EXPLANATORY MEMORANDUM TO

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

2011 No. 881

1. This explanatory memorandum has been prepared by the Department for Environment Food & Rural Affairs and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The purpose of the instrument is to enforce Regulation (EC) No. 1069/2009 (the '2009 EU ABP Regulation') which lays down health rules as regards animal by-products and derived products not intended for human consumption, and its accompanying implementing Regulation (EU) No. 142/2011 ('the EU Implementing Regulation'). The 2009 EU ABP Regulation repeals the EU ABP Regulation 1774/2002, which was adminstered and enforced in England by The Animal by-products Regulations 2005 ('ABP SI 2005/2347'), and which is being revoked and replaced by this instrument (the 'ABP SI 2011').

2.2 The criminal offences created by this instrument are largely in line with criminal offences already in place under existing legislation. The Ministry of Justice has cleared these offences.

3. Matters of special interest to the Joint Committee on Statutory Instruments and the Merits Committee

3.1 The Department for Environment, Food and Rural Affairs intends to breach the 21-day rule in regard to the ABP SI 2011, which enforces both the 2009 EU ABP Regulation and its accompanying Implementing Regulation. This SI will come into force the day after it is laid before Parliament.

3.2 The Department regrets breaching the 21-day rule but does so on the grounds that there is are clear and compelling reasons of operational urgency for such a breach. There a significant risk to public and animal health if England fails to have in place enforcement provisions as soon as possible after the coming into force (on 4 March 2011) of the 2009 EU ABP Regulation.

3.3 As the ABP SI 2011 also enforces requirements in the EU Implementing Regulation it could not be made before the publication of that Regulation. The EU Implementing Regulation was only published in the Official Journal on 26 February 2011. The Department therefore could not make the SI at a date which

would have enabled compliance with the 21 day rule. The Department has aimed to make the ABP SI 2011 as soon as possible after 26 February.

3.4 The two EU ABP Regulations enable us to exclude from the food chain animal by-products (ABPs) particularly those 'high-risk' ABPs such as Specified Risk Material which carry a significant risk to animals of Bovine Spongiform Encephalopathy (BSE) – linked to variant Creutzfeld Jacob Disease in humans. Without enforcement provisions in place there is an unacceptable risk of ABPs being incorporated into feed and leading to a disease outbreak such as BSE, or foot-and-mouth (FMD) disease. The 2001 FMD outbreak is thought to have been caused by feeding unprocessed ABPs to pigs.

4. Legislative Context

4.1 The EU ABP Regulation (EC) No.1774/2002 was reviewed in 2005 to update, simplify, and remove burdens; this resulted in the adoption of the revised 2009 EU ABP Regulation (as supplemented by the EU Implementing Regulation) which came into force on 4 March 2011. As a result the EU ABP Regulation (EC) No 1774/2002 was repealed on that day.

4.2 The ABP SI 2005/2347 provided the necessary powers to administer and enforce the provisions of the EU ABP Regulation 1774/2002 (in England). This was amended (with effect from 2 May 2009) by the Animal By-Products (Amendment) Regulations 2009 (SI 2009/1119).

4.3 The Animal By-Products (Enforcement) (England) Regulations 2011 (the ABP SI 2011) will enforce the directly applicable requirements of the two EU ABP Regulations and revoke the ABP SI 2005/2347. In addition, the ABP SI 2011 makes provision for certain areas where the member state can make decisions, for example, designation of the competent authority (the Secretary of State), and also for areas of discretion of the member state, for example, a transitional provision.

4.4 **Schedule 1** of the ABP SI 2011 sets out the requirements of the 2009 EU ABP Regulation and its implementing Regulation. Breach of these requirements will be an offence. In certain circumstances, the directly applicable EU ABP Regulations enable the member state to make national provisions and grant authorisations in respect of derogations from the EU requirements. These are set out in the SI, for example to appoint the competent authority (in England the Secretary of State), and to designate remote areas where the derogation from certain obligations on disposal of animal by-products will apply. In addition, the 2009 EU ABP Regulation also permits competent authorities to authorise other derogations. A full list of those exercised in England by the Secretary of State will be made available on the Defra website. Annex A provides more information on these authorisations.

4.5 In broad terms the approach to transposition has been to impose the minimum burden on industry consistent with meeting our obligations to enforce the 2009 EU ABP Regulation, and to take advantage of all the potential derogations available to Member States unless there are public & animal health issues which override the potential benefits.

4.6 A previous Explanatory Memorandum was prepared for the draft 2009 EU ABP Regulation and was considered in EU Scrutiny Committee (Sub-Committee D: Environment & Agriculture) on 22 April 2009.

5. Territorial Extent and Application

5.1 This instrument applies to England.

5.2 Similar domestic legislation is already in place in Scotland (The Animal By-Products (Enforcement) (Scotland) Regulations 2011 No. 171) and Wales (The Animal By-Products (Enforcement) (Wales) Regulations 2011 No. 600 (W.88)). Northern Ireland expect to bring their Statutory Regulation into force in the week commencing 21 March.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Animal By-Products (ABPs) are entire bodies, parts of animals, and products of animal origin not intended for human consumption. ABPs can present a risk to human and animal health, and their use & disposal has been controlled for many years. The EU ABP Regulation 1774/2002 was introduced 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. That Regulation consolidated, simplified and replaced 19 previous legal acts. It also introduced stricter rules for the approval of certain premises, ensured the channelling and traceability of ABPs, and made 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.

7.2 Although generally effective, the EU ABP Regulation 1774/2002 was comprehensively reviewed by the EU Commission in 2005. An initial report submitted by the Commission to the European Parliament and the Council of the European Union said 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 the Regulation 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. This resulted in the adoption of 2009 EU ABP Regulation.

7.3 The 2009 EU ABP Regulation 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 carcases 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 the the EU ABP Regulation 1774/2002 it now also:

- Gives greater clarity on scope, more clearly defining when products are no longer considered ABPs and therefore exempt from the controls of the 2009 EU ABP 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.

7.4 A Statutory Instrument is needed as the 2009 EU ABP Regulation requires member states to enforce the directly applicable requirements of the 2009 EU ABP Regulation (as supplemented by the EU Implementing Regulation). In addition the 2009 EU ABP Regulation 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 instrument.

8. Consultation outcome

8.1 Defra consulted with stakeholders in writing twice in 2006, as part of the response to the Commission on-line questionnaire issued in 2007, and by holding ad hoc meetings with key stakeholders at various intervals since 2005. A consultation on the final proposal for the 2009 EU ABP Regulation was held in late 2008. Our final consultation on the proposed approach to potential derogations and areas of national discretion took place in July 2009. The consultation was for an 8 week period (the reasons for this reduced consultation period were because of the previous extensive formal & informal consultations that had been carried out and

that the consultation was limited to technical issues in respect of derogations and authorisations). This was sent to approximately 600 representative bodies and 40 individuals; it was also made available on the Defra website. 61 responses were received.

8.2 In general responses from the spectrum of industries handling animal by-products have been positive about the changes to animal by-product rules, which in many cases open up new opportunities to convert animal waste products into useful products (such as compost or energy sources). Responses from the farming community have also, in the main, been positive.

9. Guidance

Defra has published general Guidance for industry and the public to reflect the changes arising from the directly applicable requirements of the 2009 EU ABP Regulations (as supplemented by the ABP SI 2011). For the purpose of the ABP SI 2011 the Secretary of State is the Competent Authority, and Animal Health, on behalf of the Secretary of State, has issued additional detailed guidance on the requirements for ABP operators.

10. Impact

10.1 The impact on business in general is not expected to be significant. In some instances there are cost increases, but these are expected to be minimal, and overall are more than offset by any benefits. The two main monetised benefits affect respectively the retail sector and the shellfish 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 the Impact Assessment attached at Annex B.

10.2 Although this IA has not yet received a positive opinion from the Regulatory Policy Committee, Cabinet Committee have given clearance for the Department to proceed with laying this instrument, on condition that a revised IA is submitted to the RPC by 8 April 2011, that Defra write again to the Cabinet Committee following a satisfactory RPC opinion, that the IA details any question of 'gold plating', and that Defra Ministers reinforce with officials the importance of submitting IAs to the RPC in good time.

10.3 There is no impact on charities or voluntary bodies.

10.4 There is no impact on the public sector.

10.5 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the OPSI website.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 To minimise the impact of the requirements on firms employing up to 20 people, the approach taken is to use derogations available that benefit small business e.g. on disposal of small quantities of ABPs (see table).

11.3 The basis for the final decision on what action to take to assist small business was based on extensive formal & informal consultations with industry over a 5 year period, for example with the British Retail Consortium and the Association of Convenience Stores, who represent retailers of all sizes in the UK.

12. Monitoring & review

Policy on Animal By-Products is kept under continuous review and is updated regularly in line with EU legislative developments. In addition, the outcome will be subject to internal review after 3 years to establish the impact of the new Regulation on business, and the domestic legislation may be amended accordingly (see Annex 1 of the Impact Assessment: Post Implementation Review Plan.)

13. Contact

Neil Leach at the Department for Environment, Food & Rural Affairs Tel: 0207 238 6509 (or email: neil.k.leach@defra.gsi.gov.uk) can answer any queries regarding the instrument.

Annex A

Table of authorisations in respect of derogations to be used by the Secretary of State as competent authority in accordance with the directly applicable requirements of EC Regulation 1069/2009 and EU Regulation 142/2011.

1. Use of animal by-products and derived products for feeding purposes:

Regulation 1069/2009 reference	**Regulation 142/2011 reference**	**Title of Authorisation**
N/R	Article 21; An X Ch II S4 Part II 4	Authorisation to supply other farms with colostrum for feeding purposes
Article 16(c); Article 18(1)+(3)	Article 13; An VI Ch II S1	Authorisation to feed category 3 material and certain category 2 material to zoo animals
Article 16(c); Article 18(1)+(3)	Article 13; An VI Ch II S1	Authorisation to feed category 3 material and certain category 2 material to dogs from recognised kennels or packs of hounds
Article 16(c); Article 18(1)+(3)	Article 13; An VI Ch II S1	Authorisation to feed category 3 material and certain category 2 material to dogs and cats in shelters
Article 16(c); Article 18(1)+(3)	Article 13; An VI Ch II S1	Authorisation to feed category 3 material and certain category 2 material to maggots and worms for fishing bait
Article 16(c); Article 18(1)+(3)	N/R	Authorisation to feed category 3 material and certain category 2 material to circus animals
Article 16(c); Article 18(1)+(3)	N/R	Authorisation to feed category 3 material and certain category 2 material to reptiles and birds of prey other than zoo or circus animals
Article 16(c); Article 18(1)+(3)	N/R	Authorisation to feed category 3 material to wild animals
Article 16(c); Article 18(2)+(3)	Article 14; An VI Ch II S4	Authorisation to feed zoo animals with category 1 material comprising dead animals or parts of dead animals containing specified risk material and material derived from zoo animals
Article 16(g) with Articles 12, 13 and 14	N/R	Authorisation to feed category 3 material to pet animals

2. Application of animal by-products and derived products to land:

Regulation 1069/2009 reference	Regulation 142/2011 reference	Title of Authorisation
Articles 13(f), 14(l) and 32(1)	Article 5(2) An II Ch II	Authorisation to apply certain category 2 and 3 materials to land without processing
Article 14(h)	N/R	Authorisation to apply eggshells to land
Article 16(f) with Articles 12, 13 and 14		Authorisation to use category 2 and 3 materials for the preparation and application to land of biodynamic preparations
Article 32(1)(d)	Article 22(3); An XI Ch II S1 point 3	Authorisation of the components operators must mix with organic fertilisers or soil improvers, produced from meat and bone meal derived from category 2 material or from processed animal protein, before it is applied to land

3. Disposal of animal by-products:

Regulation 1069/2009 reference	Regulation 142/2011 reference	Title of Authorisation
Article 12 Article 14(c)	Article 7	Authorisation to dispose of certain category 1 petfood and category 3 petfood and former foodstuffs in an authorised landfill
Article 16(d); Article 19(1)(a)	Article 15; An VI Ch III S1	Authorisation to dispose of dead pet animals and equidae by burial
Article 16(d); Article 19(1)(b), (2) and 4(b)	Article 15; An VI Ch III S1	Authorisation to dispose of certain category 1 material (diseased wild animals and fallen stock containing SRM), category 2 material (including other fallen stock) and category 3 material in remote areas by burial or other means
Article 16(d); Article 19(1)(c)	Article 15; An VI Ch III S1	Authorisation to dispose of certain category 1 material (fallen stock containing SRM), category 2 material (including other fallen stock) and category 3 material by burial or other means where access is difficult due to geography, climate or natural disaster
Article 16(d); Article 19(1)(e)	Article 15; An VI Ch III S1	Authorisation to dispose of category 1 material (except for TSE suspects/confirmed cases) and category 2 and 3 material by burning or burial following an outbreak of notifiable disease
Article 16(d); Article 19(1)(f)	Article 15; An VI Ch III S3	Authorisation to dispose of bees and apiculture by-products on site by burning or burial

Article 16(h) with Articles 12, 13 and 14		Authorisation to dispose on site of certain category 2 and 3 material arising from surgical intervention on live animals

4. Other Authorisations:

Regulation 1069/2009 reference	**Regulation 142/2011 reference**	**Title of Authorisation**
N/R	Article 21(2); An X Ch II S4 Part I	Authorisation to place on the national market category 3 milk, milk-based products and milk-derived products which have not been processed in accordance with Commission Regulation (EU) No 142/2011
Article 13(e)(ii)	An V	Authorisation to compost or transform into biogas certain category 2 material following or without prior processing
Article 15(1)(b)	Article 9; An IV Ch III G(3)	Authorisation to use processing methods approved before 4 March 2011 under Chapter II, Annex V of EU Regulation 1774/2002
Article 15(1)(b)	Article 8; An IV Ch IV F(2) (e)	Authorisation to move fat derived from category 1 and 2 materials to other plants for combustion
Article 15(1)(c)	Article 10(3); An V Ch III S2 (1)	Authorisation to use alternative parameters for the transformation of animal by-products and derived products in biogas and composting plants approved under Article 24(1)(g) of Regulation (EC) No 1069/2009
Article 15(1)(c)	Article 10(3); An V Ch III S2 (2) and (3)	Authorisation to use other specific requirements for transformation of catering waste, mixtures of catering waste with other materials and certain derived products, in biogas and composting plants approved under Article 24(1)(g) of Regulation (EC) No 1069/2009
Article 15(1)(i); Article 32(1)	Article 22(1); An XI Ch I	Authorisation to use different standardised process parameters for processed manure, derived products from processed manure and guano from bats to be placed on the market, provided it is demonstrated they minimise biological risks
Article 16(b); Article 17(1) and (2)	Article 11 An VI Ch I S1	Authorisation to use category 1, 2 and 3 material for diagnostic, educational or research purposes, and to transport, use and dispose of research and diagnostic samples
Article 16(b); Article 17(2)	Article 12(1) An VI Ch I S1	Authorisation to transport, use and dispose of trade samples and display items for exhibitions and artistic activities
Article 21(1)	An VIII Ch I S4	Authorisation to collect and transport manure between two points on the same farm, or between farmers and

		users within the UK, without a commercial document or health certificate
Article 21(3)	An VIII Ch III 4	Authorisation to allow a different commercial document to accompany animal by-products and derived products transported within the UK
Article 23(1)(a) + (4)	Article 20(4); An XIII Ch VI	Authorisation to exempt certain operators (those handling/generating game trophies etc or handling/disposing of research and diagnostic samples for educational purposes) from the requirement to register
Article 40	Article 24(4); An XIII Ch V A	Authorisation to allow plants handling hides and skins, including limed hides, to supply trimmings and splittings for the production of gelatine for animal consumption, organic fertilisers or soil improvers
Article 40	Article 24(4); An XIII ChVII A	Authorisation not to dry untreated feathers, parts of feathers and down sent directly from a slaughterhouse to a processing plant

Annex B: Impact Assessment (to be attached)

Title:	Impact Assessment (IA)
Impact Assessment of England only domestic legislation implementing directly applicable EU Legislation: The Animal By-Products Regulation (EC) No. 1069/2009 **Lead department or agency:** Department for Environment, Food and Rural Affairs **Other departments or agencies:**	**IA No:** DEFRA1003 **Date: 04/01/2011** **Stage:** Development/Options **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** Neil Leach 020 7238 6509

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Animal By-Products (ABPs) can present a risk to human and animal health, and their disposal has been controlled for many years. Although generally effective, the current EU ABP Regulation 1774/2002 was reviewed in 2005 to update, simplify, and remove burdens; this resulted in the adoption of the revised ABP Regulation (EC) No.1069/2009. The accompanying Implementing Regulation for the new Regulation was agreed in October 2010. This IA considers the impact of the EU legislation, of the England only domestic draft SI (which provides enforcement powers and provides for national measures), and of the derogations available under the EU regulation. Similar legislation will apply in the rest of the UK.

What are the policy objectives and the intended effects?

The objectives of the new EU ABP Regulation and the domestic legislation to implement it are to introduce a set of updated rules on ABPs providing legal certainty, simplified requirements, and reductions in the burdens on operators. It also adapts current requirements in line with advancements in science and technology, and updates the categorisation of ABPs according to the risk they pose. The effect will be to make ABP controls more effective and efficient, while ensuring continued protection of public and animal health and food safety.

What policy options have been considered, including any "alternatives to regulation". Please justify the preferred option below.

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.

Will the policy be reviewed? It **will** be reviewed **What is the basis for this review? PIR**	**If applicable, set review date 03/2016** **If applicable, set sunset clause date**
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	**Yes**

Ministerial Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, a) it represents a reasonable view of the likely costs, benefits and impact of the leading options

Signed by the responsible Minister:..... Date:.....

Summary: Analysis and Evidence

Policy Option 1

Description:

Price Base Year 2010	PV Base Year 2011	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: £161m	**High:** £216m	**Best Estimate: £189m**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

Other key non-monetised costs by 'main affected groups'

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 (see below). Attempts were made to monetise cost increases but this has proved to be not possible without disproportionate effort. Cost increases are described and a broad qualitative net impact estimated in the table below.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		£34.5m	**£161m**
High	Optional		£46.2m	**£216m**
Best Estimate			£40.4m	**£189m**

Description and scale of key monetised benefits by 'main affected groups'

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.

Other key non-monetised benefits by 'main affected groups'

The regulation is broadly deregulatory affecting a diverse range of industrial sectors and some members of the public. Many of the non-monetised benefits are expected to be quite small. Attempts were made to monetise them but in many cases this has not been possible without disproportionate effort. Benefits are described and a broad qualitative net impact estimated in the table below.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

1. Any increase in disease risks, and subsequent impact on public & animal health as a consequence of deregulatory measures has been assessed as small and manageable (negligible increase in disease risk if we apply derogations in the ways proposed). This has been verified in several instances by formal veterinary assessments of the risks associated with implementing the derogations and national rules open to us in the EU Legislation (which is otherwise directly applicable) where that was considered appropriate .

2. The level of benefits actually achieved are dependent on take up by the affected sectors (if there is lower than expected take up then the benefits will be less).

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure classified as
Costs:	**Benefits:** £40m	**Net:** £40m	**Yes/No**	**OUT**

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			04/03/2011		
Which organisation(s) will enforce the policy?			Animal Health/local authortites/FSA		
What is the annual change in enforcement cost (£m)?			broadly zero		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	
Does the proposal have an impact on competition?			Yes		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	8
Small firms Small Firms Impact Test guidance	Yes	8
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	Yes	8
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	Yes	att
Rural proofing Rural Proofing Impact Test guidance	Yes	8
Sustainable development Sustainable Development Impact Test guidance	Yes	8

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

No.	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://defra.gov.uk/corporate/consult/animal-byproducts/index.htm

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs										
Annual recurring cost										
Total annual costs										
Transition benefits										
Annual recurring benefits	40.4	40.4	40.4	40.4	40.4					
Total annual benefits	40.4	40.4	40.4	40.4	40.4					

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office Excel Worksheet

Evidence Base (for summary sheets)

Problem under consideration

1. The current EU Animal By-Products (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 example as feed (including pet food), fertiliser and for technical products and lays down rules for their transformation through composting and biogas and their disposal via rendering and incineration. It also prevents catering waste being fed to livestock.

2. The Animal By-Products Regulations 2005 (SI 2347/2005) as amended provide for enforcement of the EU Regulation in England. Similar legislation applies in the rest of the UK.

3. The current EU ABP Regulation 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.

4. In 2005 the Commission submitted a report to the European Parliament and Council reflecting on the experience of Member States in implementing the 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 burdens. It also raised the issue that the Regulation needed to be updated to reflect new scientific/technological/practical experience since the adoption of the 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.

5. The Commission therefore issued a proposal to revise the EU Regulation to address these identified shortfalls and after extensive consultation a revised Regulation was adopted in April 2009, following a first reading agreement between the European Council and the European Parliament. The accompanying technical details (Implementing Rules) for the Regulation were agreed in October 2010. The implementing rules will enter into force simultaneously with the new Regulation on 4 March 2011. These regulations require enforcement provisions in domestic legislation to be put in place by the same date.

Rationale for intervention

6. To address this requirement in England, a Statutory Instrument (SI) will enforce the directly applicable requirements of the EU 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 SI. Similar domestic legislation will be put in place in the rest of the UK.

Policy objective

7. When putting in place replacement domestic legislation to implement the EU Regulation, the Government will seek to impose the minimum burden on industry consistent with meeting its obligations to enforce the EU ABP Regulation. The Government’s view is also that it should take advantage of all the potential derogations available to Member States unless there are public & animal health issues which override the potential benefits.

Risk Assessment

8. When considering the impact of the new regulations, we have carefully looked at any potential increase in disease risk and impact on public & animal health of implementing the potential derogations and national rules open to us. In most cases no increased disease risk was identified. In a number of areas formal veterinary risk assessments were used to quantify any risks and to inform our approach to controlling them. We also took account of consultation responses, and the views of key interested parties e.g. delivery bodies such as Animal Health & LACORS. Following evaluation of these views we concluded that where small increases in risk had been identified, these could be addressed by putting in place stringent conditions on use & disposal, and setting provisions in the SI to allow restrictions relating to animal and public health to be imposed where there was specific disease risk. In addition, Guidance on good practice will be made available.

Impact Assessment detail

9. This Impact Assessment summarises the overall requirements of the new Animal By-Product rules. The IA has been divided into two areas- section 1 looks at the impact of the EU Regulation (which when it was originally proposed was the subject of a partial IA, which this IA updates); and section 2 considers the domestic SI and discretionary national measures, and derogations that the competent authority may authorise. The impacts of these are set out in a table at the end of the section.

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

10. The earlier version of this partial impact assessement looked at the impact of the European Commisson'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:

a) clarifying the scope of the regulation in relation to end of the ABP life cycle;

b) application of the regulation to wild game;

c) updating risk categorisation of some ABPs;

d) duplication of approvals for certain premises; and

e) 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:

a) the burning of tallow,

b) the disposal of fallen stock,

c) the disposal of fish material at sea, and

d) the disposal of former foodstuffs.

11. An update on these areas is set out below.

a) 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 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.

Impact: Potentially several sectors impacted, including pharmaceuticals, oleochemicals, wool industry, pet food manufacturers and tanneries. **Benefits** will be greater legal clarity which will potentially remove some direct burdens on industry. We have not identified any new **costs** to industry from this change.

Overall impact is: Small benefit.

b) Wild Game: The current ABP Regulation does not cover ABPs derived from wild game processed in Approved Game Handling Establishments (AGHEs). This absence of ABP controls posed a potential risk to public & 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.

Impact: 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 material can now be sold e.g. for pet food.

Overall impact is: Small cost & benefit- no overall change

c) 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 (Category 1 is very high risk, category 2 high risk, and category 3 is low risk) would usefully increase the scope for their usage.

Impact: 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

d) 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- e.g. 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; e.g. *transporters* of ABPs, imposing a small additional cost.

Impact: 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.

e) Derogations for research, collection of ABPs with regard to human health & safety & natural disaster: *The latest position on these derogations and their proposed application in domestic legislation are described in more detail in the table of impacts below.*

f) Interaction of the ABP Regulation & 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 and where therefore there will be no longer 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 & subject to WID.

Impact: Rendering industry and other potential operators wishing to use ABPs as fuel will be affected. **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.

Overall impact is: Small benefit

g) **Disposal of fallen stock including horses:** The latest position on disposal of fallen horses is set out in the table of impacts below. The current regulation does not permit the use of bio-reducers (vessels for storing animal carcasses pending disposal) as a means of collection & 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.

Impact: 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: Potential small benefit.

h) **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

Impact: Issue shelved- no change.

i) **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.

Impact: No change.

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

12. Regulation 1069/2009 is directly applicable in all Member States. However, it does provide for certain areas of national discretion and derogations (listed in the table of impacts below). 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.

13. 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.

14. In terms of the other specific impacts at the foot of Page 3 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.

15. The Commission experienced similar problems in quantifying its own impact assessment when making the initial proposal to amend the EU regulation- 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.

Results of consultations

16. **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 SI, but to be addressed in subsequent authorisations for which the SI 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

17. 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.

18. 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 be permitted subject to strict guidelines.

19. On the derogation relating to **feeding certain ABPs to wild animals**, it was agreed that this should be permissible with the exception of feeding ABPs to wild boar (as in this case the risk from such feeding would outweigh any benefit). 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 foetuses 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.

20. 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 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.

21. 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.

22. 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.

A comprehensive table of cost/benefits for all these options can be found in the table below.

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Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. *If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date.* A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)]; The basis of the review will be policy driven i.e. in order to better quantify the costs and benefits of the Animal By-Products Regulation
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] The review objective is intended to establish the impact of the new Regulation on business
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] Scan of stakeholder views, as this is a new area which has not been looked at before this is the most appropriate mechanism for gathering this data
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] The current ABP Regulation- little data available at present
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] 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
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] Annual request for information from various industry bodies in form of questionnairre, results placed on website and data used to inform future policy decisions
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]