

Explanatory Memorandum to the Animal By-Products (Enforcement) (No.2) (Wales) Regulations 2011

This Explanatory Memorandum has been prepared by The Department for Environment and Sustainable Development and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Animal By-Products (Enforcement) (No.2) (Wales) Regulations 2011. I am satisfied that the benefits outweigh any costs.

John Griffiths AM

Minister for Environment and Sustainable Development, one of the Welsh Ministers

27 September 2011

1. Description

Animal By-Products (ABP) Regulation (EC No.1774/2002) protected animal & public health by controlling the use and disposal of ABPs not intended for human consumption. Following extensive consultation, the new ABP Regulation (EC No. 1069/2009) updating the current rules was agreed in April 2009, following a first reading agreement between the EP & Council (published in the Official Journal on 14 November 2009) and came into force on 4 March 2011. The technical details (Implementing Rules) for the Regulation have been laid down in a separate legal act. The implementing rules, Regulation (EC) 142/2011 came into force simultaneously with the new Regulation on 4 March 2011.

The Welsh Assembly Government introduced new ABP Regulations with effect from 4 March 2011. The Animal By-Products (Enforcement) (Wales) Regulations 2011 (“the 2011 Regulations”) replaced the current Animal By-Product (Wales) Regulations 2006 thus implementing the EU requirements.

The Animal By-Products (Enforcement) (No.2) (Wales) Regulations 2011 (“the No 2 Regulations”) revoke and replace the Animal By-Products (Enforcement) (Wales) Regulations 2011. They will be made bilingually.

2. Matters of special interest to the Constitutional Affairs Committee

Due to the public and animal health risks associated with a prolonged enforcement gap, it was necessary to breach the 21 day rule and produce the 2011 Regulations in English only. The Minister agreed to this on the condition that bilingual regulations would be made and laid for 21 days in due course.

The Constitutional Affairs Committee raised a number of issues with the 2011 Regulations and the Government’s view, supported by its lawyers, is that the 2011 Regulations are fully enforceable and that the technical points raised by the report do not materially affect the enforceability of the new legislative provisions in the 2011 Regulations.

The powers of entry provisions in the 2011 Regulations have been revisited in the No 2 Regulations to take account of the human rights issues raised in the report.

The Government is satisfied that the penalties set out in the 2011 Regulations and which will be replicated in the No 2 Regulations are reasonable and proportionate. The penalties are identical to the England ABP Regulations which came into force on the 23rd March 2011. Non-compliance with the provisions of the Regulations could lead to potential severe risks to human and animal health and the penalties reflect the seriousness of this risk.

Because the revocations and amendments in the 2011 Regulations have taken effect, section 15 of the Interpretation Act is being used to revive those revocations and amendments before the No.2 Regulations can take effect.

3. Legislative background

The Welsh Ministers are designated to implement European legislation in relation to veterinary and phytosanitary fields for the protection of public health by virtue of SI 2008/1792. The proposed No.2 Regulations will be made by the Welsh Ministers under section 2(2) of the European Communities Act 1972 using this designation.

The instrument is subject to the negative procedure.

4. Purpose & intended effect of the legislation

The objectives of the new EU ABP Regulation and hence domestic legislation to implement are to introduce a set of updated rules on animal by-products providing legal certainty, simplified requirements and reductions in the administrative burden on operators. It also raised the issue that the 2002 European Regulation (1774/2002) needed to be updated to reflect new scientific/technological/practical experience since the adoption of that European Regulation, and updates the categorisation of ABPs according to the risk they pose. The effect will be to make ABP controls more effective and efficient, and reduce administrative burdens on business while ensuring continued protection of public and animal health and food safety.

In Wales there are approximately 250 premises approved to handle or dispose of ABPs. In addition to that there are approximately 200 educational establishments, taxidermists and wool collection points that use and dispose of ABPs in line with the derogations permitted in the current European Regulation.

The Council adopted the current European Regulation in April 2009 (1069/2009) (published in Official Journal 14 November 2009), following a first reading agreement with the European Parliament. The technical details (Implementing Rules) for the Regulation were laid down in a separate legal act. The implementing rules (142/2011) came into force on 4 March 2011.

The previous Animal By-products (ABP) European Regulation 1774/2002/EC was introduced in 2002 in response to a number of crises affecting the safety of public and animal health as regards 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 ABP in order to guarantee the safety of final products intended for feed or technical uses.

In 2005 the Commission submitted a report to the European Parliament and Council reflecting on the experience of Member States in implementing the 2002 Regulation. The report stated that although the legislation was working well and generally met its overall objectives, there were areas where changes need to be considered in order to update the legislation and to provide legal certainty, simplify it and thereby reduce administrative burdens. It also raised the issue that the 2002 Regulation needed to

be updated to reflect new information which has emerged since the adoption of that Regulation. For example, the products and industries in relation to ABP was wider ranging than foreseen by the legislators at the time of the adoption of the Regulation; and further information on the risks posed by certain ABP material, and the effectiveness of treatment standards in producing a “safe” product, has now become available. Furthermore some plants handling ABPs were subject to legislation under other European controls, such as pharmaceutical companies and there was duplication of control without benefit.

The Commission considered retaining the current rules unchanged or adopting non-regulatory tools but concluded that a regulatory review was most likely to provide effective solutions. Following extensive consultation, the Commission’s new 2009 Regulation has been designed to address the identified shortfalls, in particular:

- Clarity of scope
- Proportionate categorisation of ABPs
- Removal of double approvals
- Derogations
- Provision for the possibility of on farm containment of fallen stock prior to disposal subject to European Food Safety Authority approval.

5. Consultation

The details of consultation undertaken are included in the RIA below.

REGULATORY IMPACT ASSESSMENT

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 & animal health issues which override potential economic benefits. Details of the derogations and their impacts are detailed in the costs & benefits section below.

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 & overall are more than offset by any benefits. Attempts were made to monetise cost increases but this has proved to be not possible without disproportionate effort.

The two main monetised benefits affect respectively the small retail sector and the shell fish processing sector. Both benefits take the form of cost reductions to the affected sectors. In the former case this arises from food waste disposal costs and amounts to about £35m a year. In the latter case it arises from the disposal of shell material and comes to about £5.4m a year. For more detail see table of impacts below - items 7 and 14.

The EU ABP Regulations include provision for on-farm containment of carcasses prior to disposal which will provide farmers with additional options when dealing with their fallen stock. WAG has funded research into on-farm containment in the form of a bio-reducer system. Following satisfactory completion of the research, WAG will support an application to the European Food Safety Authority (EFSA) for it to be considered an accepted process under the revised regulations.

Costs & benefits

Below is an assessment of the impact of the derogations available in implementing the EU regulation in domestic legislation. The article numbers refer to ABP Regulation (EC No. 1069/2009).

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>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 humans or animals, and of Category 3 material for feeding to the following 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> <ol style="list-style-type: none"> 1) Fur animals (not applicable in UK in any case); 2) Cats and dogs in shelters (applicable); 3) Worms for fishing bait (applicable). 	<p>The Welsh Government believe that there would be a risk to animal and public health if the feeding of category 3 material was allowed for all wild animals. Therefore we will make use of this derogation but will limit the feeding of category 3 material only to wild birds in domestic gardens. We will also use the derogation to allow feeding</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>

	<p>(a) Zoo animals</p> <p>(b) Circus animals</p> <p>(c) Reptiles/birds of prey other than zoo or circus animals</p> <p>(d) Dogs from recognised kennels or packs of hounds</p> <p>(e) Maggots for fishing bait</p> <p>(f) wild animals (not currently in use in England)</p>		<p>category 2 and 3 material to cats and 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>N.B Animals are not permitted to be farmed in the UK for fur so this will not apply.</p>		
<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>The current Regulation does not allow Cat 1 material to be fed to zoo animals.</p> <p>There are no programmes approved in Wales (or the rest of the UK) for feeding Cat 1 material to necrophagous bird species - so does not apply</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. Additional controls would be attached to feeding animals containing SRM.</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>
<p>4. Derogation</p> <p>Articles 16(d) and 19(1)(a):</p>	<p>The derogation from the current Regulation</p>	<p>The derogation from the new Regulation allows MSs to authorise</p>	<p>Government intend to take advantage of this derogation</p>	<p>Costs of burial are likely to be lower than rendering/</p>	<p>Small reduction of costs associated with burial rather</p>

<p>Burial of pet animals</p> <p>Affected sectors: Pet owners, horse owners</p>	<p>allows the burial of pet animals. Wales currently apply 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 disposal by burial of dead pet animals and all equidae.</p>	<p>in full.</p> <p>Government will allow the burial of all equidae but we would recommend that the owners of dead equidae should first of all consider disposal of the carcass via the normal route for ABPs. Alternatively owners could consider the burial of the animal subject to any Environment Agency or Local Authority controls</p>	<p>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. There will be a negligible increase in disease risk of burial, as opposed to incineration.</p>	<p>than incineration. Small increase in benefits associated with wider choice of method of disposal.</p>
<p>5. Derogation</p> <p>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>Affected sectors:</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>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>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>

Landowners					
<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</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>Affected sectors: Livestock farmers, fallen stock collection and disposal sector</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 <u>access is practically impossible or where access would 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>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. There will be a very small associated increase in disease risk.</p>	<p>Small reduction in overall costs.</p>
<p>7. Derogation</p> <p>Articles 16(d) and 19(1)(d): Small Quantities of ABPs</p> <p>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</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</p>	<p>There will be considerable reduction in costs to small retailers and food manufacturers. There will be a very small associated increase in disease risk.</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</p>

		ABPR (50kg only permissible where MS have provided detailed justification to the Commission).	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.		range £30m to £40m a year (on a UK basis). 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'.
8. Derogation Article 16 (f): Use of ABPs in Bio-Dynamic preparations Affected sectors: Farmers & landowners, those wishing to prepare & apply bio-dynamic preparations to land	The current Regulation does not authorise the use of bio-dynamic preparations.	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. MS have discretion to set conditions.	The Government intend to take advantage of this derogation in full in order to meet specialist demand in this area.	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 the current position.)	
9. Derogation Article 16 (g): Use of ABPs for Pet Food Affected sectors: Pet food manufacturers, individuals wishing to feed such material	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.	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). MS have discretion to set conditions.	The Government will not be taking advantage of this derogation.	The controls necessary to address the risks identified would be equal to the existing approval process as a petfood plant, which is already provided for in the Regulations.	No direct benefit or additional costs/impacts.

<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 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>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). There would be a very small associated increase in disease risk.</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>

	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</p> <p>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 risk of spreading serious transmissible</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 the case of a notifiable disease outbreak. A requirement to</p>	<p>There would be a small benefit to suppliers/users of this waste ABP material derived from its increased potential use. There will be a very small associated increase in disease risk.</p>	<p>Small net benefit</p>

	disease.		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>	The current Regulation requires all shellfish shells to undergo at least "Method 7" processing (i.e. rendering) before use.	<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 criteria to be laid down), in which case controls on their use would be removed from the scope of the regulation.</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).	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 (UK figures).
<p>15. New provision</p>	The current Regulation requires	The new Regulation allows Category 3 egg	The Government intends to take	There will be a benefit to industry, as the cost of rendering	Egg sector acknowledge benefit but

<p>Article 14 (h): Egg shells to land</p> <p>Affected sectors: Egg Processing Industry, farmers</p>	<p>eggshells to undergo at least "Method 7" processing (i.e. rendering) before use.</p>	<p>shells to be used under conditions determined by the MS which prevent risks arising to public and animal health.</p>	<p>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>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.</p> <p>This will create additional avenues for disposal of egg shell, making the industry more viable.</p> <p>There will also be an additional saving to landowners using shells as a soil improver for application to the land.</p>	<p>unable to quantify</p>
<p>16. New Provision</p> <p>Article 32: Use of organic fertilisers</p> <p>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 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</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 public or animal health.</p> <p>The Implementing Regulation set down conditions that must be complied with.</p>	<p>The Government do not intend to impose additional national restrictions(whi ch it does at present in 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</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 are not palatable to livestock and cannot be used in animal feed.</p>	<p>Small net benefit</p>

	accordance with the Regulation. Cat 3 materials may use any of the processing standards set out in the Regulation.		OF/SI to land (the regulation permits MSs to set a minimum period of 21 days).		
<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 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</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 outweighed 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 declaration rather than individual authorisations).</p> <p>The reclassification of ABPs from e.g. Cat' 2 to 3 and the relaxation around some of</p>	Small net benefit

		<p>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 to have little impact,</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>the rules for Cat' 1 material, should increase the scope for imports and their usage, which should be beneficial for industry and Government.</p>	
<p>18. Implementing Regulation</p> <p>Annex XIV section II, Chapter IV, Part II: Colostrum for feeding</p> <p>Affected sectors: Livestock owners</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>The Government intends to apply this derogation under conditions which prevent the potential spread of animal diseases</p>	<p>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.</p>	<p>Small net benefit</p>

				Providing guidance is followed, there will only be a very small associated increase in disease risk.	
<p>19. Implementing Regulation</p> <p>Annex XVII, Chapter VII: Unprocessed wool</p> <p>Affected sectors: Wool industry</p>	The current Regulation does not permit unprocessed wool to be placed on the market.	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>The 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>	There will be a small benefit to the wool sector who can take advantage of the new potential for movement, storage and placing on the market of wool without restrictions (including for example composting of wool without restrictions). There will be a negligible associated increase in disease risk.	Small net benefit

Consultation

A six week consultation was held seeking views on how to implement the available derogations in Wales. The consultation package was sent to around 350 representative bodies and individuals, and was also made available on the Welsh Government website. Six responses were received and there was broad support for our proposals.

A summary of responses and The Welsh Assembly's response will be available at www.wales.gov.uk

As a result of the consultation the original suggestion to restrict the derogation to allow the burial of pets and equidae to pet equidae has been extended to all equidae.

Competition Assessment

The competition assessment is at Annex A

Post implementation review

A post implementation review will take place three to five years after implementation of the policy. The effect of the subordinate legislation will be assessed against the net cost saving to businesses compared with the previous regulations with no increase in risks to animal and public health.

Information will be gathered through stakeholder engagement and delivery and enforcement agency feedback. Areas that could be improved will be highlighted for possible amendment.

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of businesses/organisation?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

Conclusion

It is unlikely that there will be any detrimental effects on competition.