (eg by on-farm incineration). However, we have exempted manure from that requirement as its original inclusion was a mistake. We have also exempted by-products to which the EU Regulation does not apply (eg milk and colostrum disposed of on the farm of origin, non-diseased wild animals, etc).

32. We have simplified the record keeping requirements in regulation 36 for biogas and composting plants which receive catering waste and now require them to keep records only of the date, quantity and description of catering waste (including whether it is meat-excluded waste) and the name of the haulier. (A similar requirement for other animal by-products is already in the Regulation.)

33. In regulation 37, we have included a requirement for records to be kept of checks carried out at the critical control points in a biogas or composting plant as this is an important part of the HACCP process.

34. As explained in paragraph 27 above, regulation 39 no longer includes a requirement for the operator of a biogas or composting plant to keep records of consignments of material. We have however retained the record keeping requirements for the occupier of premises on which ruminant animals, pigs or poultry are kept and who applies compost or digestion residues.

Notice procedure

35. We have expanded the scope of the notice procedure in regulation 43. As well as being able to specify how animal by-products must be disposed of, a notice may also prohibit animal by-products being brought onto the premises or permit this only in a way specified in the notice.

36. We have deleted the previous provision which referred to the way in which notices should be served; we did not think it was necessary to spell this out in the SSI.

Powers of entry

37. We have provided inspectors (SVS and local authorities) with the power to seize animal by-products and remove records for copying (regulation 46). We have also made it an offence for operators to fail to provide inspectors with the records.

Transitional measures

38. The expiry dates of the various transitional measures are set out in regulation 50.

Schedule 1 – composting and biogas plants

39. We have rewritten the provisions of Part I of Schedule 1 in response to concerns expressed that composting is not a single treatment process, but a series of treatment stages. The new requirements clarify that the area for storing treated material shall be adequately separate from the reception area (where the untreated material is received) and the area in which vehicles and containers are washed. It also requires the site to be operated in a way that avoids contamination of treated or partially treated material by untreated material or partially treated material and for the operator to identify, control and monitor suitable critical points to demonstrate that this is achieved.

40. There were many calls for HACCP procedures to be adopted rather than having the separation issues dealt with solely by the construction of the plant. Equally, however, concerns were expressed that reliance on operational procedures to avoid contamination of treated material is unsatisfactory. Although our strong preference is for plants to be constructed in such a way that there can be no by-pass of the treatment stages, and no contamination of treated or partially treated material by other material, we recognise that this will not be possible in all cases. We have therefore provided for HACCP procedures to be adopted where appropriate (paragraph 3 of Part I of Schedule 1). We are developing detailed guidance to deal with these issues, but consider that where reliance is placed on operational measures, rather than constructional ones, there will need to be a robust and auditable sampling protocol for microbiological testing as well as thorough monitoring and recording of critical control points, and recording of action taken in response to any failure of those points.

Before approval can be given, the operator of the plant will need to determine which control points are the critical ones and demonstrate how they will be controlled, monitored and recorded, and what action will be taken in the event of a failure. Paragraph 4 of Part I of Schedule 1 requires the critical controls points to be monitored to demonstrate compliance with paragraph 3 and regulation 37 requires records to be kept of that monitoring.

41. Paragraph 5 of Part I of Schedule 1 takes account of comments made and specifies that, where catering waste is the only animal by-product being transported and the vehicle does not transport treated material, only the wheels of the vehicles need to be cleaned before they leave the site. This avoids operators having to wash the inside of dustcarts. However, any vehicle which may transport treated material must be thoroughly cleaned after transporting untreated material.

42. We have rewritten the section in Part II of Schedule 1 that deals with the parameters for treating catering waste to make the provisions clearer. We have also allowed for alternative systems to be approved. The aim is to avoid having to amend the Regulations if an operator can demonstrate that an alternative system guarantees an equivalent level of pathogen reduction to those specified in the table. However, the parameters specified in the table are based on a detailed risk assessment and we would not expect to approve any alternative systems unless the operator had carried out an equally thorough, peer-reviewed, assessment of his system. Any plant processing animal by-products other than catering waste must meet the standards in the EU Regulation (12mm particle size and 70°C for 60 minutes).

43. We have removed the original definition of meat-excluded waste and now refer to it in the appropriate paragraphs of the Schedule.

44. We have also removed the requirement for the composting phase to last for 7 days as this goes further than the EU requirements and we could not enforce it in respect of the treatment of animal by-products. However, we have made it clear in Part II of Schedule 2 that the time/temperature parameters must be achieved as part of the composting process. The Regulation defines a composting plant as one in which biological degradation of products of animal origin is undertaken under aerobic conditions and operators will need to demonstrate that the process complies with all the components of a biological degradation.

Schedule 2 – microbiological testing methods

45. In the light of comments received, we have made some minor changes to the incubation temperatures in the testing methods to ensure that they are consistent across the test methods and to include tolerances in some places.

Schedule 4 – transitional measures

46. Schedule 4 provides for the transitional measures. It should be noted that, **where the transitional measures are not complied with, the EU legislation requires the competent authority to remove an operator's approval. Approval may not be re-instated until the full requirements of the EU Regulation are complied with.**

Intraspecies recycling of fish

47. Part I provides for a transitional measure to 31 December 2003 to allow the feeding to farmed fish of processed animal protein derived from farmed fish, subject to current controls. Thereafter only processed animal protein derived from wild fish can be fed to farmed fish. We understand that the UK industry already complies with the measures to apply after 1 January 2004.

Former foodstuffs

48. Part II allows, until 31 December 2005, for certain former foodstuffs to be
- (a) transported as catering waste (ie the transport requirements of the Regulation do not apply)
 - (b) treated as catering waste (ie the foodstuffs may be treated to national standards in a biogas or composting plant); and
 - (c) disposed of to landfill, providing measures are taken to ensure that the former foodstuffs do not include raw meat.
49. Transport must be carried out by authorised collectors and we are asking collectors to notify us so that we can issue the necessary authorisations. As explained in the accompanying letter, a Task Force has been set up to prepare guidance on the implementation of these requirements.
50. Part II makes it clear that former foodstuffs means
- (a) material from food manufacturing outlets which is currently considered to be catering waste (ie “waste from the production of products which are intended to be cooked before they are eaten” does not benefit from the transition period); and
 - (b) former foodstuffs from retail outlets from which raw meat is excluded.

If former foodstuffs are mixed with other animal by-products, the mixed material must all be treated as animal by-products of the relevant Category.

Used cooking oils

51. Part III allows the continued use in animal feed of used cooking oils, until 31 October 2004. The industry already has a scheme in place to ensure that used cooking oils for use in animal feed are collected and treated according to HACCP procedures and in a way which avoids contamination and ensures traceability. The rules in Part III are essentially those of the industry scheme. Because of the limited amount of time during which the scheme will operate, we do not consider that it is appropriate to put the audit role for this scheme to open tender. We do not wish to cause unnecessary disruption to the industry by initiating a tender for a role which will only have a few months to run once the tender process is complete. In addition, the transitional measures are based on the Commission’s inspection of the existing system of control. We therefore intend to authorise the continuation of the current system. During the transition period, we also intend to monitor development of alternatives such as biodiesel production and use as fuel.

Mammalian blood

52. Part IV allows for mammalian blood to be processed by one of methods 2-5 or 7 during the transition period, which ends on 31 December 2004. At the end of that period, it will need to be processed by method 1 (the pressure cooking standard) if it is to be used as fertiliser but could

continue to be processed by one of methods 2-5 or 7 if it goes to landfill or incineration. The aim of the transition period is to allow the necessary pressure cooking equipment to be installed.

Oleochemical plants

53. Part V allows for oleochemical plants to continue to process tallow derived from both Category 2 and Category 3 material in the same equipment providing there are adequate measures in place to ensure separation of the two streams of tallow. The transitional period applies until 31 October 2005 and is intended to allow time for physical separation of the processing equipment.

Low capacity incinerators

54. Part VI allows low capacity incinerators to continue to operate without complying with the full controls imposed by the EU Regulation, until 31 December 2004. During the transition period, operators are required to comply with certain minimum requirements to ensure that animal by-products are handled safely; animal by-products are incinerated so that they are completely reduced to ash; and the ash is stored securely and disposed of safely.

Schedule 4 – amendments and revocations

55. Schedule 5 makes a number of consequential amendments to the TSE (Scotland) Regulations 2002 to remove those provisions which are now dealt with by the EU Regulation. We have included two new amendments to the TSE (Scotland) Regulations 2002 -

(a) the first amends the definition of mammalian meat and bone meal (MMBM) in relation to the fertiliser controls in regulation 13 of the TSE Regulations. This now permits the application to land of compost and biogas residues derived from animal by-products (but not the application of MMBM or of compost or digestion residues derived from MMBM).

(b) the second removes the prohibitions in regulations 33(4) and 34(2) on allowing Specified Risk Material to come into contact with other animal by-products, but requires that animal by-products that do come into contact with SRM are all treated as SRM. This will permit the mixing of SRM and other animal by-products.