

EXECUTIVE NOTE

THE ANIMAL BY-PRODUCTS (ENFORCEMENT) (SCOTLAND) REGULATIONS 2011

SSI 2011/171

The Animal By-Products (Enforcement) (Scotland) Regulations 2011 (the new Regulations) are made by Scottish Ministers in exercise of powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972. These Regulations make provisions for laying down health rules for animal by-products not intended for human consumption.

Policy Objectives

The purpose of this instrument is to revoke and replace the Animal by-Products (Scotland) Regulations 2003 as amended.

The new Regulations will provide powers to enforce the requirements of EU Regulation 1069/2009 (EUCR) the Control Regulation and EU Regulation 142/2011 (EUIR) its corresponding Implementing Regulation. It will also make provision for derogations and areas of national discretion available under such legislation. The EUCR and EUIR will jointly revoke and replace the current EU Regulation 1774/2002 (“ABPR 1774/2002”).

Policy Background

The introduction of EUCR and EUIR to revoke and replace ABPR 1774/2002 is in 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 (ABPs).

An initial report submitted by the Commission to the European Parliament and the Council of the European Union in 2005 stated that although the legislation was working well and generally met its overall objectives, there were areas where changes needed to be considered in order to update the legislation and to provide legal certainty, simplify it and thus reduce the burden on business. Consequently, the Commission consulted extensively, including all Member States, with a view to recasting ABPR 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.

EUCR continues to have a 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 hooves. 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 ABPs, for example, as feed (including pet food), 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 of EUCR it now also:

- Gives greater clarity on the scope of the Regulation, more clearly defining when products are no longer considered ABPs and therefore exempt from the controls of the Regulation;
- Improves the categorisation of ABPs 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

Amendments which amount to new policy

Schedule 1 of the new Regulations sets out the ABP requirements. The scope of these requirements may be affected by Competent Authority Authorisations. The Competent Authority Authorisations will be separate documents setting out the requirements for the uses of ABPs.

Schedule 1 also contains provisions for further derogations made by the Member State under the EUCR and EUIR.

Annex A provides more information on the new provisions/derogations set out in Schedule 1 of the new Regulations.

Consultation

An eight week public consultation was undertaken on the Scottish Government's proposal to update and replace the Animal By-Products (Scotland) Regulations 2003 in August 2010 and a total of 26 responses were received.

In line with the Commission's EU review in 2005, the Scottish Government consulted with interested parties in writing twice in 2006, as part of its response to the Commission's 2007 on-line questionnaire and again on the Commission's proposed changes to ABPR 1774/2002 from December 2008 to February 2009. The Scottish Government has also held various ad hoc meetings with key representatives at various intervals from 2005 to date.

Financial Effects

A Business Regulatory Impact assessment has been prepared and placed in the Scottish Parliament Information Centre.

Animal Health & Welfare Division
Enterprise and Environment Directorate
The Scottish Government

February 2011

Table of new provisions/derogation the Animal By-Products (Enforcement) (Scotland) Regulations 2011

New Provision/ Derogation	Current Position	New derogation/ provision	Use of derogation/ provision
<p>1. New Provision/ Derogation</p> <p>Articles 16 (b) and 17: Use of ABPs for exhibitions, artistic activities, and for diagnostic, educational or research purposes</p>	<p>The derogation from the current regulation allows MSs to set conditions for disposal of these ABPs to control the risks to public and animal health.</p> <p>At present we set minimal conditions on use and disposal, except where high risk material is used.</p>	<p>The derogation from the new regulation allows MSs to set conditions for use and disposal of these ABPs to control the risks to public and animal health.</p> <p>New provision: There is a new requirement for premises using these materials to register and some conditions laid down which operators must follow when the derogation is implemented.</p>	<p>Scottish Government intend to take advantage of this derogation in full.</p> <p>Will continue to set conditions on use and disposal, consistent with the minimum required by the regulation</p>
<p>2. Derogation</p> <p>Articles 16 (c) and 18 (1): Use of certain ABPs for feeding to animals</p>	<p>The derogation from the current regulation allows MSs to set conditions to control public and animal health risks for the collection and use of</p> <p>Category 2 material from animals which were not killed or did not die from actual or suspected disease communicable to humans or animals, and of Category 3 material for feeding to the following animals:</p> <p>(a) Zoo animals (b) Circus animals (c) Reptiles/birds of prey other than zoo or circus animals (d) Dogs from recognised kennels or packs of hounds (e) Maggots for fishing bait (f) wild animals</p>	<p>The derogation from the new regulation allows MSs to set conditions to control public and animal health risks for the collection and use of these materials for the following additional categories of animals:</p> <p>1) Fur animals (not applicable in UK in any case); 2) Cats and dogs in shelters (applicable); 3) Worms for fishing bait (applicable).</p>	<p>Scottish Government intend to take advantage of this derogation in part.</p> <p>Will restrict feeding low risk Category 3 material to garden birds only e.g. allowing the public to put out fat ball in their garden.</p> <p>Will also use the derogation to allow feeding to cats & dogs in shelters, (although we are not aware of any demand for this), and to allow feeding to worms used for fishing bait, which will regularise the current position.</p> <p>NB: Government will not use the derogation which refers to fur animals, as animals are not permitted to be farmed for fur in the UK.</p>
<p>3. Derogation</p> <p>Articles 16 (c) and 18 (2): Feeding of Category 1 material to zoo animals & necrophagous birds</p>	<p>The current Regulation does not allow Cat 1 material to be fed to zoo animals.</p> <p>There are no programmes approved in the UK for feeding Cat 1 material to necrophagous bird species- so does not</p>	<p>The derogation from the new Regulation allows MSs to authorise the feeding to zoo animals of Category 1 material under Article 8(b) (ii) (i.e. entire bodies/parts of dead animals containing SRM at time of disposal), and of material derived from zoo animals.</p>	<p>Scottish Government intend to take advantage of this derogation in full.</p> <p>This would allow zoos etc to “re-cycle” their own fallen stock that fall under Category 1 (e.g. entire deceased antelopes,</p>

<p>4. Derogation Articles 16(d) and 19(1)(a): Burial of pet animals</p>	<p>apply</p> <p>The derogation from the current Regulation allows the burial of pet animals. The UK currently applies this derogation, and includes ‘pet horses’ under the description of ‘pet animals’.</p> <p>Other equidae are not currently included in derogation.</p>	<p>The derogation from the new Regulation allows MSs to authorise the disposal by burial of dead pet animals and all equidae.</p>	<p>zebras) to their carnivorous animals (e.g. big cats) in addition to the Cat 2 material that is already permitted. Additional controls would be attached to feeding animals containing SRM.</p> <p>Scottish Government intend to take advantage of this derogation in part.</p> <p>Scottish Government will allow the burial of all pet equidae only.</p> <p>Extending the derogation to all equidae would be more difficult to control and enforce and we are not aware that widening the scope would have any significant benefit.</p> <p>Waste controls will still apply.</p>
<p>5. Derogation Articles 16(d) and 19(1)(b): Disposal in remote areas by burning/burial on site or by other means under official supervision of Category 1 material under Article 8(a)(v) (i.e. wild animals) and 8(b)(ii) (i.e. entire bodies or parts of dead animals containing SRM at time of disposal), and Category 2 + 3 material.</p>	<p>The derogation from the current Regulation is the same as the one presented in the new Regulation- but the present derogation does not allow MSs to authorise disposal of diseased wild animals in remote areas, instead requiring their disposal by rendering or incineration.</p>	<p>The derogation from the new Regulation now includes Cat 1 wild animals, when suspected of being infected with diseases communicable to humans or animals.</p> <p>It also allows for burial.</p>	<p>Scottish Government intend to take advantage of this derogation in full.</p> <p>We consider that burial is the most expedient and practical method of disposal in remote areas.</p>
<p>6. Derogation Articles 16 (d) and 19 (1) (c): Disposal of fallen Stock carcasses in areas where <u>access is practically impossible or where access would only be possible under</u></p>	<p>The current Regulation says that fallen stock must be collected and disposed of in line with ABPR, except in a very few specific circumstances.</p>	<p>The new derogation from the Regulation says that MSs may now authorise the disposal by burning/burial on site or by other means under official supervision of Category 1 material under Article 8(b)(ii), (i.e. entire bodies/parts of dead animals containing SRM at time of disposal), Category 2 and Category 3</p>	<p>Scottish Government intend to take advantage of this derogation in full, where the farmer is able to demonstrate that the appropriate criteria are met. Will provide guidance on the conditions to apply to ensure the derogation is not subject to abuse.</p>

<p>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 disproportionately onerous means of collection.</p>		<p>material in areas where access is <u>practically impossible</u> or where access would <u>only be possible under circumstances</u>, 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 disproportionately onerous means of collection.</p>	
<p>7. Derogation Articles 16(d) and 19(1)(d): Small Quantities of ABPs</p>	<p>The current Regulation says that all ABPs must be disposed of in line with the Regulation.</p>	<p>The derogation from the new Regulation says that MSs may authorise the disposal of 20kg (or potentially 50kg) per week of raw meat and fish arising from retailers outside of the control of the ABPR (50kg only permissible where MS have provided detailed justification to the Commission).</p>	<p>Scottish Government intend to take advantage of this derogation in full using the 20kg limit, as the terms which the Commission has set out for the detailed justification required to apply the 50kg limit cannot be met in the UK</p> <p>In any case bodies representing retailers have said that the 20kg limit will accommodate the requirements of most small retail outlets.</p>
<p>8. Derogation Article 16 (f): Use of ABPs in Bio-Dynamic preparations</p>	<p>The current Regulation does not authorise the use of bio-dynamic preparations.</p>	<p>The derogation from the new Regulation says that MSs may allow Cat 2 and 3 materials to be used for the preparation and application to land of bio-dynamic preparations as per Article 12(1) (c) of Regulation 834/2007.</p> <p>MS have discretion to set conditions.</p>	<p>Scottish Government intend to take advantage of this derogation in full in order to meet specialist demand in this area.</p>
<p>9. Derogation Article 16 (g): Use of ABPs for Pet Food</p>	<p>Under the current Regulation only “petfood”, (processed or raw) which has been prepared in accordance with the requirements of the regulation may be fed to pet animals.</p>	<p>The derogation from the new Regulation allows MSs to set out conditions which permit Category 3 material to be used for feeding to pets (instead of the regulation’s requirements which apply to manufacturers of raw and processed petfood products).</p> <p>MS have discretion to set conditions.</p>	<p>Scottish Government do not intend to take advantage of this derogation.</p>

<p>10. Derogation</p> <p>Article 16 (h): Disposal of ABPs on farm</p>	<p>The current Regulation does not permit the disposal of ABPs arising from surgical intervention or birth of animals on farm, they must be disposed of in line with the Regulation (rendering/ incineration).</p>	<p>The derogation from the new Regulation allows MSs to authorise ABPs (except Category 1 material) arising from surgical intervention on live animals or during birth of animals on farm to be disposed of on that farm.</p> <p>MS have discretion to set conditions.</p>	<p>Scottish Government intend to take advantage of this derogation in part.</p> <p>We propose to allow material to be disposed of on farm, with the exception of foetuses or placenta, where there may be a risk of spreading disease to humans or animals (e.g. aborted calf foetuses/placenta where there may be a risk of diseases such as brucellosis).</p>
<p>11. New Provision</p> <p>Article 13 (e) (ii): ABPs used for Composting & biogas</p>	<p>The current Regulation permits the composting or anaerobic digestion (biogas) of Category 3 ABPs. A limited number of Category 2 materials such as manure and milk can also be composted or anaerobically digested, provided they are not considered a disease risk.</p>	<p>The new Regulation maintains this regime and expands it slightly to include milk products, and Category 2 egg and egg products.</p>	<p>Scottish Government intend to take advantage of this new provision in full.</p> <p>The new provision allows a wider range of material to be used without a significantly increased disease risk. It also removes a previous anomaly where Category 2 milk could be composted but not products derived from the milk.</p>
<p>12. Relaxation of current domestic controls</p> <p>National provisions on composting of catering waste on the premises on which it originates.</p> <p>Affected sectors: Composting/ anaerobic digestion community (including domestic householders), specifically small community composting or</p>	<p>The current Regulation says that catering waste intended for composting or anaerobic digestion must be sent to an AH approved plant.</p> <p>There is a current exception for 'home composting' which permits the composting of catering waste on the premises of origin without the need for an approval from AH, provided that the resultant compost is used only on those premises.</p>	<p>The Government intend to broaden the home composting exception to allow for composting and anaerobic digestion on the premises of origin or elsewhere, without approval from AH, provided that livestock cannot gain access to this material.</p>	<p>Scottish Government intend to relax the current national controls to allow for off-site disposal of 'home composting'</p>

anaerobic digestion projects.			
<p>13. New Provision</p> <p>Article 13 (f): Application of ABPs to land</p>	<p>The current Regulation allows Category 2 digestive tract content separated from digestive tract, milk and colostrum to be applied to land without processing, if the MS considers this does not present a risk of spreading serious transmissible disease.</p>	<p>The new Regulation maintains this regime, also now enables Category 2 milk-based products to be spread to land unprocessed, and also certain lower risk Category 3 materials.</p>	<p>Scottish Government intend to take advantage of this new provision in full.</p> <p>With milk and milk products there may be a potential risk of disease spread when they are applied to land in the case of a notifiable disease outbreak. A requirement to allow restrictions relating to animal and public health to be imposed if necessary would be included in any new provision to mitigate the increased disease risk.</p>
<p>14. New provision</p> <p>Article 14 (h): Use of shellfish shells</p> <p>Affected sectors: Shellfish sector</p>	<p>The current Regulation requires all shellfish shells to undergo at least “Method 7” processing (i.e. rendering) before use.</p>	<p>1) The new Regulation enables MSs to determine conditions for disposal of shells from shellfish in which soft tissue remains.</p> <p>2) Article 2.2(d) in any case removes from scope shells where no soft tissue remains.</p>	<p>Scottish Government intend to take advantage of this new provision subject to the following conditions:</p> <p>1) Any shells with flesh present would need to be processed (subject to rendering/heat treatment) in accordance with the Regulation to ensure there is no public and animal health risk.</p> <p>2) operators will be required to demonstrate that the shells are “free of flesh” (using criteria to be laid down), in which case controls on their use would be removed from the scope of the regulation. .</p>
<p>15. New provision</p> <p>Article 14 (h): Egg shells to land</p>	<p>The current Regulation requires eggshells to undergo at least “Method 7” processing (i.e. rendering) before use.</p>	<p>The new Regulation allows Category 3 egg shells to be used under conditions determined by the MS which prevent risks arising to public and animal health.</p>	<p>Scottish Government intends to take advantage of this new provision, to put in place less burdensome control measures which operators may use as an alternative to processing but which will still protect animal and public health.</p>
<p>16. New Provision</p> <p>Article 32: Use of organic</p>	<p>The current Regulation permits the application to land of organic fertilisers and soil improvers (OF/SI) derived from</p>	<p>The new Regulation allows MSs to adopt national rules imposing conditions or restrictions on the use of organic fertilisers</p>	<p>Scottish Government do not intend to impose additional national restrictions (which it does at present in</p>

<p>fertilisers</p>	<p>processing Cat '2 or Cat '3 material in an approved processing (rendering) plant. Cat' 1 material cannot be used for the production of OF/SI. Cat' 2 material can only be used where it is pressure-rendered in accordance with the Regulation. Cat 3 materials may use any of the processing standards set out in the Regulation.</p>	<p>and soil improvers if they are justified to protect public or animal health.</p> <p>The Implementing Regulation set down conditions that must be complied with.</p>	<p>relation to certain material)</p> <p>However, would propose to keep a grazing restriction of two months in the case of pigs, and 21 days for other livestock after application of OF/SI to land (the regulation permits MSs to set a minimum period of 21 days).</p>
<p>17. New Requirements Article 41 Imports of ABPs from third countries into the EU</p>	<p>The current Regulation sets down detailed rules for the importation of ABPs from third countries and the documentation which needs to accompany the consignments (usually in the form of health certificates).</p>	<p>The new Regulations requirements update and consolidate the existing import rules.</p> <p>Notable changes are:</p> <ol style="list-style-type: none"> 1) Scope has been increased (and correspondingly the model declaration) for use of intermediate products (ABPs which have undergone a degree of processing but are not finished). For example, the definition now includes medicinal products, veterinary medicinal products and active implantable medical devices; some Cat 1 & Cat 2 materials are now specifically included; and blood from live animals (including from livestock species) is now listed for use as an intermediate product. 2) Import authorisation requirements for specific ABPs (such as aquatic and terrestrial invertebrates, rodentia and lagomorpha) are now less prescriptive. 3) Research and diagnostic samples imported via another Member State need to be presented to a BIP on entry to the EU, but not vet checked, and the Member State of destination notified via TRACES. Most research and diagnostic samples are imported directly into the UK, so likely to have little impact, 	<p>Scottish Government intends to fully implement the changes in the new Regulation, which tend to simplify and consolidate the requirements for both importers and for the Competent Authority.</p>

		<p>4) Trade samples and display items need to be imported via a BIP for vet checks. Trade samples also need to be channelled to their final destination. It is estimated that in 2010 only 18 trade samples and 8 display items were imported, leading to a small additional cost to industry.</p>	
<p>18. Implementing Regulation (EC No. 142/2011) Annex XIV section II, Chapter IV, Part II: Colostrum for feeding</p>	<p>The current Regulation does not permit the supply of colostrums directly from one farm to another farm within the same MS for feeding purposes.</p>	<p>The new Implementing Regulation provides by way of derogation from controls on colostrum for the competent authority to authorise the supply of colostrum from one farm to another farm within the same MS for feeding purposes under conditions which prevent the transmission of health risks.</p>	<p>Scottish Government intends to apply this derogation under conditions which prevent the potential spread of animal diseases</p>
<p>19. Implementing Regulation (EC No. 142/2011) Annex XVII, Chapter VII: Unprocessed wool</p>	<p>The current Regulation does not permit unprocessed wool to be placed on the market.</p>	<p>The new Implementing Regulation provides for the competent authority to authorise the placing on the market of unprocessed wool under conditions which prevent the transmission of health risks.</p>	<p>Scottish Government intends to apply this derogation without restrictions, provided the operator registers with Animal Health to enable tracing of the wool in case. restrictions needed to be put in place in the case of a notifiable disease outbreak.</p> <p>Otherwise, no controls are proposed as the risks, are minimal.</p>

Title of proposal

The Animal By-Products (Enforcement) (Scotland) Regulations 2011

Purpose and intended effect

- **Objectives**

The purpose of this proposed legislation is to enforce the directly applicable requirements of the EU Animal By-Products (ABP) Regulation (as supplemented by the ABP EU Implementing Regulation). In addition the EU legislation also gives the Member State discretion to put in place national controls and for competent authorities to authorise derogations in certain circumstances and powers to do this are provided for in the SSI. Similar domestic legislation will be put in place in the rest of the UK.

- **Background**

The current EU ABP Regulation (EC/1774/2002) controls the use and disposal of animal by-products (i.e. entire bodies, parts of animals, and products of animal origin not intended for human consumption). The regulation has 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 blood, hides, feathers, some shells, wool, bones, horns and hoofs. In addition, it covers carcasses of fallen stock on farms, pet animals and wild animals where they are suspected of being diseased. It also controls the use of ABPs for feed (including pet food), fertiliser and for technical products and lays down the rules for their transformation through composting and biogas and their disposal via rendering and incineration. It also prevents catering waste being fed to livestock.

The Animal By-Products (Scotland) Regulations 2003 (SSI 2003/411) as amended provide for enforcement of the EU Regulation in Scotland. Similar legislation applies to the rest of the UK.

- **Rationale for Government intervention**

The current EU ABP Regulation was introduced in 2002 in response to a number of crises affecting the safety of public and animal health due to products of animal origin linked in particular to Transmissible Spongiform Encephalopathies, dioxin contamination and outbreaks of Classical Swine Fever and Foot and Mouth Disease. The Regulation consolidated, simplified and replaced 19 previous legal acts. It also introduced stricter rules for the approval of certain premises, the channelling and traceability of ABPs and controls based on risk categories for different types of ABPs in order to guarantee the safety and final products intended for feed or technical uses.

This ties in with the wealthier and fairer strategic objectives of the National Performance Framework. The Regulation should restrict crises of TSE outbreaks and exotic diseases, and increase the productivity and profitability of businesses by

reducing costs associated with disease such as increased mortality and reduced fertility. This would have positive environmental benefits for Scotland due to reduced greenhouse gas emissions and increased animal welfare.

Consultation

- **Within Government**

Discussions have taken place within Government regarding feedback of Consultation responses and propose to impose the minimum burden on industry consistent with meeting its obligations to enforce the EU ABP Regulation.

In the Scottish Government, talks have taken place with technical staff on how best to implement the Regulations on the back of feedback from the Consultation. Marine Scotland also replied to the Consultation with their views. Most of the discussion took place between UK Government via the ABP Project Board. These are regular meetings between UK Government, Enforcement Agencies and monitoring agencies

- **Public Consultation**

A consultation was issued regarding The Animal By Products (Enforcement) (Scotland) Regulations 2011 in August 2010. The consultation consisted of a questionnaire seeking views on the Scottish Governments proposal to update and replace the Animal By-Products (Scotland) regulations 2003 in order to implement the new controls on animal by-products introduced by EU Regulation 1069/2009 and its corresponding Implementing Regulation.

The consultation attracted 26 responses from a variety of groups including Councils, SEPA, Scottish Water, Schools, Marine Scotland, RSPB and the British Horse Society. The findings from the consultation were discussed under 21 questions covering controls, conditions and proposals to restrict, expand, or maintain derogations. Most of the proposals were agreed with, or agreed with under a number of conditions. There were some points of disagreements also. A number of respondents also added general comments based on the consultation document.

One respondent commented on several points of the consultation document, stating that recategorisation seemed sensible and is to be supported as a way of increasing reuse and recovery options. They also commented on wild game and suggested that where game is brought into handling premises the Animal By-product should be treated the same as that of slaughtered farm animals. Animal By-product from wild game remaining in the wild should be disposed of in accordance of good hunting practice.

Another respondent welcomed greater clarity on the scope of the Regulations, and improvement on the categorisation of ABPs in line with the risk they pose. They support the removal of duplication for certain premises and to provide further derogations for Member States to use.

A respondent would like to see detailed written guidance on the requirements made by Animal Health in relation to the initial set up/construction of ABP facilities.

A link to the full Consultation can be found at the end of this document under the References section.

- **Business Consultation**

ABP sector, Landowners/farming community, food producers: In general the spectrum of industries handling ABPs have been positive about the changes to ABP rules, which in many cases open up new opportunities to convert animal waste products which currently go for disposal into useful by-products such as compost or energy sources.

The newly revised ABP legislation also includes some useful deregulatory provisions which benefit farmers and landowners as well as other sectors handling ABPs (e.g. retailers) particularly in relation to some of the potential derogations (not directly set out in the SSI, but to be addressed in subsequent authorisations for which the SSI provides powers)- e.g. in relation to relaxing controls on use of colostrum, unprocessed wool and the application of certain by-products on the land such as shellfish shells and egg shells, and the potential to dispose of ABPs arising from surgical intervention or birth of animals on farm. Responses from the farming community have in general been positive.

Areas given special consideration: In most cases the impact of the changes brought about by the new regulations are expected to be small. However, there are some areas where we have had to consider whether we might want to limit the way in which we apply the potential derogations, or approach areas of national discretion; either because of the animal and public health risks, because the sectors affected do not necessarily want the derogations, or because it may cause more work for enforcement bodies and the cost to these will be disproportionate to the benefit.

With regard to allowing **feeding of a wider range of material to pets**, there were conflicting views raised. The pet food industry voiced strong arguments (principally on hygiene and food safety) and also had concerns around the potential impact of this on their businesses. Balanced against this, pet owners would potentially have a cost benefit from being able to obtain cheaper material to feed to their pets. To quantify the risks on this issue, a veterinary risk assessment was conducted. Following consideration of this, Government have decided that such feeding should not be permitted. The potential increased risks to human and animal health from being unable to guarantee the microbiological safety of the material to be fed, far outweigh any potential benefits.

On the derogation relating to **feeding certain ABPs to wild animals**, it was agreed that this should be restricted to feeding low risk category 3 material to garden birds only. E.g To provide a legal basis to allow the public to put fat balls in their garden. Similarly, when considering the **disposal on site of material arising from on farm birth or surgical intervention** on live animals, a veterinary risk assessment showed

unacceptable risks of disease from allowing disposal of fetuses and placenta on site. However, provided the material surgically removed came from otherwise healthy animals (e.g. material resulting from castrations or amputations, etc) and was disposed of in accordance with guidance on safe disposal and in compliance with environmental controls, veterinary views were that permitting the latter to be disposed of on-farm by burial or incineration would not increase the associated health risks. This was also the view taken on feeding of raw colostrum obtained from animals on one farm to animals on another farm- that it was acceptable providing that there were appropriate controls in relation to TB related risks, with safeguard powers to prevent such feeding in case of suspicion and/or confirmation of an outbreak of a notifiable disease e.g. FMD, brucellosis or enzootic bovine leukosis, and that farmers should be aware of other potential disease risks associated with supply of raw colostrum for animal feeding, such as Johne's disease, classical scrapie, Bovine Viral Diarrhoea and zoonotic organisms, e.g. Salmonella, E.coli, Campylobacter, etc.

On the issue of **home composting**, this previously was permitted only on the premises of origin. This covered domestic garden composting and other premises such as schools, hospitals, prisons etc. However, because it did not permit off-site disposal, it particularly restricted small-scale community composting or anaerobic digestion projects, which were then required to apply to Animal Health to be a fully approved premises. Permitting the exception to allow for off-site disposal in certain situations where livestock cannot gain access will be of significant benefit to such small scale and neighbourhood composting and anaerobic digestion projects, who may be able to run their schemes without requiring full approval from Animal Health.

The issue with the biggest potential impact is the new derogation permitting **small quantities** (20kg p/w, or 50kg where the Member State can provide detailed justification) of ABPs to be disposed of outside the Regulation. As anticipated the final EU implementing rules restrict this derogation to those generating small quantities of food waste containing ABPs, i.e. low risk category 3 material, to be disposed of with other general waste. Our consultations have showed that in principle this derogation would be of considerable short term financial benefit to small retailers and food manufacturers (>£30 million p/a). Our view is that although the derogation would potentially increase by a small amount the quantity of food waste going to landfill, this would not be significant (with the impact on greenhouse gas omissions also being minimal) and in any case would only be in the short term, as most retail outlets are moving away from use of landfill given the economic drivers in place to progressively use more sustainable alternative routes such as AD and composting. We have consulted with industry, who have said they are content with the 20kg threshold and have not sought to make a case for particular circumstances where a 50kg threshold would be appropriate. Therefore Government intend to implement this derogation, using the 20kg limit.

Options

During its review the Commission considered various options for updating the EU ABP legislation, such as retaining the current rules unchanged, or adopting non-regulatory tools, but concluded that regulatory change was most likely to provide effective

solutions. The Government agrees with this analysis. In order to minimise the impact on business, when putting in place replacement domestic legislation the Government proposes to impose the minimum burden on industry consistent with meeting its obligations to enforce the EU ABP Regulation. The Government's view is that it should take advantage in full of the majority of the potential derogations available to member states, seeking to leave in place controls only in the minority of cases where there are public and animal health issues which override potential economic benefits.

Two options were identified:

Option 1: No change

The first option is not to update legislation, but this would also mean that there would be no enforcement and infraction proceedings at European Level. By meeting the Government's legal obligation to enforce the EU ABP Regulations, option 1 would not be viable.

Option 2: Introduce the new Regulation to set updated rules on ABPs providing legal certainty, simplified requirements, and reductions in the burdens on operators. This is a legal responsibility of the Scottish Government and so is the only viable option.

The effect will be to make ABP controls more effective and efficient, while ensuring continued protection of public and animal health food and safety.

This BRIA summarises the overall requirements of the new Animal By-Product rules. The Assessment has been divided into two areas- section 1 looks at the impact of the EU Regulation (which when it was originally proposed was originally the subject of a partial Impact Assessment which this updates) and section 2 at the domestic SSI and discretionary national measures, and derogations that the competent authority may authorise.

Sectors And Groups Affected

There is likely to be some impact for example in the areas of small firms, the environment and the rural economy but these are similarly difficult to quantify, are likely to be minimal, and it would take disproportionate effort to assess them. Therefore no detailed analyses have been possible on these in the limited time available, instead judgements based on consultation responses and sectoral knowledge have determined our position

The legislation places different requirements on the ABP sector, Landowners/farming community and food producers. In general the spectrum of industries have been positive about the changes to ABP rules, which in many cases open up new opportunities to convert animal waste products which currently go for disposal into useful by-products such as compost or energy sources.

The newly revised ABP legislation also includes some useful deregulatory provisions which benefit farmers and landowners as well as other sectors handling ABPs (e.g retailers) particularly in relation to some of the potential derogations (not directly set out in the SSI, but to be addressed in subsequent authorisations for which the SSI

provides powers)- e.g. in relation to relaxing controls on use of colostrum, unprocessed wool and the application of certain by-products on the land such as shellfish shells and egg shells, and the potential to dispose of ABPs arising from surgical intervention or birth of animals on farm. Responses from the farming community have in general been positive.

Section I: EU ABP Regulation- update on options & issues identified in earlier partial impact assessment and outcome in EU ABP Regulation 1069/2009

The earlier version of this partial impact assessment looked at the impact of the European Commission's initial proposal for a revised EU ABP regulation and highlighted five main areas identified by the Commission for change, and detailed the Government's initial views on the Commission's proposed approach to these changes.

The five areas were:

- 1a) clarifying the scope of the regulation in relation to end of the ABP life cycle;
- 1b) application of the regulation to wild game;
- 1c) updating risk categorisation of some ABPs;
- 1d) duplication of approvals for certain premises; and
- 1e) derogations for research, and collection of ABPs with regard to human health & safety and natural disasters.

In addition, four areas of particular importance to the UK were also analysed further:

- 2a) the burning of tallow,
- 2b) the disposal of fallen stock,
- 2c) the disposal of fish material at sea, and
- 2d) the disposal of former foodstuffs.

An update on these areas is set out below:

1a) Clarifying the scope of the regulation – end of the ABP life cycle: The rules in the current EU ABP regulation 1774/2002 were not clear in some places about when material which had been processed into a product ceases to be a controlled ABP (for example finished petfood). This legal uncertainty resulted in inconsistent enforcement, distortion of competition, and in some cases application of disproportionate rules when there was a negligible risk to health.

Preferred Option: The Government supported the introduction of an end point in the life cycle of ABPs which will determine when the Regulation no longer applies.

Benefits and Costs: Potentially there are several sectors impacted, including pharmaceuticals, oleochemicals, wool industry, pet food manufacturers and tanneries. Benefits will include legal clarity which will potentially remove some direct burdens on industry.

No new costs have been identified from this change.

1b) Wild Game: The current ABP Regulation does not cover ABPs derived from wild game processed in Approved Game Handling Establishments (AGHEs). The absence of ABP controls posed a potential risk to public and animal health. Preferred Option: The Government agreed that these ABPs should be covered by the ABP Regulation to ensure consistency with Community Food Hygiene Legislation.

Benefits and Costs: AGHEs affected . There are fewer than 100 AGHEs in the UK. Their total annual throughput is about 80,000 large animals (mainly deer and boar) and about 3 million birds and rabbits. This provision will be a new cost to AGHEs, who will now have to dispose of ABPs in accordance with the Regulations. However, this will be offset by the new benefit that this new material can now be sold e.g for pet food.

The overall impact from this is small cost and benefit – no overall change.

1c) Re-categorisation of ABPs in proportion to risk: This includes blood from young ruminants which have passed a TSE test, day old chicks, invertebrates and casein. These materials can now be used for various purposes such as livestock feed, pet food/fish food, and cosmetics.

Preferred option: The Government agreed that the reclassification of certain low risk ABPs from category 2 to category 3 (where category 1 is very high risk, category 2 is high risk and category 3 is low risk) would usefully increase the scope for their usage.

Benefits and Costs: impact of this is that producers and users of invertebrates for feed will be affected. Small benefit of wider economic uses of these by-products without significant increase in risks. No costs identified. Overall impact is small benefit.

1d) Duplication of approvals for some types of premises: The relationship between the current ABP Regulation and other Community sector legislation is not always clear and in some cases overlapping. As a consequence, there have been legal uncertainties in the application of requirements of similar objectives.

Preferred option: The Government supported changes to the new Regulation which removed the need for dual approvals and reduced administrative burdens. However the Regulation also now requires all plants handling ABPs to be registered under the ABP Regulation – eg some operators will need to be registered instead of approved which will be a benefit. However, some operators who are currently not approved or registered will now need to be registered, eg transporters of ABPs, imposing a small additional cost.

Benefits and Costs: Premises handling ABPs and ABP transporters will be affected. There will be in some cases a small benefit for premises currently 'approved' to handle ABPs who will now only need to be registered. In other cases there will be a small new cost to currently unregistered premises that handle or transport ABPs, and to Animal Health who will register these premises.

Overall impact is broadly neutral.

1e) Derogations for research, collection of ABPs with regard to human health and safety and natural disaster:

The latest position on these derogations and their proposed application in domestic legislation are described in more detail in Annex A.

2a) Interaction of the ABP Regulation and the Waste Incineration Directive (WID) with regard to the burning of tallow:

The current ABP regulation requires incineration of tallow to be carried out in compliance with WID. The rules do not provide clear guidance to regulators on the circumstances where tallow and other ABPs/derived products should be either regarded as being used as fuel for combustion (where WID would not apply), or disposed of as waste either by incineration or with energy recovery in a co-incineration process (where WID would still apply).

Preferred Option: The Government supported the automatic reference to WID compliance being removed from the new Regulation and provision made for ABPs (including tallow) to be used as a fuel for combustion. However, the Government considers the wording in the new Regulation as insufficient for providing legal certainty about the circumstances when burning of tallow and other ABPs would be regarded as a use for fuel, therefore there will no longer be a need for compliance with the WID. The Government is pressing the Commission to come forward with proposals which would provide detailed rules for combustion of ABPs as fuel, and guidance providing further clarification on when burning of tallow and other ABPs would be regarded as a waste disposal operation and subject to WID.

Benefits and Costs: Rendering industry and other potential operators wishing to use ABPs as fuel will be affected. There is a benefit of using tallow for fuel. However few rendering plants have implemented WID, so any benefit will be from not having to comply in the future. NB: Changes to the ABPR alone will not remove the need for compliance – parallel changes will also be needed in waste legislation. No costs identified and the overall impact is of small benefit.

2b) Disposal of fallen stock including horses:

The current regulation does not permit the use of bio reducers (vessels for storing animal carcasses pending disposal) as a means of collection and temporary storage of fallen stock. The Government wishes to encourage research into this area with the aim of getting these approved for use and so giving farmers further choice when disposing of their fallen stock.

Preferred option: The Government supported changes to the Regulation which included provisions which would make it more straightforward to approve the use of bio-reducers for on farm storage of fallen stock pending collection.

Benefits and Costs: Livestock farmers, local enforcement authorities, fallen stock collection and disposal sector will be affected. Potential benefit to some farmers who may be able to use bio-reducers in future to reduce their costs of fallen stock disposal.

Overall impact is of a potential small benefit.

2c) Disposal of diseased sea fish:

The current position is that material from the on-board evisceration of fish showing signs of disease, including parasites, communicable to humans can be disposed of at sea. At first the Commission's intention was that sea fish showing such signs of disease should be brought ashore for disposal.

Preferred option: The Government did not support this position, as the cost implications for the fishing industry would have been significant and the requirements difficult to enforce with no benefit to health. The issue was shelved in regulation 1069/2009 pending further evidence of the effectiveness of such measures.

The issue is shelved and there will be no change.

2d) Disposal of Former Foodstuffs:

There is a current derogation that allows disposal of former foodstuffs to authorised landfill under controls set by the Member States.

Preferred Option: The Government agreed that should still be permitted under the new Regulation and a provision is available in regulation 1069/2009.

Benefits and Costs: The impact results in no change.

Section II: Domestic SSI and areas of national discretion- enforcing and implementing regulation 1069/2009 in Scotland

Regulation 1069/2009 is directly applicable in all Member States. However, it does provide for certain areas of national discretion and derogations (listed in Annex A). This section is about the impact of proposed domestic legislation enforcing Regulation 1069/2009, the national controls and derogations that can be authorised under the EU Legislation, and the Government's proposed approach to implementation and enforcement in areas where discretion is available.

The new Regulation and implementing rules give rise to a number of diverse impacts in various sectors associated with use and disposal of animal by-products. This diversity, lack of relevant data concerning the affected sectors and individuals and uncertainty about take up of derogations means that the impacts have been very difficult to quantify in any detail without recourse to extensive, time consuming and expensive public surveys. Broadly speaking the measures should enhance competition since they tend to be deregulatory in nature. They therefore allow a

wider range of routes for disposal and profitable use of animal by-products and the technologies for processing them. It is difficult to be precise about uptake in specific cases but the existence of a wider range of choice should stimulate fair competition.

In terms of the other specific impacts there is likely to be some impact for example in the areas of small firms, the environment and the rural economy but these are similarly difficult to quantify, are likely to be minimal, and it would take disproportionate effort to assess them. Therefore no detailed analyses have been possible on these in the limited time available, instead judgements based on consultation responses and sectoral knowledge have determined our position.

The Commission experienced similar problems in quantifying its own impact assessment when making the initial proposal to amend the EU regulation, as there is a lack of data on the volumes and price effects as the impacts tend to be on sectors where such data is not collected. In attempting to quantify the impacts of the new Regulation we have consulted industry on a number of occasions, through formal and informal consultation exercises, by direct approaches to relevant industry bodies, and via our website, where we have highlighted issues upcoming, and asked for feedback from those who would be affected. In considering the way forward, our default assumption has been that we should maximise the use of derogations and areas of national discretion in order to impose the minimum burden on operators and enforcement bodies.

A comprehensive table of cost/benefits for all these options can be found in Annex A which is attached separately.

The regulation is broadly deregulatory affecting a diverse range of industrial sectors and some members of the public. In some instances there are cost increases but many of these are expected to be quite small and overall they are more than offset by benefits. Attempts were made to monetise cost increases but this had proved to be not possible without disproportionate effort.

Scottish Firms Impact Test

Due to the positive nature of these regulations and the extensive consultations with a wide variety of industry stakeholders we decided it would be disproportionate to carry out further face-to-face discussions with business. Industry stakeholders contributed to, and helped with the development of these proposals and the views they expressed have been explained in the consultation section.

- **Competition Assessment**

There is likely to be a competitive advantage from the benefit of greater ABP control and with this being attained, increased market prices. In the long term this is expected to have a result of costs being cut, making the industry more efficient and competitive.

When identifying possible restrictions on competition resulting from these policy proposals it was found that they will not directly limit the number or range of suppliers and will not award exclusive rights to a supplier or create closed procurement or

licensing programmes. Neither will they indirectly limit the number or range of suppliers and raise costs to smaller entrants relative to larger existing suppliers. The proposal will not limit the ability of suppliers to compete as a competition advantage is expected, or reduce suppliers incentive to compete vigorously. After this competition filter was applied to the proposed legislation, it was found that a competition assessment was not needed.

- **Test run of business forms**

There will be no specific business forms involved with the implementation of the proposed legislation. The level of benefits actually achieved are dependant on take up by the affected sectors and the impact is difficult to quantify, is likely to be minimal and it would take disproportionate effort to assess them. No detailed analysis has been possible on business forms, instead judgements based on consultation responses and sectoral knowledge have determined the position.

- **Legal Aid Impact Test**

The Access to Justice policy team have confirmed that after consideration and consultation with the Scottish Legal Aid Board, there is unlikely to be any impact on the Legal Aid stemming from the policy changes planned.

Enforcement, sanctions and monitoring

Criminal offences are being created, although these are largely in line with criminal offences already in place under existing legislation (The Animal By-Products (Scotland) Regulations 2003 as amended).

Criminal sanctions along with powers to suspend or revoke approval for animal by products plants to operate where they are not complying with the regulation have provided a strong deterrent effect in this area. We therefore expect the same if not fewer cases to come before the courts if we maintain this strong deterrent. Seeking to apply criminal sanctions as the ABPR is in place to manage the risk to human and animal health posed by transmissible Spongiform Encephalopathies (TSEs) such as BSE and CJD and other serious animal diseases. Criminal sanctions have provided a strong deterrent in the past decade and criminal sanctions have been agreed to (and thus maintained) in the associated TSE Regulations 2010.

The Meat Hygiene Service enforces in slaughterhouses and cutting plants. Local Authorities enforce the current legislation at all other premises. Animal Health carries out official inspections on farms and premises and are responsible for monitoring the Regulations. Monitoring is case by case and is risk based and normally carried out during routine inspections. Local authorities are responsible for enforcement procedures. It is proposed that responsibility for enforcing the new legislation will remain as is

Finally, **on enforcement costs**, we are proposing to enforce by the same criminal sanctions as are currently in place under (EC) 1774/2002, i.e. 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. Under the current ABPR regime all sanctions are criminal; we therefore envisage zero new impact on resources and correctional services costs.

Implementation and delivery plan

This will be implemented by an SSI and this is due to come into force on 4th March 2011. However it may be delayed as the EU implementing measures have yet to be published in the Official Journal.

- **Post-implementation review**

The basis of the review will be policy driven in order to better quantify the costs and benefits of the Animal By-Products Regulation and its objective is intended to establish the impact of the new Regulation on business. The approach of this is a scan of stakeholder views, as this is a new area which has not been looked at before and this is deemed to be the most appropriate mechanism for gathering this data. The new Regulation results in a net cost saving to business compared with Regulation 1774/2002 with no increase in risks to animal and public health. Areas which could be improved will be highlighted for possible amendment. There will be an annual request for information from various industry bodies in form of questionnaire, results placed on website and data used to inform future policy decisions.

Summary and Recommendation

During its review the Commission considered various options for updating the EU ABP legislation, such as retaining the current rules unchanged, or adopting non-regulatory tools, but concluded that regulatory change was most likely to provide effective solutions. The Government agrees with this analysis. In order to minimise the impact on business, when putting in place replacement domestic legislation the Government proposes to impose the minimum burden on industry consistent with meeting its obligations to enforce the EU ABP Regulation. The Government's view is that it should take advantage in full of the majority of the potential derogations available to member states, seeking to leave in place controls only in the minority of cases where there are public & animal health issues which override potential economic benefits.

Declaration and Publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options. I am satisfied that business impact will be assessed with the support of businesses in Scotland.

Signed by the responsible Minister:.....

Date:.....

References:

N o.	Legislation or publication
1	ABP regulation 1069/2009: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:300:0001:0033:EN:PDF
2	ABP implementing rules (unpublished) http://defraweb/foodfarm/byproducts/documents/comreg-draft1011.pdf
3	Consultation on revised ABP regulation http://sh45inta/Publications/2010/08/19161058/0

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Issue and sectors affected	Current Position/ Baseline	New derogation/ provision	Use of derogation/ provision	Costs and Benefits relative to current position/baseline	Overall impact
<p>1. New Provision/ Derogation</p> <p>Articles 16 (b) and 17: Use of ABPs for exhibitions, artistic activities, and for diagnostic, educational or research purposes</p> <p>Affected sectors: Research institutes, educational establishments, artists, etc</p>	<p>The derogation from the current regulation allows MSs to set conditions for disposal of these ABPs to control the risks to public and animal health.</p> <p>At present we set minimal conditions on use and disposal, except where high risk material is used.</p>	<p>The derogation from the new regulation allows MSs to set conditions for use and disposal of these ABPs to control the risks to public and animal health.</p> <p>New provision: There is a new requirement for premises using these materials to register and some conditions laid down which operators must follow when the derogation is implemented.</p>	<p>Government intend to take advantage of this derogation in full.</p> <p>Will continue to set conditions on use and disposal, consistent with the minimum required by the regulation</p>	<p>The new mandatory requirement to register will be a new one off cost to business and government. The regulation also lays down controls which must be complied with by operators even when Member States implement the derogation in full. This may also impose some costs on operators.</p>	<p>Although the Government proposes to implement the derogation in full, there are some unavoidable direct costs to operators resulting from the directly applicable legislation. However, registration requirements should be minimal and the conditions laid down in the legislation should in any case be followed by most operators already.</p> <p>Operators have been asked to estimate compliance costs but no information has been received.</p>
<p>2. Derogation</p> <p>Articles 16 (c) and 18 (1): Use of certain ABPs for feeding to animals</p> <p>Affected sectors: Fishing bait producers/ users, those feeding certain wild animals /birds, cat & dog shelters</p>	<p>The derogation from the current regulation allows MSs to set conditions to control public and animal health risks for the collection and use of Category 2 material from animals which were not killed or did not die from actual or suspected disease communicable to</p>	<p>The derogation from the new regulation allows MSs to set conditions to control public and animal health risks for the collection and use of these materials for the following additional categories of animals:</p> <ol style="list-style-type: none"> 1) Fur animals (not applicable in UK in any case); 2) Cats and dogs in 	<p>Government intend to take advantage of this derogation in part.</p> <p>Will restrict feeding low risk Category 3 material to garden birds only e.g. allowing the public to put out fat ball in their garden.</p> <p>Will also use the derogation to allow feeding to cats &</p>	<p>Compared with current position, there will be a very small benefit as this largely regularises the current position</p>	<p>Small net benefit</p>

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<p>3. Derogation</p> <p>Articles 16 (c) and 18 (2): Feeding of Category 1 material to zoo animals & necrophagous birds</p> <p>Affected sectors: Zoos,</p>	<p>humans or animals, and of Category 3 material for feeding to the following animals:</p> <p>(a) Zoo animals (b) Circus animals (c) Reptiles/birds of prey other than zoo or circus animals (d) Dogs from recognised kennels or packs of hounds (e) Maggots for fishing bait (f) wild animals</p> <p>The current Regulation does not allow Cat 1 material to be fed to zoo animals.</p> <p>There are no programmes approved in the UK for feeding Cat 1 material to necrophagous bird species- so does not apply</p>	<p>shelters (applicable);</p> <p>3) Worms for fishing bait (applicable).</p>	<p>dogs in shelters, (although we are not aware of any demand for this), and to allow feeding to worms used for fishing bait, which will regularise the current position.</p> <p>NB: Government will not use the derogation which refers to fur animals, as animals are not permitted to be farmed for fur in the UK.</p>		
	<p>The derogation from the new Regulation allows MSs to authorise the feeding to zoo animals of Category 1 material under Article 8(b) (ii) (i.e. entire bodies/parts of dead animals containing SRM at time of disposal), and of material derived from zoo animals.</p>	<p>Government intend to take advantage of this derogation in full.</p> <p>This would allow zoos etc to "re-cycle" their own fallen stock that fall under Category 1 (e.g. entire deceased antelopes, zebras) to their carnivorous animals (e.g. big cats) in addition to the Cat 2 material that is already permitted.</p> <p>Additional controls</p>	<p>Government intend to take advantage of this derogation in full.</p> <p>This would allow zoos etc to "re-cycle" their own fallen stock that fall under Category 1 (e.g. entire deceased antelopes, zebras) to their carnivorous animals (e.g. big cats) in addition to the Cat 2 material that is already permitted.</p> <p>Additional controls</p>	<p>Compared with the current position, there will be a small benefit to those few zoos which want to feed carnivorous animals in this way. Many zoos will be unaffected as they do not keep carnivorous species.</p>	<p>Very small net benefit overall</p>

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<p>4. Derogation Articles 16(d) and 19(1)(a): Burial of pet animals Affected sectors: Pet owners, horse owners</p>	<p>The derogation from the current Regulation allows the burial of pet animals. The UK currently applies this derogation, and includes 'pet horses' under the description of 'pet animals'. Other equidae are not currently included in derogation.</p>	<p>The derogation from the new Regulation allows MSs to authorise the disposal by burial of dead pet animals and all equidae.</p>	<p>would be attached to feeding animals containing SRM. Government intend to take advantage of this derogation in part. Government will allow the burial of all pet equidae only. Extending the derogation to all equidae would be more difficult to control and enforce and we are not aware that widening the scope would have any significant benefit. Waste controls will still apply.</p>	<p>Costs of burial are likely to be lower than rendering/incineration in most cases, but burial is not always practical and the horse industry does not anticipate there will be a major increase in burial from horse owners.</p>	<p>Small reduction of costs associated with burial rather than incineration. Small increase in benefits associated with wider choice of method of disposal.</p>
<p>5. Derogation Articles 16(d) and 19(1)(b): Disposal in remote areas by burning/burial on site or by other means under official supervision of Category 1 material under Article 8(a)(v) (i.e. wild animals) and</p>	<p>The derogation from the current Regulation is the same as the one presented in the new Regulation- but the present derogation does not allow MSs to authorise disposal of diseased wild animals in remote areas, instead</p>	<p>The derogation from the new Regulation now includes Cat 1 wild animals, when suspected of being infected with diseases communicable to humans or animals. It also allows for burial.</p>	<p>Government intend to take advantage of this derogation in full. We consider that burial is the most expedient and practical method of disposal in remote areas.</p>	<p>In practice few dead diseased wild animals will come to the attention of landowners and the effect should be minimal.</p>	<p>There will be a very small reduction in the costs to landowners.</p>

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<p>8(b)(ii) (i.e. entire bodies or parts of dead animals containing SRM at time of disposal), and Category 2 + 3 material.</p> <p>Affected sectors: Landowners</p>	<p>requiring their disposal by rendering or incineration.</p>				
<p>6. Derogation</p> <p>Articles 16 (d) and 19 (1) (c): Disposal of fallen Stock carcasses in areas where <u>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</u>, 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 disproportionately onerous means of collection.</p>	<p>The current Regulation says that fallen stock must be collected and disposed of in line with ABPR, except in a very few specific circumstances.</p>	<p>The new derogation from the Regulation says that MSs may now authorise the disposal by burning/burial on site or by other means under official supervision of Category 1 material under Article 8(b)(ii), (i.e. entire bodies/parts of dead animals containing SRM at time of disposal), Category 2 and Category 3 material in areas where access is <u>practically impossible or where access would only be possible under circumstances, related to geographical or climatic reasons or due to a natural disaster</u>, which would</p>	<p>The Government intend to take advantage of this derogation in full, where the farmer is able to demonstrate that the appropriate criteria are met. Will provide guidance on the conditions to apply to ensure the derogation is not subject to abuse.</p>	<p>There will be a small reduction in costs for livestock farmers who will be now able to dispose of fallen stock in areas meeting these criteria by burial on site or leaving them to degrade naturally (depending on the circumstances), rather than being obliged to arrange for their collection & disposal by rendering/ incineration.</p>	<p>Small reduction in overall costs.</p>

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<p>Affected sectors: Livestock farmers, fallen stock collection and disposal sector</p>		<p>pose a risk to the health and safety of the personnel carrying out the collection or where access would necessitate the use of disproportionately onerous means of collection.</p>			
<p>7. Derogation Articles 16(d) and 19(1)(d): Small Quantities of ABPs Affected sectors: Small Retailers</p>	<p>The current Regulation says that all ABPs must be disposed of in line with the Regulation.</p>	<p>The derogation from the new Regulation says that MSs may authorise the disposal of 20kg (or potentially 50kg) per week of raw meat and fish arising from retailers outside of the control of the ABPR (50kg only permissible where MS have provided detailed justification to the Commission).</p>	<p>The Government intend to take advantage of this derogation in full using the 20kg limit, as the terms which the Commission has set out for the detailed justification required to apply the 50kg limit cannot be met in the UK In any case bodies representing retailers have said that the 20kg limit will accommodate the requirements of most small retail outlets.</p>	<p>There will be considerable reduction in costs to small retailers and food manufacturers.</p>	<p>Evidence provided by the British Retail Consortium and the Association of Convenience Stores suggests the cost saving to this sector could be in the range £30m to £40m a year. This is based on a cost saving of about £1,000 a year per shop across the sector. Within the sector there might be in the order of 20,000 non-affiliated independent convenience stores which would probably fall within the definition of 'small business'.</p>
<p>8. Derogation Article 16 (f): Use of ABPs in Bio-Dynamic preparations</p>	<p>The current Regulation does not authorise the use of bio-dynamic preparations.</p>	<p>The derogation from the new Regulation says that MSs may allow Cat 2 and 3 materials to be used for the preparation</p>	<p>The Government intend to take advantage of this derogation in full in order to meet specialist demand</p>	<p>There will be a small benefit to those wishing to prepare and apply bio-dynamic preparations to land, (although in practice this change largely regularises</p>	

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<p>Affected sectors: Farmers & landowners, those wishing to prepare & apply bio-dynamic preparations to land</p>		<p>and application to land of bio-dynamic preparations as per Article 12(1) (c) of Regulation 834/2007.</p> <p>MS have discretion to set conditions.</p>	<p>in this area.</p>	<p>the current position.)</p>	
<p>9. Derogation</p> <p>Article 16 (g): Use of ABPs for Pet Food</p> <p>Affected sectors: Pet food manufacturers , individuals wishing to feed such material</p>	<p>Under the current Regulation only "petfood", (processed or raw) which has been prepared in accordance with the requirements of the regulation may be fed to pet animals.</p>	<p>The derogation from the new Regulation allows MSs to set out conditions which permit Category 3 material to be used for feeding to pets (instead of the regulation's requirements which apply to manufacturers of raw and processed petfood products).</p> <p>MS have discretion to set conditions.</p>	<p>The Government do not intend to take advantage of this derogation.</p>	<p>The potential increased risks to human and animal health from being unable to guarantee the microbiological safety of the material to be fed, far outweigh any potential benefits.</p>	<p>Small net benefit</p>

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<p>10. Derogation</p> <p>Article 16 (h): Disposal of ABPs on farm</p> <p>Affected sectors: Livestock farmers</p>	<p>The current Regulation does not permit the disposal of ABPs arising from surgical intervention or birth of animals on farm, they must be disposed of in line with the Regulation (rendering/incineration).</p>	<p>The derogation from the new Regulation allows MSs to authorise ABPs (except Category 1 material) arising from surgical intervention on live animals or during birth of animals on farm to be disposed of on that farm.</p> <p>MS have discretion to set conditions.</p>	<p>The Government intend to take advantage of this derogation in part.</p> <p>We propose to allow material to be disposed of on farm, with the exception of foetuses or placentas, where there may be a risk of spreading disease to humans or animals (e.g. aborted calf foetuses/placentas where there may be a risk of diseases such as brucellosis).</p>	<p>The derogation as proposed would bring a small benefit to livestock farmers who would benefit from a reduction in certain disposal costs (although to some extent this may just regularise current practice).</p> <p>If the derogation were fully implemented, there might be a further slight reduction in costs to farmers, but with significant potential disease risks which might then result in higher costs, e.g. if animals were suffering from a notifiable disease, or burial was not carried out correctly.</p>	<p>Small net benefit</p>
<p>11. New Provision</p> <p>Article 13 (e) (ii): ABPs used for Composting & biogas</p> <p>Affected sectors: Biogas plants, those supplying them with raw material</p>	<p>The current Regulation permits the composting or anaerobic digestion (biogas) of Category 3 ABPs. A limited number of Category 2 materials such as manure and milk can also be composted or anaerobically digested, provided they are not considered a</p>	<p>The new Regulation maintains this regime and expands it slightly to include milk products, and Category 2 egg and egg products.</p>	<p>The Government intend to take advantage of this new provision in full.</p> <p>The new provision allows a wider range of material to be used without a significantly increased disease risk. It also removes a previous anomaly where Category 2 milk</p>	<p>There will be a small benefit to compost and biogas plants and those who supply them, who will now be able to supply/use a wider range of material.</p>	<p>Small net benefit</p>

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	disease risk.		could be composted but not products derived from the milk.		
<p>12. Relaxation of current domestic controls</p> <p>National provisions on composting of catering waste on the premises on which it originates.</p> <p>Affected sectors: Composting/ anaerobic digestion community (including domestic householders), specifically small community composting or anaerobic digestion projects.</p>	<p>The current Regulation says that catering waste intended for composting or anaerobic digestion must be sent to an AH approved plant.</p> <p>There is a current exception for 'home composting' which permits the composting of catering waste on the premises of origin without the need for an approval from AH, provided that the resultant compost is used only on those premises.</p>	<p>The Government intend to broaden the home composting exception to allow for composting and anaerobic digestion on the premises of origin or elsewhere, without approval from AH, provided that livestock cannot gain access to this material.</p>	<p>The Government intend to relax the current national controls to allow for off-site disposal of 'home composting'</p>	<p>Compared with the current position, if Government implement this new provision there will be a significant benefit to the composting/ anaerobic digestion community particularly for small-scale community composting and anaerobic digestion projects who may be able to operate without the requirement for a full plant approval from Animal Health</p>	<p>Benefit to sector likely but sector unable to quantify due to uncertainty about potential take up</p>
<p>13. New Provision Article 13 (f): Application of ABPs to land</p> <p>Affected sectors: Landowners, users/ suppliers of certain waste ABP material</p>	<p>The current Regulation allows Category 2 digestive tract content separated from digestive tract, milk and colostrum to be applied to land without processing, if the MS considers this does not present a</p>	<p>The new Regulation maintains this regime, also now enables Category 2 milk-based products to be spread to land unprocessed, and also certain lower risk Category 3 materials.</p>	<p>The Government intend to take advantage of this new provision in full.</p> <p>With milk and milk products there may be a potential risk of disease spread when they are applied to land in</p>	<p>There would be a small benefit to suppliers/users of this waste ABP material derived from its increased potential use.</p>	<p>Small net benefit</p>

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	risk of spreading serious transmissible disease.		the case of a notifiable disease outbreak. A requirement to allow restrictions relating to animal and public health to be imposed if necessary would be included in any new provision to mitigate the increased disease risk.		
<p>14. New provision</p> <p>Article 14 (h): Use of shellfish shells</p> <p>Affected sectors: Shellfish sector</p>	<p>The current Regulation requires all shellfish shells to undergo at least "Method 7" processing (i.e. rendering) before use.</p>	<p>1) The new Regulation enables MSs to determine conditions for disposal of shells from shellfish in which soft tissue remains.</p> <p>2) Article 2.2(d) in any case removes from scope shells where no soft tissue remains.</p>	<p>The Government intend to take advantage of this new provision subject to the following conditions:</p> <p>1) Any shells with flesh present would need to be processed(subject to rendering/heat treatment) in accordance with the Regulation to ensure there is no public and animal health risk.</p> <p>2) operators will be required to demonstrate that the shells are "free of flesh" (using</p>	<p>There would be a substantial benefit to the shellfish sector from the potential sale of shells without flesh remaining for productive uses, and from the less costly disposal requirements, compared with current requirement (rendering).</p>	<p>Net benefit to industry of removing shells from scope of the regulation. This amounts to about £4.4m a year as a consequence of a disposal cost saving of about £70/t rising to over £6m a year after 5 years as the tonnage increases.</p>

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<p>15. New provision Article 14 (h): Egg shells to land Affected sectors: Egg Processing Industry, farmers</p>	<p>The current Regulation requires eggshells to undergo at least "Method 7" processing (i.e. rendering) before use.</p>	<p>The new Regulation allows Category 3 egg shells to be used under conditions determined by the MS which prevent risks arising to public and animal health.</p>	<p>criteria to be laid down), in which case controls on their use would be removed from the scope of the regulation. . . The Government intends to take advantage of this new provision, to put in place less burdensome control measures which operators may use as an alternative to processing but which will still protect animal and public health.</p>	<p>There will be a benefit to industry, as the cost of rendering is approximately twice that of putting shell onto land without processing. There will also be some potential reduction in the carbon footprint from not needing to render product, as well as a benefit to the land to which shell would be applied. This will create additional avenues for disposal of egg shell, making the industry more viable. There will also be an additional saving to landowners using shells as a soil improver for application to the land.</p>	<p>Egg sector acknowledge benefit but unable to quantify</p>
<p>16. New Provision Article 32: Use of organic fertilisers Affected sectors: Landowners, renderers</p>	<p>The current Regulation permits the application to land of organic fertilisers and soil improvers (OF/SI) derived from processing Cat '2 or Cat '3 material in</p>	<p>The new Regulation allows MSs to adopt national rules imposing conditions or restrictions on the use of organic fertilisers and soil improvers if they are justified to protect</p>	<p>The Government do not intend to impose additional national restrictions(which it does at present in relation to certain material)</p>	<p>Compared with the current position there will be a small benefit to industry, permitting the use of category 2 and category 3 processed animal protein in organic fertilisers and soil improvers provided that they are mixed with a suitable material so that they</p>	<p>Small net benefit</p>

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	<p>an approved processing (rendering) plant. Cat' 1 material cannot be used for the production of OF/SI. Cat' 2 material can only be used where it is pressure-rendered in accordance with the Regulation. Cat 3 materials may use any of the processing standards set out in the Regulation.</p>	<p>public or animal health.</p> <p>The Implementing Regulation set down conditions that must be complied with.</p>	<p>However, would propose to keep a grazing restriction of two months in the case of pigs, and 21 days for other livestock after application of OF/SI to land (the regulation permits MSs to set a minimum period of 21 days).</p>	<p>are not palatable to livestock and cannot be used in animal feed.</p>	
<p>17. New Requirements</p> <p>Article 41 Imports of ABPs from third countries into the EU</p> <p>Affected sectors: Importers of ABPs,</p>	<p>The current Regulation sets down detailed rules for the importation of ABPs from third countries and the documentation which needs to accompany the consignments (usually in the form of health certificates).</p>	<p>The new Regulations requirements update and consolidate the existing import rules. Notable changes are:</p> <p>1) Scope has been increased (and correspondingly the model declaration) for use of intermediate products (ABPs which have undergone a degree of processing but are not finished). For example, the definition now includes medicinal products, veterinary medicinal products</p>	<p>The Government intends to fully implement the changes in the new Regulation, which tend to simplify and consolidate the requirements for both importers and for the Competent Authority.</p>	<p>Compared with the current position the Government expects that when the changes are considered in aggregate they should have a positive benefit/outcome (with any small costs being out-weighed by the benefits) for both Government and Industry, since the changes tend to be de-regulatory, allowing industry to make greater use of ABPs with less intervention from Government.</p> <p>These changes should enable greater use of intermediate products with savings for both industry and Government (e.g. more widespread use of the model</p>	<p>Small net benefit</p>

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		<p>and active implantable medical devices; some Cat 1 & Cat 2 materials are now specifically included; and blood from live animals (including from livestock species) is now listed for use as an intermediate product.</p> <p>2) Import authorisation requirements for specific ABPs (such as aquatic and terrestrial invertebrates, rodentia and lagomorpha) are now less prescriptive.</p> <p>3) Research and diagnostic samples imported via another Member State need to be presented to a BIP on entry to the EU, but not vet checked, and the Member State of destination notified via TRACES. Most research and diagnostic samples are imported directly into the UK, so likely</p>		<p>declaration rather than individual authorisations).</p> <p>The reclassification of ABPs from e.g. Cat' 2 to 3 and the relaxation around some of the rules for Cat' 1 material, should increase the scope for imports and their usage, which should be beneficial for industry and Government.</p>	
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			to have little impact, 4) Trade samples and display items need to be imported via a BIP for vet checks. Trade samples also need to be channelled to their final destination. It is estimated that in 2010 only 18 trade samples and 8 display items were imported, leading to a small additional cost to industry.			
18. Implementing Regulation Annex XIV section II, Chapter IV, Part II: Colostrum for feeding Affected sectors: Livestock owners	The current Regulation does not permit the supply of colostrums directly from one farm to another farm within the same MS for feeding purposes.	The new Implementing Regulation provides by way of derogation from controls on colostrum for the competent authority to authorise the supply of colostrum from one farm to another farm within the same MS for feeding purposes under conditions which prevent the transmission of health risks.	The Government intends to apply this derogation under conditions which prevent the potential spread of animal diseases	There will be a small benefit to livestock owners due to the increased availability and reduced cost of obtaining commercial colostrum. The likely demand for transferring colostrum from one farm to another is not, according to the dairy industry, thought to be very great	Small net benefit	
19. Implementing Regulation Annex XVII,	The current Regulation does not permit unprocessed wool	The new Implementing Regulation provides for the competent	The Government intends to apply this derogation without restrictions,	There will be a small benefit to the wool sector who can take advantage of the new potential for movement,	Small net benefit	

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<p>Chapter VII: Unprocessed wool</p> <p>Affected sectors: Wool industry</p>	<p>to be placed on the market.</p>	<p>authority to authorise the placing on the market of unprocessed wool under conditions which prevent the transmission of health risks.</p>	<p>provided the operator registers with Animal Health to enable tracing of the wool in case. restrictions needed to be put in place in the case of a notifiable disease outbreak.</p> <p>Otherwise, no controls are proposed as the risks, are minimal.</p>	<p>storage and placing on the market of wool without restrictions (including for example composting of wool without restrictions).</p>	
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