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FOOD STANDARDS AGENCY CONSULTATION

THE FOOD HYGIENE (ENGLAND)(AMENDMENT) REGULATIONS 2012

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
9 December 2011	2 March 2012

Who will this consultation be of most interest to?

Border Inspection Posts, businesses importing food, the farmed game industry and veterinarians working with the farmed game industry.

What is the subject of this consultation?

i) Draft of the Food Hygiene (England)(Amendment)Regulations 2012 which:

- give effect to recent EU food hygiene legislation
- provide for an 'ambulatory reference' that will automatically give effect to certain changes to the technical annexes of EU food regulations in future; and
- provide a special health mark to be applied to emergency slaughtered animals or their carcases; and

ii) Impact assessments on recent EU Regulations and a proposed EU Regulation.

What is the purpose of this consultation?

i) To let stakeholders comment on the current draft of the Food Hygiene (England) (Amendment) Regulations 2012, due to come into force in April 2012, noting in particular the 'ambulatory reference' and the health mark for meat from animals subject to 'emergency slaughter';

ii) to ask stakeholders for comments on the FSA's assessment of the impact of two areas of change to EU food hygiene legislation, relating to the import of composite products and the certification of farmed game as set out in two impact assessments;

ii) to ask stakeholders to indicate whether an impact assessment should be undertaken on any of the other changes to food hygiene legislation that are covered by this consultation, and

iv) to otherwise raise awareness among stakeholders about new and proposed EU legislation.

Responses to this consultation should be sent to:

Name David Gray
Division/Branch:
Hygiene & Microbiology
Tel: 020 7276 8940

Email:
EU.hygiene.amendments.2012@foodstandards.gsi.gov.uk
Postal address:
Food Standards Agency, Room 3C Aviation House, 125 Kingsway, London WC2B 6NH

Is an Impact Assessment included with this consultation?	Yes ☒	No ☐ See Annexe A for reason.

INVESTOR IN PEOPLE

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.

POSITIVE ABOUT DISABLED PEOPLE

CONSULTATION ON THE DRAFT FOOD HYGIENE (ENGLAND)(AMENDMENT) REGULATIONS 2012

Introduction

1. The principal EU Regulations covering food hygiene[1] are amended on a regular basis by other EU Regulations. While EU food hygiene Regulations apply *directly* in the UK, it is necessary for each country of the UK to make national law in the form of a Statutory Instrument (SI) to enable full application of the EU Regulations (e.g. to provide for the enforcement of new requirements of the EU regulations).

2. The SI that is the subject of this consultation (The Food Hygiene (England) (Amendment) Regulations 2012) is required to:

    a. give full effect to EU food hygiene regulations that have been made since April 2010[2] when the national food hygiene legislation was last amended;

    b. make provision for an 'ambulatory reference' that will in future automatically give effect to technical changes to EU food regulations without the need to make new national regulations to give effect to the changes; and

    c. introduce a national special health mark for carcases and packaged meat from 'emergency slaughtered' animals as required by EU law.

3. Similar consultations are being undertaken in Scotland, Wales and Northern Ireland.

4. Stakeholders should note that this proposed SI has already been consulted on in an earlier form between 31 March 2010 and 23 June 2010 as the Food Hygiene (England)(Amendment) (No 2) Regulations 2010. The ambulatory provisions (see 2b above) and the special health mark provisions (2c above) were included in that draft SI. The consultation documents and stakeholders' responses can be seen on the FSA's web site[3]. No objections were raised by stakeholders to the introduction of the ambulatory reference.

5. Since the March 2010 consultation closed, some amendments have been added to the SI; the ambulatory reference provision has been amended (detail in BOX 1) and as more recent EU Regulations have been adopted, where appropriate they have been added to the draft SI's Schedule 1 in order that the Schedule gives effect to the most recent EU Regulations (these are set out at Annex F).

6. The Food Standards Agency (FSA) is obliged to consult interested parties on all changes to food law, both EU and national and where there is any likelihood that the impacts of changes to laws may be significant, the FSA will make an impact assessment (IA) formally setting out its considered views on the costs and/or benefits

[1] Regulation (EC) No 852/2004 of 29 April 2004 on the hygiene of foodstuffs; Regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) No 854/2004 of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. There is also Regulation (EC) 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

[2] The Food Hygiene (England) (Amendment) Regulations 2010 (S.I. 2010/534).

[3] http://www.food.gov.uk/consultations/consulteng/2010/foodhygieneregs2010engamend2

of these changes. Impact assessments (IAs) are normally started at the early stage of the life of a proposed EU regulation and updated accordingly.

7. Two draft IAs are included in this consultation on which the FSA asks stakeholders to comment on its considered views on the costs and/or benefits of the following:

    a. changes to the documentation requirements for the import of composite products; and
    b. issues relating to the certification of the slaughter of farmed game.

    Regulation (EC) 1162/2009 and Regulation (EU) 150/2011 have both been cited in Schedule 1 of the draft Food Hygiene (England) (Amendment) Regulations 2012.

8. Throughout the IAs, questions for stakeholders to consider and respond to or comments drawing stakeholders' attentions to particular pieces of information are underlined.

The consultation package

9. Broadly the consultation falls into four main parts, which are set out below and are expanded on in paragraphs 11 through to 20. Further detail can also be found in Boxes 1 to 4. The four main parts are:

    a. the draft of the proposed Food Hygiene (England) (Amendment) Regulations 2012;
    b. the existing EU food hygiene Regulations that will be given effect by the proposed national regulations;
    c. proposed EU food hygiene Regulations; and
    d. two impact assessments on changes required under EU law relating to the documentation requirements for the (i) import of composite products and (ii) issues relating to the certification of the slaughter of farmed game.

10. The FSA asks whether stakeholders have any views on the current draft of the Food Hygiene (England) (Amendment) Regulations 2012, in particular noting the introduction of the ambulatory reference and the special health mark for meat from emergency slaughtered animals.

11. The FSA also asks for stakeholders' views on the two IAs on composite product imports and on the certification of farmed game as well as asking stakeholders to consider if the FSA should produce IAs on other EU Regulations covered or referred to by this consultation.

The draft national regulations

12. See Annexe D for copies of these regulations.

13. It is proposed that the Food Hygiene (England) (Amendment) Regulations 2012 ("the 2012 Regulations") will come into force on 1 April 2012. This SI will amend the Food Hygiene (England) Regulations 2006 and provide for the following three changes:

a. *gives effect in England to EU food hygiene Regulations* listed at Annex F that have been made since the national food hygiene legislation was last amended.

b. *introduces the ambulatory reference* so from the point that the 2012 Regulations come into force (expected to be April 2012) changes to EU technical rules (i.e. as found in the Annexes of EU Regulations) will be automatically given effect by the ambulatory reference (this SI has been amended since the previous consultation which ended in June 2010 to make it clear that this applies only to technical amendments). This effectively removes the necessity to write new national amending regulations each time EU Regulations are amended, although the FSA will continue to consult stakeholders on all proposals for EU Regulations. Stakeholders should see Box 1 for an explanation of how the ambulatory reference will operate and an explanation of how EU amendments published from now until 1 April are also to be given effect in English law; and

c. *introduces the special health mark* for meat from 'emergency slaughtered' animals to be applied to carcases and to packaging for meat from animals slaughtered outside of an approved establishment. UK countries are required to introduce such a mark by EU law. Stakeholders should see Box 2 for more detail about the special health mark.

BOX 1

The ambulatory reference

This confirms that an 'ambulatory reference' for the EU food hygiene Regulations becomes active with the coming into force of the Food Hygiene (England) (Amendment) Regulations 2012, which is expected to be in April 2012. This means that from April 2012, future amendments to the Annexes to EU Regulations or to Directives listed in Schedule 1 to the Food Hygiene Regulations (England) 2006 will be automatically given effect by the English legislation that executes and enforces them without the need to amend that English legislation each time there is a change to EU rules (i.e. to amend Schedule 1 to the 2006 Regulations.)

The wording of the ambulatory reference is slightly amended from the one that was included in the consultation in 2010. The new wording makes it clear that the ambulatory provision applies to amendments to the Annexes of Regulations (i.e. solely to technical amendments) and not to amendments that fundamentally alter the purpose or nature of the regulation contained in the Articles.

In regard to EU amending Regulations that may be adopted or published from now until before 1 April 2012 when the ambulatory reference becomes active, these will still be given effect by English national legislation from 1 April 2012. This is because a reference, in an amending SI (such as the Food Hygiene (England) (Amendment) Regulations 2012) to an EU instrument is deemed to be a reference to that EU instrument as amended at the time the SI is made.

BOX 2

Special health mark

The coming into force of the Food Hygiene (England) (Amendment) Regulations 2012 will introduce a special health mark to be applied to carcases of animals subject to 'emergency slaughter' on farm and the application of a similar special mark in meat plants producing packaged meat, meat products, meat preparations, minced meat and mechanically separated meat derived from such animals.

Existing EU food hygiene Regulations that will be given effect by the proposed national regulations

14. See Annexe F for a list of the EU Regulations and Box 3 for a detailed breakdown of all the new requirements.

15. A number of amendments to the principal EU food hygiene Regulations (see Annex E) have been published since the last amending SI came into force in March 2010. Where it is appropriate to refer to these EU Regulations in the 2012 Regulations (usually because they are the last amendment to those EU Regulations), they have been cited in a revised Schedule 1 attached to the 2012 Regulations. A list of the EU Regulations concerned together with links to copies of these EU Regulations can be found in Annex F. A full list of all EU food hygiene Regulations including the principal EU food hygiene Regulations and all of the amendments to those can be found on the FSA web site[4].

16. Other than for changes to the health import conditions for composite products at Article 3 of Regulation (EC) 1162/2009, the FSA has chosen not to make IAs for the other amending regulations as it considers that the impact of the amendments will be negligible.

17. Stakeholders are asked to note that Article 4 of Regulation (EC) 1162/2009 amending Regulation (EC) 853/2004 deals with composition criteria and labelling requirements for minced meat. Policy responsibility for this work transferred to the Department for Environment, Food and Rural Affairs (Defra) as part of machinery of Government changes following the General Election. Any enquiries on this issue should be emailed to: michael.talbot@defra.gsi.gov.uk

18. Stakeholders are invited to comment if they consider that Impact Assessments should also have been made for changes other than for the health import conditions for composite products. If stakeholders consider this to be the case, they are asked to provide any information on the costs and benefits which might result from the introduction of the Regulations concerned.

BOX 3

EU Regulations adopted since 2009

The EU Regulations set out below amend, clarify or provide transitional arrangements for other EU Regulations and will be of interest to industry, enforcers and the not-for-profit sector. In some cases recent EU Regulations have been cited in the Food

[4] http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/foodhygimptrans

Hygiene (England) (Amendment) Regulations 2012. These changes cover:

Regulations adopted since 2009 (reference in brackets)

- The making permanent of a transitional measure that allows livestock producers to provide food chain information to slaughterhouse operators when the animals are sent for slaughter rather than having to provide this information 24 hours in advance; (Regulation (EC) 1161/2009);

- transitional measure - continuation of the exemption for the direct supply of small quantities of meat from poultry and lagomorphs (rabbits and hares) to the final consumer; (Regulation (EC) 1162/2009);

- transitional measure – continuation of exemption of imports of composite products from requirements applying to the production of other food of animal origin (Regulation (EC) 1162/2009);

- transitional measure - accreditation of laboratories for the purposes of official controls on Trichinella (Regulation (EC) 1162/2009);

- amending official controls as regards harvesting outside of production areas for pectinidae and live marine gastropods not filter feeders (Regulation (EC) 505/2010)

- the hygiene of poultry and lagomorphs during/after cutting and boning - a requirement for slaughterhouse operators to chill meat from poultry and lagomorphs as soon as possible to 4°C before transport, but allowing the competent authority to authorise exceptions to this for the transport of livers for the production of foie gras (Regulation (EU) 558/2010);

- a requirement for meat from poultry and lagomorphs that is intended for freezing to be frozen without undue delay; (Regulation (EU) 558/2010)

- the transport or storage of fishery products (Regulation (EU) 558/2010);

- the extension of the lists of raw materials permitted in the production of gelatine and collagen for human consumption (Regulation EU) 558/2010);

- manufacture of ready-to-eat foods and of salt in terms of microbiological controls for Listeria monocytogenes (Regulation (EU) 365/2010);

- manufacture of pasteurised milk and other pasteurised liquid dairy products in terms of microbiological controls for Enterobacteriaceae (Regulation (EU) 365/2010);

- an amendment of the introductory information in the EU Regulation 853/2004 as regards live bivalve molluscs (Regulation (EC) 558/2010);

- official controls concerning pectinidae and live marine gastropods not filter feeders harvested outside classified production areas (Regulation (EU) 505/2010)

- further testing methods for detecting marine biotoxins in live bivalve molluscs (Regulation (EU) 15/2011)

- changes permitting FBOs to certify the slaughter of farmed and wild game in certain circumstances (Regulation (EU) 150/2011);

- changes to official veterinarian duties as regards the certification of the slaughter of farmed and wild game (Regulation (EU) 151/2011);

- changes to the duties of the official veterinarian as regards: ante and post-mortem inspection; laboratory testing; action following controls as regards infectious agents in the OIE lists; decisions concerning unfit meat and the frequency of controls (Regulation (EU) 739/2011);

- amending both animal health rules and the microbiological criteria Regulation as regards salmonella in fresh poultry meat (Regulation (EU) 1086/2011); and

- amending Annex I of Regulation (EC) 2075/2005 as regards equivalent methods for testing *Trichinella* .(Regulation (EU) No 1109/2011).

Proposed future EU Regulations that will automatically be given effect in England by virtue of the ambulatory reference (pdf copies at Annexe G)

19. See Box 4 for the current proposals for EU Regulations (see Impact Assessment at Annexe B with regard to sanco/10492/2010).

20. With regard to the proposal to amend Annex III of Regulation (EC) 853/2004 as regards requirements for FBOs concerning parasites in fishery products for human consumption (sanco/11487/2009), an Impact Assessment is being prepared separately by the FSA office in Scotland but will be issued for consultation on a UK basis.

BOX 4

Proposed regulations (current SANCO reference in brackets – please note such documents are subject to revisions):

- Proposal to lay down requirements for imports into and transit through the EU and amend Decision 2007/275/EC and Regulation (EC) 1162/2009 (sanco/10492/2010) – Stakeholders should refer to the Impact Assessment at Annexe B;

and

- Proposal to amend Annex III of Regulation (EC) 853/2004 as regards requirements for FBOs concerning parasites in fishery products for human consumption (sanco/11487/2009). (see paragraph 20 for further information)

Impact Assessments (IAs)

21. Copies of the full IAs can be found at Annexe B.

22. The FSA has provided two IAs showing the considered costs and benefits of adopted and proposed EU Regulations as follows.

    a. *imports of composite products* – the IA covers an EU Regulation (Article 3 of Regulation (EC) 1162/2009) and a proposed Regulation (SANCO/10492/2010) on the harmonisation of requirements for documentation for food of animal origin (FOAO) imported from third countries for animal health purposes with that of documentation for FOAO in composite products imported from third countries for public health purposes. This IA will be of particular interest to food importers and to enforcers at Border Inspection Posts (BIPs).

    b. *certification of farmed game* – the IA covers two EU Regulations: Regulation (EC) 150/2011 allows food business operators (FBOs) to certify that farmed game has been slaughtered and bled correctly and Regulation (EC) 151/2011 which requires the competent authority to carry out regular checks to verify that those slaughtering and bleeding farmed game are competent to do so. The IA sets out the history of the negotiations. This IA will be of interest to the farmed game industry and to veterinarians working with the farmed game industry.

23. Stakeholders are invited to consider and comment on the two IAs at Annexe B.

    Regulation (EC) 1162/2009 (related to 4a) and Regulation (EU) 150/2011 (related to 4b) have both been cited in Schedule 1 of the draft Food Hygiene (England) (Amendment) Regulations 2012.

BOX 5

Questions asked in this consultation: stakeholders are asked to consider the issues and questions included in the document and in the IAs, which ask specifically about the costs and benefits (if any) of the impact of the various Regulations.

The FSA is always keen to hear from stakeholders who may be affected by the amendments highlighted in the IAs. In particular, any information on specific costs and/or benefits resulting from the amendments or information about impacts that can be costed (e.g. whether an amendment results in food businesses taking more or less time to do something or whether there is an effect on competitiveness).

Consultation after the ambulatory reference is in force

24. Stakeholders can be reassured that the introduction of the ambulatory reference will not stop consultation on proposals for new EU Regulations issued by the European Commission. The FSA must ensure that stakeholders are properly consulted on all

changes to food law including the provision of assessments of the considered costs and benefits of any changes to the law on which stakeholders can comment. Reports of EU meetings where the policy amendments to the EU food hygiene Regulations are discussed are usually published on the FSA's website[5].

Responses

25. Responses are required by **2 March 2012**, ideally by email to:

    EU.hygiene.amendments.2012@foodstandards.gsi.gov.uk

26. Stakeholders wishing to return consultation responses by post may do so to:

    David Gray
    Food Standards Agency
    Aviation House
    Room 3c, 125 Kingsway
    London WC2B 6NH

27. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and please say if you do not wish your private details to be published.

28. It would also be helpful if you could state whether your organisation's response relates to the whole of the UK or specifically to England, Scotland, Wales or Northern Ireland or to any combination of those countries.

29. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

    Yours faithfully,

David Gray
Hygiene & Microbiology Division
Food Standards Agency

Attached:

Annexe A: Standard Consultation Information	Annexe E: List of the principal EU hygiene regulations (for information)
Annexe B: Impact Assessments	Annexe F: List of EU Regulations related to this consultation and web links to copies of them
Annexe C: List of interested parties	Annexe G: Copies of proposed EU Regulations
Annexe D: Draft of The Food Hygiene (England)(Amendment) Regulations 2012	

[5] www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/

Queries **ANNEXE A**

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc** Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of the Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annexe C. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.

7. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

8. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: **http://www.berr.gov.uk/files/file47158.pdf** The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult
Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 — Duration of consultation exercises
Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact
Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises
Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 Responsiveness of consultation exercises
Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 Capacity to consult
Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

9. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*.

10. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. **Please see paragraph 1b for more detail of impact assessments associated with this consultation.**

11. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

12. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc**

13. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc** The questionnaire can also be used to update us about your existing contact details.

Title:

The certification of the correct slaughter and bleeding of farmed game (Regulation (EU) 150/2011 and Regulation (EU) 151/2011)

Lead department or agency:
Food Standards Agency

Other departments or agencies:
none

Impact Assessment (IA)
IA No: FOOD0034
Date: 19/01/2011
Stage: Consultation
Source of intervention: EU
Type of measure: Secondary legislation
Contact for enquiries: Abi Abdul (Tel: 0207276 8386) Email: Abi.Abdul@foodstandards.gsi.gov.uk

Summary: Intervention and Options

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

Government intervention was needed to ensure that farmed game is allowed to be slaughtered and bled on the farm in a way that is comparable with the slaughter of animals in an abattoir, and that this can be certified by someone competent to assess that the slaughtering and bleeding has been performed correctly other than an official veterinarian or an approved veterinarian (OV/AV).

What are the policy objectives and the intended effects?

To allow food business operators (FBOs) to continue to carry out the certification of the correct slaughter and bleeding of farmed game, including the date and time of slaughter at the place of origin, subject to the FBO or their slaughterer having had appropriate training, rather than it have been necessary for this to be carried out by an OV/AV.

This has had the effect of allowing FBOs to continue to carry out on-farm slaughter and ensure the burden on the farmed game industry is minimised but with protection of public health remaining in place.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1. Do nothing.
Option 2. Implement the relevant requirements of Regulations 853/2004 and 854/2004 from 1 January 2010 until the coming into force of Regulations (EU) 150/2011 and Regulation (EU) 151/2011 on 11 March 2011.
Option 3. Implement Regulation (EU) 150/2011 and Regulation (EU) 151/2011 and give them effect in English law.

Option 3 is the preferred option. By comparison with Option 2, which would have remained the only Option had Regulation (EU) 150/2011 and Regulation (EU) 151/2011 not been adopted, the cost to FBOs is lower and the necessary level of public health protection has been maintained providing the FBO or the slaughterer has the appropriate training to undertake the certification.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date: June** 2016	
What is the basis for this review? Duty to review. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Not applicable

SELECT SIGNATORY Sign-off For consultation stage Impact Assessments:

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

Signed by the responsible Chief Executive: _____ Date: 7/12/11

URN 10/1268 Ver. 2.0 12/10

Summary: Analysis and Evidence

Policy Option 1

Description: Do nothing.

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	1	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	0		0	**0**

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

No incremental costs associated with this policy option

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

None

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	N/A	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	**N/A**

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

No incremental benefits associated with this policy option

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

None

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

There are no incremental costs associated with policy option 1 – *do nothing*, as it is the baseline to which all other options are compared.

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

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			13/06/2010		
Which organisation(s) will enforce the policy?			FSA		
What is the annual change in enforcement cost (£m)?			Unchanged		
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:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Distribution of annual cost (%) by organisation size (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. check page numbers

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	Yes	15
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	14
Small firms Small Firms Impact Test guidance	Yes	14
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	Throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	Yes	14

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes – this page is needed only for preferred option (see highlighted text below)

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

No.	Legislation or publication
1	
2	
3	
4	

stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures

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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring cost	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual costs	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

Summary: Analysis and Evidence

Policy Option 2

Description: Implemented the relevant requirements of Regulations 853/2004 and 854/2004 from 1 January 2010 until the coming into force of Regulations (EU) 150/2011 and Regulation (EU) 151/2011 on 11 March 2011.

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: - 0.69	**High: - 1.89**	**Best Estimate: - 1.29**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	1	0.08	0.69
High	N/A		0.22	1.89
Best Estimate	0.01		0.15	**1.29**

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

Total cost of policy option: £1.50m (Constant Prices). Total industry: £714k (Constant Prices) in inspection costs; £788k (Constant Prices) in certification cost; £525 in familiarisation costs. Total Local Authority: £6,116 in familiarisation costs.

The total equivalent annual cost of familiarisation to industry over 10 years is approximately £772

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

Non-monetised costs were not identified (see monetised costs above)

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	N/A	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	**N/A**

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

No monetised benefits; see non-monetised benefits below.

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

Regular OV/AV verification checks may benefit industry in terms of public perception over the welfare and slaughter conditions of animals.

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

Time taken for Industry and FSA to familiarise themselves with proposal: one hour. Equivalent Annual Costs (EAC) is applied to 'one-off' transition costs (familiarisation) in order to compare, on an equivalent basis, across policies spanning different time periods i.e. policies in excess of a one year time period.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: 0.15	**Benefits:** N/A	**Net:** 0.15	No	IN/OUT

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			13/06/11		
Which organisation(s) will enforce the policy?			FSA		
What is the annual change in enforcement cost (£m)?			Unchanged		
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:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** 83%	**< 20** 0%	**Small** 15%	**Medium** 2%	**Large** 0%
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. check page numbers

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[2] Statutory Equality Duties Impact Test guidance	Yes	15
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	14
Small firms Small Firms Impact Test guidance	Yes	14
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	Throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	Yes	14

[2] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes – this page is needed only for preferred option (see highlighted text below)

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

No.	Legislation or publication
5	
6	
7	
8	

stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures

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	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
Annual recurring cost	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150	0.150
Total annual costs	0.151	0.151	0.151	0.151	0.151	0.151	0.151	0.151	0.151	0.151
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

Summary: Analysis and Evidence

Policy Option 3

Description: Implement Regulation (EU) 150/2011 and Regulation (EU) 151/2011 and give them effect in English law to allow certification of correct slaughter and bleeding by the FBO subject to the FBO or their slaughterer having had appropriate training and subject to verification checks by the OV/AV.

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -0.007	**High:** -0.010	**Best Estimate: -0.008**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	0.0002	**0.007**
High	Optional		0.0005	**0.010**
Best Estimate	0.006		0.0003	**0.008**

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

Total cost of policy option in England: £9k (Constant Prices). Total industry: £3k in verification costs; £6k in initial training costs.

Over a 10 year period the Equivalent Annual Net Cost of initial one-off training in England is approximately £646

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

Non-monetised costs were not identified

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

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

No monetised benefits; see non-monetised benefits below.

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

Regular OV/AV verification checks may benefit industry in terms of public perception over the welfare and slaughter conditions of animals.

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

We have assumed that one employee per business will attend initial training based on the opportunity cost of a farmer attending training for two days. Equivalent Annual Net Costs (EANC) is applied to 'one-off' transition costs' (initial one-off training) in order to compare, on an equivalent basis, across policies spanning different time periods i.e. policies in excess of a one year time period.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: 0.001	**Benefits:** N/A	**Net:** 0.001	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/03/2010		
Which organisation(s) will enforce the policy?			FSA		
What is the annual change in enforcement cost (£m)?			Unchanged		
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:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** 83%	**< 20** 0.000	**Small** 15%	**Medium** 2%	**Large** 0.000
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. Check page references when complete

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	Yes	15
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	14
Small firms Small Firms Impact Test guidance	Yes	14
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	Throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	Yes	14

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain 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
9	Regulation (EU) 150/2011: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:046:0014:0016:EN:PDF
10	Regulation (EU) 151/2011: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:046:0017:0020:EN:PDF
11	
12	

+ 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	0.0056	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring cost	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003
Total annual costs	0.0059	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

* 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. Under transitional arrangements in place from 1 January 2006 until 31 December 2009 food business operators (FBOs) were able to undertake the certification of the correct slaughter and bleeding and the date and time of slaughter of farmed game[4] at the point of origin. The transitional arrangements allowed practices to continue that were in place before 1 January 2006 (i.e. the date at which Regulation (EC) 853/2004 and Regulation (EC) 854/2004 applied).

2. To ensure that FBOs carrying out the certification of farmed game at the point of origin could continue to do so after 31 December 2009 (i.e. when the transitional arrangements expired), government intervention in the form of amendments to Regulation (EC) 853/2004 and Regulation (EC) 854/2004 were required. Otherwise, it would have become a requirement for the certification task to be performed by an Official Veterinarian (OV) or Approved Veterinarian (AV) at additional cost to the industry with no improvement in public health protection.

Rationale for Intervention

3. Consumers, retailers and food manufacturers need to be confident that meat is of the nature, substance, and quality that they wish to buy, but they cannot assess this fully from its appearance when it is offered for sale. Government intervention in the form of regulation is needed to ensure that farmed game slaughtered on farm is killed and bled correctly to ensure that the meat is of the necessary hygienic standard. Government intervention therefore ensures that public confidence is maintained, and that the risk of meat-borne disease is managed appropriately. Consequently, meat official controls are carried out by competent authorities in order that these objectives are achieved. These controls need to be risk-based and proportionate, with all the costs of compliance fully justified by the benefits.

Policy objective and Intended effect

4. During negotiations at EU level, the UK's intention was to maintain sufficient official controls at the place of origin, (i.e. place of slaughter) to ensure that public health is protected, while at the same time ensuring these controls were not unnecessarily burdensome for the FBOs affected nor for the Food Standards Agency (FSA - which is the competent authority on farms where farmed game (in England this is almost exclusively deer) is slaughtered for human consumption). Slaughter of farmed game animals is carried out on farm as this is beneficial from an animal welfare perspective.

5. There are two linked Regulations (Regulation (EU) 150/2011 and Regulation (EU) 151/2011[5]) that from March 2011amend the EU food hygiene Regulations (Regulation (EC) 853/2004 and Regulation (EC) 854/2004) respectively, which allow FBOs to certify that the correct slaughter and bleeding of farmed game has taken place and the date and time of slaughter. These Regulations now require the FBO or those carrying out the slaughter and bleeding of the animals to be competent to perform these tasks. They also require regular checks by Official or Approved Veterinarians (OVs or AVs) to assess the performance of those who shoot and bleed farmed game on the farm.

[4] "Farmed game" is defined in Regulation (EC) 853/2004, Annex 1 as farmed ratites (ostriches) and farmed land mammals (e.g. deer and alpacas) *but does not include* domestic ungulates, porcine, ovine, caprine and domestic solipeds. Bison also are not taken to slaughterhouses because it is unsafe to do so.

[5] As proposals they were titled SANCO/10308/2010 and SANCO/10309/2010 respectively.

6. Regulation (EU) 150/2011 and Regulation (EU) 151/2011 also make some amendments to the requirements for wild game. They allow the whole heads of wild animals susceptible to *Trichinella* infestation, such as wild boar, to be sent to an establishment for producing a hunting trophy, pending the result of the required test for *Trichinella,* provided that there is full traceability. They also allow for a single declaration by a trained person to cover a number of large wild game animals, rather than requiring a declaration for each animal to be provided. The declaration indicates that no evidence has been found following examination after killing that the meat presents a health risk and that the animal displayed no abnormal behaviour before it was shot.

7. These arrangements were introduced in June 2011.

Background

8. Regulation (EC) 854/2004[6] applied from 1 January 2006 and lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It requires the 'competent authority' (in England, the FSA) to ensure sufficient official controls are undertaken at the place of origin where farmed game is slaughtered, to protect public health.

9. A transitional measure in Regulation (EC) 2076/2005, in place until 31 December 2009, provided for an amendment to Regulation (EC) 854/2004 therefore continuing the arrangements that were in place under the previous hygiene legislation prior to 1 January 2006. This transitional measure waived the requirement for an Approved Veterinarian (AV) or an Official Veterinarian (OV) to be present when the animals were shot and bled following the ante mortem inspection of the animals which the AV or OV would otherwise have been required to carry out. If the transitional measure had not been in place, the OV or AV would have been required to certify that correct slaughter and bleeding had taken place or to certify the date and time of slaughter - instead, the transitional measure allowed this to continue to be done by the FBO. Regulation (EU) 150/2011 and Regulation (EU) 151/2011 allow the continuation of this practice subject to the FBO or their slaughterer having had appropriate training and being subjected to regular verification checks by the OV/AV; this has been welcomed by farmed game businesses.

10. Before the four-year exemption provided by Regulation (EC) 2076/2005 expired on 31 December 2009, the UK sought to continue the transitional arrangements but the European Commission indicated that these would not be extended. The UK therefore presented a proposal to the Commission in May 2009 to allow the FBO to certify the slaughter and bleeding of farmed wild game, subject to certain conditions. The UK's proposal was discussed at the Commission Working Group meeting on 21 September 2009 and received a large majority support from the Member States. Based on this support, the Commission agreed to take this issue forward and it put forward a suitable proposal at the Commission Working Group meeting on 11 November 2009. There were a number of subsequent Commission Working Group meetings as well as meetings of the Standing Committee on the Food Chain and Animal Health (SCOFCAH) to discuss a number of additional proposals, some of which related to wild game. The proposed measures were adopted at a meeting of SCOFCAH in September 2010 and were adopted and published in the EU Official Journal on 15 February 2011 (i.e. as Regulation (EU) 150/2011 and Regulation (EU) 151/2011).

[6] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0083:0127:EN:PDF

Sectors and groups affected Industry

11. The major industry stakeholder in the UK representing the farmed game sector is the British Deer Farmers Association (BDFA). Informal consultation with the BDFA indicated that there are between 500 and 600 deer farmers and approximately 35,000 farmed deer in the UK, of which approximately 10,000 are slaughtered annually. In England, there are 31 approved on-farm slaughter facilities for farmed deer.

12. The FSA considered that the rules covering the slaughter of farmed game in Regulation (EC) 853/2004 were disproportionate when seen with comparative rules covering wild game and the domestic slaughter of cattle, sheep, goats and pigs, which are killed with no veterinary involvement in the assessments of the correct slaughter and bleeding.

13. All farmed deer slaughtered on-farm in the UK are shot by trained marksmen/women holding a recognised qualification which includes the ability to bleed deer in the correct manner. An additional feature of the new legislation requires these trained marksmen/women to be authorised in the same way as slaughtermen working in an abattoir. This could be verified by a veterinarian and subject to a regular check to assess the performance of these marksmen/women.

14. Only trained marksmen/women proficient in the use of firearms and who hold an appropriate firearms certificate can currently carry out field slaughter of farmed deer with rifles. The adopted proposal would require those who shoot and bleed game on farm to hold a certificate of competence and be authorised in the same way as abattoir slaughtermen to carry out slaughter operations. This reflects the requirements in the new EU welfare at slaughter Regulation (1099/2009) which comes into force on 1 January 2013 and which will require the authorisation of all those who slaughter animals for human consumption whether they work in a slaughterhouse or on farm.

15. The number of on-farm slaughter establishments affected by the proposal is set out below in table 1 by country and size of business.

Question 1 – the Agency would be grateful if industry stakeholders could provide information telling us <u>which of the five categories of business they fall into</u> and /or <u>about the size of businesses</u> in the farmed game sector as covered by this IA.

Table 1 - Number of on-farm slaughter establishments by country

Location/ Firm Size	Micro	<20	Small	Medium	Large	Total
England	25	0	6	0	0	31
Wales	0	0	0	3	0	3
Scotland	9	0	1	0	0	10
GB	**34**	**0**	**7**	**3**	**0**	**44**

Note: Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; < 20 – 10-20 employees; Small – 20-49 employees; Medium – 50-249 employees; Large – more than 250 employees. Distribution of size of business is based on an estimate using FSA Operations data on approved establishments and previous consultation responses.

<u>Enforcement</u>

16. There should be no additional enforcement costs arising from these measures.

<u>Consumers</u>

17. Consumers can be reassured that the new measures require those carrying out the slaughter and bleeding of farmed deer to be competent to do so to the same standard as those carrying out these activities in a slaughterhouse.

Q2: Do you agree with our assessment of the sectors, distribution of size of business and groups affected? If not please state which other groups or size business should be included.

Options considered

18. The options considered were:

- **Option 1**: Do nothing. Following the expiry of the transitional measures on 31 December 2009, simply continue the practices that had been permitted by the transitional measures in non-compliance with Regulation (EC) 853/2004 and Regulation (EC) 854/2004. This would have meant no additional burdens for FBOs and competent authorities but was not permissible for any sustained length of time without approval from the European Commission.

- **Option 2:** Following the expiry of the transitional measures on 31 December 2009, apply the requirements of Regulations 853/2004 and 854/2004 for the first time. This would have required an Approved Veterinarian (AV) or Official Veterinarian (OV) to confirm that the animals were correctly slaughtered and bled at the place of origin from that date and would have meant additional unnecessary burdens for FBOs and the competent authority. This Option would also have become non-compliant from 11 March 2011.

- **Option 3**: In line with the now adopted Regulations 150/2011 and 151/2011, allow the certification of the correct slaughter and bleeding at the place of origin under the supervision of the FBO, subject to the FBO or their slaughterer having had appropriate training and being subject to regular verification checks by the OV/AV. Provide for national legislation to give effect to these Regulations. **Option 3 is the preferred Option.**

Q3. Do you agree that Option 3 is the preferable option? If not please state which would be your preferred option and why.

Costs and Benefits of Options

Costs

Option 1

19. Although there would have been a benefit of no additional costs arising from this Option, it does not comply with the requirements of the EU Regulations and the UK could be subject to infraction proceedings.

Option 2

Industry

Inspection costs

20. Farmers would have incurred inspection costs for an OV or AV carrying out an ante mortem inspection per slaughtering occasion. An average of 5-10 animals are slaughtered and inspected per occasion. It is assumed that 10,000 farmed deer are slaughtered annually in Great Britain (GB) at 44 approved on-farm slaughter facilities; approximately 227[7] animals per farm per annum. On average this equates to between approximately 23 - 45 slaughtering occasions per year.

21. It is envisaged that a typical inspection will last one hour with an additional two hours for travelling to and from the location; meaning a total inspection time of 3 hours. The cost per inspection can be quantified by multiplying the time a typical inspection takes (3 hours) by the hourly wage rate of an AV (£22.57[8]), which results in a cost per inspection of £67.70[9]. To quantify the annual inspection cost per farm we multiply the number of inspections carried out per farm (ranging from 23 – 45 per year) by cost per inspection (£67.70). We estimate an average inspection cost per farm of approximately £1,557 to £3,047 per year. In England we estimate the total average annual cost of inspections to farmers would range from £48,273 - £94,447[10]. Taking the midpoint we derive a best estimate of £71,360[11]. Table 2 displays the number of farms and the range of inspection costs by country.

Table 2– Inspection costs broken down by country

Country	Total cost of inspections (Lower Bound)	Total cost of inspections (Upper Bound)	Total cost of inspections (Best Estimate)
England	**£48,273**	**£94,447**	**£71,360**
Wales	£4,672	£9,140	£6,906
Scotland	£15,572	£30,467	£23,019
GB *	£68,516	£134,054	£101,285

Note: Figures may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

Q4. Do stakeholders agree with the assumptions and figures used to quantify inspection costs to industry?

Certification costs

22. We assume that the requirement for certification of slaughter and bleeding would have increased the cost from £45 per consignment of animals by an additional £45 - £90, depending on how long the process would have taken. Taking the midpoint we derive a best estimate of £67.50[12]. We estimate that between 713 and 1,395 slaughtering occasions are carried out each year in England[13]; resulting in an incremental annual total cost to industry for

[7] 10,000 animals slaughtered per annum / 44 on-farm slaughter GB establishments = 227
[8] Wage rate obtained from The Annual Survey of Household Earnings (2010) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of 'Veterinarians' is used (£17.36 plus 30% overheads)
[9] 3 hours * £22.57 = £67.70
[10] Lower bound estimate £48,273) = Cost per inspection per farm (£1,557.19) * Number of on-farm slaughter establishments in England (31)
Upper bound estimate (£94,447) = Cost per inspection per farm (£3,046.68) * Number of on-farm slaughter establishments in England (31)
[11] Calculated by taking the midpoint of the range: (£48,273+ £94,447)/2 =£71,360
[12] Calculated by taking the midpoint of the range: (£45 + £90)/2 = £67.50
[13] Lower bound estimate (713) = 23 inspections per annum per farm * 31 on-farm slaughtering establishments in England
Upper bound estimate (1395) = 45 inspections per annum per farm * 31 on-farm slaughtering establishments in England

certification of around £32,085 - £125,550 per year. Taking the midpoint we derive a best estimate of £78,818[14].Table 3 displays the incremental cost of certification.

Table 3 – Cost of certification broken down by country

Country	Total cost of certification (Lower Bound)	Total cost of certification (Upper Bound)	Total cost of certification (Best Estimate)
England	**£32,085**	**£125,550**	**£78,818**
Wales	£3,105	£12,150	£7,628
Scotland	£10,350	£40,500	£25,425
GB	£45,540	£178,200	£111,870

Note: Figures may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

Q5. Do stakeholders agree with the assumptions and figures used to quantify certification costs to industry?

Familiarisation Costs

23. There would have been a reading and familiarisation cost to farmed game establishments for reading Regulation (EC) 853/2004. It is estimated that it would have taken 1 hour per business to read and become familiar with the Regulation's requirements and disseminate this through the business. Based on current estimation there are 31 farmed game establishments operating in England that would have been directly affected. To quantify the one off familiarisation cost to industry we calculated the familiarisation cost per business by multiplying the hourly wage rate of a farm manager (£16.94)[15] by the one hour taken to understand the regulation, resulting in a familiarisation cost per business of £16.94[16]. To estimate the overall one off familiarisation cost to industry we multiply the familiarisation cost per firm by the number of businesses in England (31) affected by the regulation; which results in a one-off familiarisation cost to businesses of £525. Table 4 displays the familiarisation cost to industry broken down by country.

Table 4 – Industry familiarisation cost by country

Country	Number of Farmed Game Establishments	Total Familiarisation Cost
England	**31**	**£525**
Wales	3	£51
Scotland	10	£169
GB	44	£745

Note: Figures may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

[14] Calculated by taking the midpoint of the range: (£29,298 + £119,970)/2 = £74,633

[15] Wage rate obtained from The Annual Survey of Household Earnings (2010) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Managers In Farming, Horticulture, Forestry And Fishing' is used (£13.03 plus 30% overheads)

[16] 1 hour * £16.94 = £16.94

Equivalent Annual Costs (EAC)

24. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula[17] . Under Standard HMT Green book guidance a discount rate of 3.5% is used.

25. Total one-off familiarisation costs to industry in England have been estimated to total £525. This yields an EAC for industry in England of approximately £61 over 10 years and for GB as a whole approximately £87.

Table 5 – EAC to industry by country

Country	Industry EANC
England	**£61**
Wales	£6
Scotland	£20
GB	£87

Enforcement

Certification costs

26. There would have been no additional cost associated with the need to verify the competence including checks on certification of those who slaughter and bleed farmed deer as this could have been done when the AV or OV carried out an ante mortem inspection of the animals prior to slaughter.

Familiarisation Costs

27. There would have been a familiarisation cost to the Agency as OVs and AVs would have been required to have read and familiarised themselves with Regulation (EC) 853/2004 and Regulation (EC) 854/2004 and any relevant national legislation as they applied to this industry sector. We estimate that each OV would have invested 1 hour reading and familiarising themselves with the Regulations and disseminating to key staff in the organisation. To quantify the familiarisation cost to the Agency we need to calculate the familiarisation cost per OV reading the regulation. An hourly wage rate of £22.57[18] has been applied to an OV, and when multiplied by the reading time equates to a familiarisation cost per OV of £22.57. To quantify familiarisation costs to the Agency in England we multiply the familiarisation cost per OV by the number of OV's in England (271), which equates to a one-off familiarisation cost of £6,116[19] . Table 6 displays the number of OV's along with the familiarisation cost for the Agency broken down by country.

[17] The equivalent annual cost formula is as follows: EANCB = PVNCB/a_{tr}, Where a_{tr} is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^{j} \left(\frac{1}{1+r_i} \right)$$

PVNCB is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.
. http://www.hm-treasury.gov.uk/data_greenbook_index.htm

[18] Wage rate obtained from The Annual Survey of Household Earnings (2010) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Veterinarians' is used (£17.36 plus 30% overheads)

[19] 271 * £22.57 = £6,116

Table 6 – Familiarisation cost to the Agency

Country	Number of OV's	Total familiarisation cost
England	**271**	**£6,116**
Wales	35	£790
Scotland	52	£1,174
GB	358	£8,079

Note: Totals may not sum due to rounding. Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

Equivalent Annual Costs (EAC)

28. As with one off costs to industry the one off cost to the Agency requires equivalently annualising in line with Green Book guidance. The total one-off cost to the Agency in England is an estimated £6,116. This yields an EAC for industry in England of approximately £711 over 10 years and for GB as a whole approximately £939.

Table 7 – EAC to Local Authorities

Country	EAC
England	**£711**
Wales	£92
Scotland	£136
GB	£939

Q6. Do stakeholders agree with the one hour familiarisation time we have applied to industry and enforcement?

Total Cost of Policy Option 2

29. The total cost associated with policy Option 2 is estimated at between £803,580 and £2,199,971 over 10 years with a best estimate of £1,501,775; an annual average cost of £150,178. Once these costs are discounted at a rate of 3.5% over four years we obtain a present value total cost of £1,292,681. Total one-off and on-going costs associated with option 2 are presented in table 8.

Table 8 – Total Cost of Policy Option 2

Costs	Year 0 2010/11	Year 1 2011/12	Year 2 2012/13	Year 3 2013/14	year 4 2014/15	Year 5 2015/16	Year 6 2016/17	Year 7 2017/18	Year 8 2018/19	Year 9 2019/20	Total Cost	Average Annual	NPV
One-off Costs													
Familiarisation cost to industry	£525										£525	£525	£525
Familiarisation cost to Enforcement	£6,116										£6,116	£6,116	£6,116
Total One-off Costs	£6,641										£6,641	£6,641	£6,641
On-going Costs													
Industry - Inspection													
Best Estimate	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£71,360	£713,600	£71,360	£614,245
Lower Bound	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£48,273	£482,730	£48,273	£415,518
Upper Bound	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£94,447	£944,471	£94,447	£812,971
Industry - Certification													
Best Estimate	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£78,818	£788,175	£78,818	£678,436
Lower Bound	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£32,085	£320,850	£32,085	£276,178
Upper Bound	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£125,550	£1,255,500	£125,550	£1,080,695
Total Cost													
Best Estimate	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£150,178	£1,501,775	£150,178	£1,292,681
Lower Bound	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£80,358	£803,580	£80,358	£691,696
Upper Bound	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£219,997	£2,199,971	£219,997	£1,893,666

Option 3

Industry

Verification Costs

30. **This is the preferred Option** as it will allow FBOs to continue to carry out on-farm slaughter while ensuring the burden on the deer farming industry is minimised and with the adequate protection of public health remaining in place

31. There may be some small additional costs for the FBO. There will be an additional cost arising from the verification check on the competence of the person carrying out slaughter and bleeding operations. Although this will fall to a person, who is unlikely in most cases to be the FBO, the cost is likely to be passed on to the FBO as part of the overall cost of carrying out this work. The verification checks will need to be carried out on a regular basis but could be once every 2-3 years at a cost of about £20 - £30 each time. Taking the midpoint we derive a best estimate of £25 per verification. To account for the uncertainty surrounding the frequency and cost of verification checks, ranges have been applied. With the frequency of verification checks ranging from every 2 to 3 years; we estimate that between 10 and 16 on-farm slaughter establishments in England will be verified each year. Table 9 displays the number of establishments verified each year by country.

Table 9 – Number of establishments verified each year

	Number of Verifications - Lower Bound	Number of Verifications - Upper Bound	Number of Verifications - Best Estimate
England	**10**	**16**	**13**
Wales	1	2	1
Scotland	3	5	4
GB Total	15	22	18

Note: Totals may not sum due to rounding

32. To calculate the average annual cost to industry we multiply the upper and lower bound annual frequency of verification checks as shown in table 2 by the cost per verification, which results in an average annual verification cost in England of £207 to £465. Taking the midpoint we derive a best estimate of £336. Table 10 displays the average annual cost of verification by country.

Table 10 – Verification costs to industry by country

	Lower Bound Verification Cost	Upper Bound Verification Cost	Best Estimate Verification Cost
England	**£207**	**£465**	**£336**
Wales	£20	£45	£33
Scotland	£67	£150	£108
GB Total	£293	£660	£477

Note: Totals may not sum due to rounding

Q7. Do stakeholders agree with the assumptions and figures used to quantify verification costs to industry?

Training Costs

33. There may be a small additional burden for those that undertake the slaughter and bleeding to undertake the necessary training. However, for those who currently carry out this work the Agency will seek to establish whether the training that they have carried out in the past is sufficient to meet the needs of this element of the proposal that such people who slaughter and bleed farmed game are competent to do so. We understand that a number of those who carry out this work are already trained to act as the trained person in wild game hunting parties. We have assumed that one employee per business will attend initial training. It is estimated that the average one-off training cost to industry in England would equate to approximately £5,563. The cost of training is based on the opportunity cost of a farmer attending training for two days. The training cost applied is quantified by multiplying two working days of a farmer lost to training (14 hours) by the hourly wage rate of a farmer (£12.82[20]), which equates to a cost per farmer being trained of £179.45. Table 11 displays the training costs to business by country.

Table 11 – Training costs to industry by country

	Training cost
England	**£5,563**
Wales	£538
Scotland	£1,795
GB	£7,896

[20] Wage rate obtained from The Annual Survey of Household Earnings (2010) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Farmers' is used (£9.86 plus 30% overheads)

Note: Totals may not sum due to rounding

Equivalent Annual Net Costs (EANC)

34. It is necessary to equivalently annualise one off costs in line with Green Book guidance. The total one-off costs to industry in England have been estimated as £5,563. This yields an EANC for industry in England of approximately £646 over 10 years and for GB as a whole approximately £917.

Table 12 – EANC to Industry by country

	EANC
England	**£646**
Wales	£63
Scotland	£208
GB	£917

Note: Totals may not sum due to rounding

Total Cost of Policy Option 3

35. The total cost associated with policy Option 3 is estimated at between £7,630 and £10,213 over 10 years with a best estimate of £8,921; an annual average cost of £892. Once these costs are discounted at a rate of 3.5% over four years we obtain a present value total cost of £7,872. Total one-off and on-going costs associated with option 3 are presented in table 13.

Table 13 – Total Cost of Policy Option 3

Costs	Year 0 2010/11	Year 1 2011/12	Year 2 2012/13	Year 3 2013/14	year 4 2014/15	Year 5 2015/16	Year 6 2016/17	Year 7 2017/18	Year 8 2018/19	Year 9 2019/20	Total Cost	Average Annual	NPV
One-off Costs													
Training costs to industry	£5,563	£0	£0	£0	£0	£0	£0	£0	£0	£0	£5,563	£5,563	£5,563
Total One-off Costs	£5,563	£0	£0	£0	£0	£0	£0	£0	£0	£0	£5,563	£5,563	£5,563
On-going Costs													
Industry - Vertification													
Best Estimate	£336	£336	£336	£336	£336	£336	£336	£336	£336	£336	£3,358	£336	£2,309
Lower Bound	£207	£207	£207	£207	£207	£207	£207	£207	£207	£207	£2,067	£207	£1,421
Upper Bound	£465	£465	£465	£465	£465	£465	£465	£465	£465	£465	£4,650	£465	£3,196
Total Cost													
Best Estimate	£5,899	£336	£336	£336	£336	£336	£336	£336	£336	£336	£8,921	£892	£7,872
Lower Bound	£5,770	£207	£207	£207	£207	£207	£207	£207	£207	£207	£7,630	£763	£6,984
Upper Bound	£6,028	£465	£465	£465	£465	£465	£465	£465	£465	£465	£10,213	£1,021	£8,759

Q8: Are the costs described above a good estimate of impact on business and public sector of the each of the options being considered? Further evidence of the impact would be welcome.

Benefits

Option 1

36. There are no incremental benefits associated with this option. This option is the baseline for comparison.

Option 2

37. Compared to option 3 this is a more costly option with little or no additional benefit. Industry may benefit in terms of public perception over animal welfare as option 2 would require an AV and OV to confirm that animals were correctly slaughtered and bled in line with animal welfare considerations.

38. No additional benefit would have arisen from the need for an OV or AV to verify that animals were slaughtered and bled correctly as the OV in a slaughterhouse is not required to provide similar verification that all animals were slaughtered and bled correctly in a slaughterhouse. Regular OV/AV verification checks may benefit industry in terms of public perception over the welfare and slaughter conditions of animals, but this is difficult to quantify.

Enforcement

39. No particular benefits for enforcement were envisaged although the cost of this option would be much greater for the industry with little or no additional benefit in public health terms.

Consumer

40. The benefit for the consumer arises from the requirement for farmed deer to be slaughtered and bled correctly and for this to be verified. This provides assurance that farmed deer are slaughtered and bled by competent persons in the same way that animals in a slaughterhouse would be and ensures that animal welfare is not compromised and that the animals are bled hygienically.

Option 3

Industry

41. The main benefit for industry arising with this option is reduced costs when compared with option 2

Enforcement

42. There are no particular benefits for enforcement.

Consumer

43. The benefit for the consumer arises from the requirement for farmed deer to be slaughtered and bled correctly and for this to be verified. This provides assurance that farmed deer are slaughtered and bled by competent persons in the same way that animals in a slaughterhouse would be and ensures that animal welfare is not compromised and that the animals are bled hygienically.

Q9: Are the benefits described above a good estimate of beneficial impact on business and public sector costs of the each of the options being considered? Further evidence of the benefits would be welcome.

Administrative Burden Costs

44. Informal consultation with Industry suggested that the administrative burden costs would be minimal compared to when an OV/AV would have to be present every time animals are shot and bled. Also, it is likely that the authorisation for FBOs would be in the form of a 'certificate of competence' to be issued by the OV/AV. There will be a cost attached to the time involved and this will be a new cost for FBOs or those that slaughter and shoot farmed game but it is not expected to be significant.

Consultation

45. The original UK proposal for amendment of Regulation (EC) 853/3004 and Regulation (EC) 854/2004 (as described in paragraph 10) was developed with the knowledge and support of the farmed game sector which was worried about the increased cost likely to arise in 2010 following the end of the transitional measure. The BDFA fully supports the way that the UK has sought to keep additional burdens on the industry to a minimum during negotiations. The BDFA believed that the additional cost of requiring a veterinarian to come to a farm to attest to the correct slaughter and bleeding and the time and date of slaughter would have rendered their businesses uneconomic.

Enforcement

46. The FSA remains responsible for enforcement of official controls. FBOs performing official control duties will do so subject to the FBO or their slaughterer having had appropriate training and the FBO or those that slaughter and bleed the animals being subject to regular verification checks by the OV or AV.

Simplification

47. The measure can allow businesses to retain the flexibility to carry out official controls, which can reduce their costs of operation. It also allows some further flexibility with the declarations required by the trained person for wild game.

Implementation and Review

48. The EU Regulations have applied from 11 March 2011. A review will take place in June 2016.

Annexes – Specific Impact Tests

Competition Assessment

49. The requirements of Regulation (EU) 150/2011 and Regulation (EU) 151/2011 are not expected to either directly or indirectly limit the number or range of suppliers. It should

not limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.

50. As a result of the application of the new EU regulations, the market for FBOs or those undertaking the certification of correct slaughter and bleeding or the date and time of slaughter should actually open and encourage competition. This would encourage efficiency in official controls in the farmed game sector. As the number of deer farmers in the UK is estimated at between 500 and 600, there is obviously a limited number of trained marksmen/women who are proficient in the use of firearms and who hold an appropriate firearms certificate to carry out field slaughter with rifles. This will encourage an ongoing level of turnover that will support a small market for training and/or contracting. That market will be open to all interested parties.

Small Firms Impact Test

51. Approximately 500 farmers are engaged in deer farming in the UK and most are small enterprises. Throughout 2009, the FSA consulted with deer farmers through their trade association, the British Deer Farmers Association (BDFA). The BDFA believed that the additional cost of requiring a veterinarian to come to a deer farm to attest to the correct slaughter and bleeding and the time and date of slaughter would have rendered the deer business uneconomic. The BDFA was keen for the Agency to submit a proposal to the Commission in May 2009 that allowed the FBO to continue to certify that correct slaughter and bleeding had taken place, once it became clear that the transitional arrangements could not be extended.

Sustainable development

52. Regulation (EU) 150/2011 and Regulation (EU) 151/2011 will have little, if any impact, on the delivery of the principles of the three pillars of sustainable development, particularly on the environment, or in relation to public health. With the strong support of farmed game operators the effect of the new regulations will give deer farmers the incentive to be more efficient, and to decrease the total costs of official controls. These enable resources to be reduced, with the FSA ensuring that this does not compromise the level of health protection. This should contribute to more sustainable decision making.

Race equality issues

53. No impact on race equality is anticipated.

Gender equality issues

54. No impact on gender equality is anticipated.

Disability equality issues

55. No impact on disability equality is anticipated.

Q10: Are stakeholders aware of any impacts under the specific impact tests from the amendment? Any evidence that stakeholders can provide to support those views will be helpful.

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)];
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?]
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]
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]
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]
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]
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]

Add annexes here.

Title: **Changes to Import Certificates for 'composite products' (SANCO/10492/2010)**	Impact Assessment (IA)
Lead department or agency: Food Standards Agency	**IA No:** 0063
Other departments or agencies: Defra	**Date: 15/08/2011**
	Stage: Consultation
	Source of intervention: EU
	Type of measure: Primary legislation
	Contact for enquiries: Liz Stretton (020 7276 8357) Email: liz.stretton@foodstandards.gsi.gov.uk

Summary: Intervention and Options

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

Currently there is inconsistency between the requirements for animal health purposes and public health purposes relating to the importation of food of animal origin (FOAO).'Composite products' (i.e. foodstuffs made both of processed FOAO and food of plant matter) are not subject to the same official animal health control checks at EU borders that apply to other FOAO. This is due to an exemption in place until December 2013 allowing exporters in third countries to adjust to changes in EU food hygiene rules which they would otherwise have to meet. In light of the exemption ending, Government intervention is required to ensure that regulations covering these areas are harmonised and consistent.

What are the policy objectives and the intended effects?

To ensure that the hygiene requirements for FOAO in composite products are covered by similar documentation as other FOAO imported from third countries into the European Union, thus harmonising the animal health controls of FOAO in composite products with animal health controls for other FOAO.

This will ensure that food safety measures are fully in place to protect public health in regard to all imports into the European Union of FOAO which potentially could cause a risk to human health.

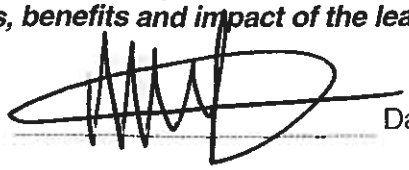
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

1. Do nothing - allow the current transitional measures containing the exemption to fall.
2. Comply with the requirements of Article 6.4 of Regulation (EC) No 853/2004 through introducing staged compliance providing industry with time to comply. There is a benefit from government intervention both to require proof that the required hygiene standards are being met with the production of a health certificate from the food business operators and that this provides enforcement agencies with information enabling them to enforce the requirements. **This is the preferred option.**
3. Issue guidance.
4. Negotiate with the European Commission to extend the derogation.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 2/2016	
What is the basis for this review? Duty to review. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Not applicable

SELECT SIGNATORY Sign-off For consultation stage Impact Assessments:

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

Signed by the responsible SELECT SIGNATORY:  Date: 7/12/11

URN 10/1268 Ver. 2.0 12/10

Summary: Analysis and Evidence

Policy Option 2

Description: Comply with the obligation to meet the requirements of Article 6.4 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply. This is the preferred

Price Base Year 2010	PV Base Year 2010	Time Period Years10	Net Benefit (Present Value (PV)) (£)		
			Low: Optional	**High:** Optional	**Best Estimate: -127k**

COSTS (£)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	1	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	127k		N/A	**127K**

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

Total UK cost of policy option (constant price): £127k. Total UK industry: £112.5k one-off familiarisation costs. Total one-off familiarisation costs to UK LAs and PHAs: £14.5k.

Over a 10-year period the total equivalent annual cost of familiarisation for industry is estimated to be approximately £13.1k.

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

None identified. See below for key assumptions.

BENEFITS (£)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

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

None identified. See below for non-monetised benefits.

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

Help facilitate trade as FBOs would be able to trade composite products across Member States if they are compliant with the correct certification when entering another Member State.

Will enhance and strengthen current food safety measures, protect human health and assist with traceability of foods.

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

It is anticipated that there will be limited costs to industry as many food business operators already provide health certificates for foodstuffs which technically do not currently require them under the legislation.

Time taken for Industry to familiarise themselves with proposal: 2 hours

Time taken for LAs and PHAs to familiarise themselves with proposal: 1 hour and 30 minutes

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: 0.01	**Benefits:**	**Net:** 0.01	No	IN/OUT

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/03/2012		
Which organisation(s) will enforce the policy?			FSA		
What is the annual change in enforcement cost (£m)?			0		
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?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**		**Benefits:**
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** N/A	**< 20** N/A	**Small** N/A	**Medium** N/A	**Large** N/A
Are any of these organisations exempt?	Yes/No	Yes/No	Yes/No	Yes/No	Yes/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	Yes	13
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	13
Small firms Small Firms Impact Test guidance	Yes	13
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	Throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	Yes	13

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain 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	Regulation (EC) 1162/2009: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0010:0012:EN:PDF
2	SANCO/10492/2010 (***Draft Regulation****) laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009*
3	
4	

+ 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	0.13	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Annual recurring cost	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total annual costs	0.13	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total annual benefits	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

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

Evidence Base (for summary sheets)

Problem under consideration

1. There is currently a derogation[1] which means that food business operators who import 'composite products' (i.e. products which contain both products of plant origin and processed products of animal origin) from third countries[2] do not have to meet the same requirements as imports of products of animal origin. Products of animal origin being imported into the EU have to have come from approved premises in approved countries and be accompanied by a health certificate.
2. The European Commission has proposed that the transitional measures providing the derogation should fall by the end of February 2012. This proposal aims to harmonise the requirements for the importation of food containing both processed products of animal origin and products of plant origin into the European Union with the existing requirements for animal health purposes, during which time consideration can be given to whether the public health measures suggested are appropriate for composite products.

Rationale for intervention

3. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies government intervention is required.
4. This means that there is a benefit from government intervention both to require proof that hygiene standards which are required are being met in the form of the production of a health certificate from the food business operators and that enforcement agencies are being provided with suitable information to enable them to enforce the requirements.
5. If the UK does not take the necessary steps to apply the requirement, it could lead to UK industry being put at a disadvantage as it would no longer be able to trade composite products across Member States if they are not accompanied by the correct certification when entering another Member State. It would also prevent UK businesses from importing composite products from third countries if the requirement to provide the health certificate is not met. It would also mean the UK would be in breach of European legislation which could lead to infraction proceedings being brought against the UK.

Policy Objective and intended effect

6. The underlying policy objective is to ensure that all food products entering the European Union are produced safety, hygienically and present no risk to human health. By harmonising the requirements for animal health and composite food products, this will ensure that all food products which contain product of animal origin are treated in the same manner and should ensure that food safety for consumers is improved.

Additional information relating to co-decision

7. The Commission is currently looking at the issues involving the importation of composite products as part of the work which it is undertaking on amending the hygiene package via co-decision. This work is independent of the proposals which are discussed in this Impact Assessment and does not at this time impact this work. If the Commission does take forward its proposals re the hygiene package, the UK will negotiate and will undertake to keep stakeholders informed.

[1] Regulation (EC) No 1162/2009 provides transitional measures and applies from 1 January 2010 until 31 December 2013. Article 3 of 1162/2009 provides a derogation from Article 6.4 of Regulation (EC) No 853/2004.

[2] Countries outside the European Union

Options considered

8. Four options have been considered:

Option 1 - Do nothing; allow the current derogation to fall at the end of February 2012.

Option 2 – Comply with the obligation to meet the requirements of Article 6.4 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply.

Option 3 – Issue guidance.

Option 4 – Negotiate with the European Commission to extend the derogation

In summary: Option 2 is the preferred Option because there is a benefit from intervention both to require proof that the required hygiene standards are being met with the production of a health certificate from the food business operators and that this provides enforcement agencies with information enabling them to enforce the requirements.

An assessment of each option is set out below:

Option 1 – do nothing and allow the current derogation to fall at the end of February 2012

9. If the UK did not comply with the rules after the current derogation falls at the end of February 2012, the UK could be subject to infraction proceedings by the EU. Non-compliance could have implications for businesses and trade as if they did not ensure the correct health certificates were completed, they would be unable to import their products into the EU or trade them within the Member States. There would be no improvement to, and possibly a worsening of, the risk to public health.

Option 2 – apply the rules on the coming into force of the Regulation. This is the preferred policy option

10. Support the obligation for businesses in third countries exporting into the EU to meet the requirements of Article 6.4 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply. The staged compliance involves the introduction of the certification for the products listed in the second bullet point below from 1 March 2012, then subject to the outcome of the EU's scientific committees' consideration, the requirements for all composite products from 1 January 2013. This period would run from 1 March 2012 until 31 December 2012 and would provide time for the EU's scientific committees to consider what public health measures are appropriate for composite products. This is the preferred policy option as it would:

- require that composite products which are imported into the EU which contain any processed meat, and composite products which contain half or more processed milk or fishery or egg product or other POAO content, and composite products which contain less than half milk product which does not meet certain conditions[3] will need to be accompanied by a health certificate. This will enhance current food safety measures by ensuring that composite products which are manufactured in third countries are produced to the same hygiene standards as stipulated in EU Regulations for other POAO foods;
- harmonise the public health requirements with the animal health requirements with advantages for the efficacy of enforcement of the animal health rules; and
- allow the UK to fulfil the UK's obligations under EU law.

[3] This where the final products in not shelf-stable at ambient temperature or where they have not clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance, so that any raw product is not denatured.

Option 3 – Issue guidance

11. This option has been considered and rejected on the grounds that any guidance provided would not be legally binding. It would not be a sufficient discharge of our Treaty obligation only to produce guidance when the expectation of the UK would be to have the systems in place to be able to enforce Regulation (EC) No 853/2004 if necessary.

Option 4 – Negotiate with the European Commission to extend the derogation

12. This option has been considered and rejected on the grounds that the original derogation was granted in order to allow Member States time to explore the most appropriate measures needed to apply the requirement. Member States, including the UK, agreed during the negotiations that this measure should be included in the final version of Regulation (EC) No 853/2004 as it would strengthen the measures which could be used to assist in the protection of human health. During the original negotiations, it was understood that the health import requirements for food of animal origin would not be completely harmonised for certain types of products and the import conditions applicable to such products during the transitional period should be made clear. It was agreed during the original negotiations that this derogation was a transitional measure which would come to an end at this time. There is little likelihood of success in influencing change to the legislation were negotiations to be opened up. The UK could be seen as reneging on its previous position which might mean other negotiations become more difficult with potentially worse comparable outcomes.

Costs and benefits

Sectors and groups affected

Industry

13. The Regulation will affect industry as it will have to ensure that all imported composite products as described in the first bullet point of paragraph 10 are accompanied by a new health certificate. This will mean that the FBO importer will need to be satisfied that all of the relevant POAO in the composite product which are required to have the health certificate are sourced from approved premises in approved countries. No substantial concerns were raised by industry during an informal consultation.

14. Informal consultation with enforcement officers at a Border Inspection Post (BIP) indicated that the majority of composite products imported into the European Union are already accompanied with a health certificate although they do not currently require one. If this is the case, then the impact of the proposal on industry should be minimal.

Q1: It is our assumption that there will be limited costs to industry as indications are that the majority of food business operators already provide health certificates for foodstuffs which do not currently require them under the legislation. We invite businesses to comment on this assessment particularly the costs of familiarisation. Do you agree? If not, please provide evidence to support your views.

15. Number and type of food import businesses likely to be directly affected. Including table showing the number firms by size and country (below):

Table 1 – Number of firms affected by proposal, by location and size.

Location/ Firm Size	Micro	Small	Medium	Large	Total
England	1,049	368	155	59	1,630
Wales	87	30	13	5	135
Scotland	212	74	31	12	330
NI	77	27	11	4	120
UK	**1,425**	**500**	**210**	**80**	**2,215**

Source: The Inter Departmental Business Register is accessible via the Office for National Statistics, http://www.statistics.gov.uk/idbr/idbr.asp

Notes:

1) Totals may not sum due to rounding
2) Figures are the sum of premises listed under SIC 10.13 Production of meat and poultry meat products, SIC 10.20 Processing and preserving of fish, crustaceans and molluscs, SIC 10.51 Operation of dairies and cheese making, SIC 10.52 Manufacture of ice cream, SIC 10.85 Manufacture of prepared meals and dishes and SIC 10.89 Manufacture of other food products n.e.c.
3) Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

Q2: Do stakeholders agree with the number and composition of businesses affected by this policy?

Enforcement

16. This proposal would replace and widen the remit of foodstuffs which require a health certificate. However, there would be a minimal impact on LAs or enforcement authorities as officials at BIPs already check existing health certificates when food is imported. Inland LAs are only likely to look at the certificate during investigations inland (for example of suspected illegal imports when they may seek documentation to check legality). This should not differ from the existing position.

Consumers

17. The impact on consumers should be positive in that this is a further measure to ensure the safety of food for human consumption entering the EU. It would provide assurance that the hygiene requirements in the countries where the products are produced meet the same requirements as within the EU**.** These measures should also increase consumer confidence in the product. The costs and benefits of options are set out below:

Costs

Option 1 – do nothing; allow the current derogation to fall at the end of February 2012.

18. There are no incremental costs to this option as it is the baseline against which the other options are compared. If the UK did not comply with the rules after the current derogation falls at the end of February 2012, the UK could be subject to infraction proceedings by the EU. Non-compliance could have implications for businesses and trade as if they did not ensure the correct health certificates were completed, they would be unable to import their products into the EU or trade them within the Member States. There would be no improvement to, and possibly a worsening of, the risk to public health.

Option 2 – Comply with the obligation to meet the requirements of Article 6 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply.

Industry

19. This will have a cost implication for businesses as they will need to ensure that their suppliers and the sources of their suppliers are all meeting the requirements of Article 6 of Regulation (EC) No 853/2004.

Familiarisation costs

20. There will be a one-off cost to industry for reading and familiarising themselves with the Regulation. It is estimated that it will take 1 hour per business to read and familiarise themselves with the new arrangements and a further 1 hour disseminating to key staff[4]. This means a total of 2 hours for familiarising. There are currently 2,215 food businesses operating in the UK which are directly affected by the proposal. Table 1 above displays the number of businesses affected in the UK broken down by location and size.

21. To quantify the one-off familiarisation cost to industry we calculate the familiarisation cost per business by multiplying the hourly wage rate of a 'business manager' of £25.39[5] by the 2 hours taken to understand the Regulation resulting in a familiarisation cost per business of £50.78[6]. To quantify the overall one-off familiarisation cost to industry we multiply the familiarisation cost per firm by the number of businesses affected by the regulation. This results in an average one-off familiarisation cost to UK businesses of £112,473. Table 2 displays the familiarisation cost to industry broken down by location and firm size.

Table 2 - Familiarisation costs to industry by location and business size

Location/ Firm Size	Micro	Small	Medium	Large	Total	Total Rounded
England	£53,248	£18,684	£7,847	£2,989	£82,768	£83,000
Wales	£4,410	£1,547	£650	£248	£6,855	£7,000
Scotland	£10,780	£3,783	£1,589	£605	£16,757	£17,000
NI	£3,920	£1,375	£578	£220	£6,093	£6,000
UK	**£72,359**	**£25,389**	**£10,663**	**£4,062**	**£112,473**	**£112,000**

Notes:
1) Totals may not sum due to rounding
2) Firm size is based on the number of employees within an organisation. Micro 0 - 9 employees, Small 10 – 49 employees, Medium 50 – 249 employees and Large 250+ employees

Equivalent Annual Net Costs (EANC)

22. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula[7]. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

23. A total one-off cost to industry affected by this proposal in the UK is an estimated £112,473. This yields an EANC of approximately £13,067 in the UK over 10 years. This breaks down to an EANC in England of £9,616, £796 in Wales, £1,947 in Scotland and £708 in Northern Ireland. Table 3 displays the breakdown of the EANC per country.

Table 3 –Equivalent Annual Net Costs (EANC) to industry by location

[4] While the FSA recognises that dissemination of information will result in an opportunity cost in terms of time of key staff members it is anticipated that this will be minimal and the additional hour will cover these costs.
[5] Wage rate obtained from The Annual Survey of Household Earnings, 2010) (See: http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of 'Production Manager' (£19.53 + 30% to cover overheads = £25.39).
[6] £50.78 = £25.39 (hourly wage rate) * 2 hours (familiarisation time)
[7] The equivalent annual cost formula is as follows: EAC=PVC/A, where A =[1-1/(1+r)^t]/r, where PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

Location	Industry EANC
England	£9,616
Wales	£796
Scotland	£1,947
NI	£708
UK	**£13,067**

Note: Totals may not sum due to rounding

Enforcement authorities

24. This will have a cost implication for Local Authorities (LAs) as they will need to ensure that FBOs are compliant with the requirements of Article 6 of Regulation (EC) No 853/2004.

Familiarisation costs

25. There will be a one-off cost to enforcement officers working in Environmental Health Departments or at a BIP for reading and familiarising themselves with the Regulations.

26. It is expected that one Environmental Health Officer (EHO) and one official from each Port Health Authority (PHA) will read the Regulations and disseminate the information to staff. It may materialise that enforcement of the regulation might be carried out by an EHO or a Trading Standards Officer (TSO). We have used the wage rate of an EHO to calculate the familiarisation costs because it is a higher wage rate value than the TSO wage rate, which means the costings covers either an EHO or TSO reading the regulation. We estimate that an officer will invest 30 minutes to read and familiarise themselves with the Regulations, and a further one hour disseminating the key points to other authorised officers in the organisation[8]. This means a total of one and a half hours for familiarisation. The familiarisation cost per enforcement authority is calculated by multiplying the reading time, one and a half hours, by the average hourly wage rate applied to an EHO of £20.45[9], generating a familiarisation cost per enforcement authority of £30.67[10]. To quantify the overall familiarisation cost to enforcement authorities we multiply the familiarisation cost per LA by the number of LAs in the UK. There are 474 enforcement authorities in the UK with responsibility for the enforcement of food hygiene legislation, who will need to familiarise themselves with this proposal. This includes 354 LAs and 39 Port Health Authorities (PHAs) in England[11], 32 LAs in Scotland; 22 LAs and one PHA in Wales; and 26 LAs in Northern Ireland. The total one off familiarisation cost for enforcement authorities in the UK totals £14,539[12]. Table 4 displays the number of LAs and PHAs per country with familiarisation cost.

Table 4 - Familiarisation cost to Local Authorities and Port Health Authorities in the UK

[8] While the FSA recognises that dissemination of information will result in an opportunity cost in terms of time of key staff members it is anticipated that this will be minimal and the additional hour will cover these costs.
[9] Wage rate obtained from The Annual Survey of Household Earnings, 2010) (See: http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of 'Environmental health officers' (£15.73 + 30% to cover overheads = £20.45).
[10] 1.5 hours * £20.45 = £30.67
[11] The number of English local authorities has been updated to reflect boundary changes and the creation of nine new Unitary authorities
[12] £30.67 (familiarisation cost per LA) * 474 (total LA's and PHA's) = £14,539

Location	Number of LA's	Familiarisation cost	Rounded familiarisation cost
England[1]	393	£12,055	£12,100
Wales[2]	23	£705	£700
Scotland	32	£982	£1,000
NI	26	£798	£800
UK	**474**	**£14,539**	**£14,500**

1. Includes 39 Port Health Authorities
2. Includes 1 Port Health Authority

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in a rounding error.

Q3: It is our assumption that there is a limited familiarisation cost for enforcement authorities associated with the regulation. We invite enforcement authorities to comment on our estimation of half an hour for familiarisation and a further hour for dissemination the information. Do you agree? If not, please provide evidence to support your views. We would also be grateful for any information as to how this might make enforcement easier or more efficient in the long-term.

Equivalent Annual Costs (EAC)

27. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula[13] . Under Standard HMT Green book guidance a discount rate of 3.5% is used.

28. The total one-off familiarisation cost to enforcement authorities affected by this proposal in the UK is an estimated £14,539. This yields an EANC of approximately £1,689 in the UK over 10 years, which per country equates to £1,400 in England, £82 in Wales, £114 in Scotland and £93 in Northern Ireland. Table 5 displays the breakdown of the EANC per country

Table 5 – Equivalent Annual Net Cost (EANC) for Enforcement Authorities by location

Location	Enforcement Authorities EANC
England	£1,400
Wales	£82
Scotland	£114
NI	£93
UK	**£1,689**

Note: Totals may not sum due to rounding

Benefits

Option 1 – do nothing

29. There are no incremental benefits. It is the baseline against which the other options are being compared.

Option 2

Industry

30. Help facilitate trade as FBOs would be able to trade composite products across Member States if they are compliant with the correct certification when entering another Member State. Harmonising the requirements, so that foods containing both products of animal origin and processed products of animal origin being imported in the European Union require the same certification as for animal health purposes and are subject to veterinary checks at Border Inspection Posts, will enhance and

[13] The equivalent annual cost formula is as follows: EAC=PVC/A, where A =[1-1/(1+r)^t]/r, where PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

strengthen current food safety measures, make enforcement easier, protect human health and assist with traceability of foods.

Consumer

31. Option 2 would deliver public health benefits. It will minimise the potential health risk to consumers posed by food business operators handling imports of composite products of animal origin to the EU. Although the benefits of this option are unquantifiable any option which contributes towards a reduction in foodborne disease is likely to have a significant economic benefit.

Q4: Do stakeholders agree with the assumptions used in generating the costs and benefits for this proposal? If stakeholders feel certain figures are incorrect can they send a breakdown of the costs they believe should be used?

Risks and Assumptions

32. Introduction of the harmonised arrangements will result in the need to provide information and training for Enforcement Officers and Port Health Inspectors working at BIPs. It is assumed that it would take an half an hour for an Enforcement Officer to become familiar with the revised requirements. Companies who import composite products from third countries will need to be made aware of the requirements and ensure that the correct health certificates are completed prior to the consignments being imported into the EU.

Wider impacts

33. The main impact will be the effect on importers of composite products. Importers may take a while to adapt to the revised requirements as, previously other POAO such as cheese and milk have not been required to have health certification if they form part of a composite product. This impact is not expected to be significant however (as described in paragraph 13).

Summary and preferred option with description of implementation plan

34. The preferred option is to implement the requirements of Article 6.4 of Regulation (EC) No 853/2004 by introducing a staged compliance to assist industry with time to comply. From 1 March 2012, importers will need to ensure that composite products which contain any processed meat, or half or more processed milk or fishery or egg product or other POAO content, or less than half milk products which do not meet certain conditions (*see footnote to paragraph 8*) for entering the European Union are accompanied by the correct health certificate.

Consultation responses

35. To be completed following formal consultation. No substantial concerns were raised by industry during an informal consultation.

Specific Impact Tests

Competition Assessment

36. The proposal is not expected to either directly or indirectly have any impact on competition.

Small Firms Impact Test

37. This proposal will affect a large number of micro, small and medium-sized businesses. From the statistics it appears that the main sector likely to be impacted by the proposal is the micro firms; these are firms that have 9 or fewer employees. However, it would not be appropriate to exempt such businesses from the requirements of the legislation. Risk must be the main criterion in considering what food safety procedures food businesses are required to undertake and the level of risk does not depend on the number of employees or turnover.

Sustainable development

38. The proposed regulations will have little, if any, impact on the delivery of the principles of two of the three pillars of sustainable development i.e. economic growth or environmental protection. In relation to social process (health) the regulation will harmonise the requirements for food with those for animal health and this provide a further measure to ensure the safety of food for human consumption entering the EU. It should also work towards increasing consumer confidence that food produced outside the EU has to meet the same hygiene requirements of food produced with the EU.

Race equality issues

39. No impact on race equality is anticipated.

Gender equality issues

40. No impact on gender is anticipated.

Disability equality issues

41. No impact on disability is anticipated.

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: [
Review objective
Review approach and rationale:
Baseline:
Success criteria:
Monitoring information arrangements:
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]

Add annexes here.

ANNEXE C
List of Interested Parties

Consultation on the Food Hygiene (England)(Amendment) Regulations 2012

ADAS
Agriculture and Horticulture Development
Association of Bakery Ingredients Manufacturers
Association of British Abattoir Operators
Association of British Salted Fish Curers and Exporters
Association of Convenience Stores
Association of Independent Meat Suppliers
Association of Meat Inspectors
Association of Port Health Authorities
Association of Public Analysts
Association of Sea Fisheries Committee of England and Wales
Association of Unpasteurised Milk Producers and Consumers
Assured Food Standards
Automatic Vending Association
Bakers of Nailsea Ltd
Bernard Matthews
Biotechnology and Biological Sciences Research Council
British Association for Shooting and Conservation
British Cattle Veterinary Association
British Deer Farmers Association
British Deer Society
British Egg Industry Council
British Goat Society
British Hospitality Association
British Institute of Agricultural Consultants
British Meat Processors Association
British Oat and Barley Millers Association
British Pig Association
British Ports Association
British Poultry Council
British Retail Consortium
British Soft Drinks Association
British Veterinary Association
British Wild Boar Association
C A Leech & Son
C S Morphet & Son Ltd
Campden and Chorleywood Food Research Association
CEFAS

Chamber of Shipping
Chartered Institute of Environmental Health
Chilled Food Association
CMi Consulting
COCERAL
Compassion in World Farming
Co-op
Co-operative Wholesale Society
Country Land and Business Association
Crab Processors Association
Dairy Council
Dairy UK
Deer Initiative
Deer Management Qualification
Defra
Department for Business, Innovation and Skills
European Snacks Association
Environment Agency
Farming and Countryside Education UK
Federation of British Port Wholesale Fish Merchants' Association
Federation of Wholesale Distributors
Food and Drink Federation
Food Commission
Food Ethics Council
Foodaware
Food Storage and Distribution Federation
Food Solutions
Forum of Private Business
Games Conservancy Trust
Geest
Grimsby Fishing Vessel Owners' Association
Guild of Lamb and Beef Suppliers
H J Heinz
Haemolytic Uraemic Syndrome Help
Halal Food Authority
Health Protection Agency
Health and Safety Executive
Highfield
Human BSE Foundation
Iceland Frozen Foods
Inglehurst Foods
Institute of Fisheries Management
Institute of Food Science and Technology
International Meat Traders Association
Islamic Cultural Centre
Lawlabs
LEAF
Leatherhead Food International

Local Government Regulation
Marks & Spencer
Meat Training Council
Medvék Consultancy Limited
Milk Development Council
Muslim Council of Britain
National Association of Agricultural Contractors
National Association of British and Irish Millers
National Association of British Market Authorities
National Association of Catering Butchers
National Association of Master Bakers
National Beef Association
National Consumer Federation
National Council of Shechita Boards
National Council of Women of Great Britain
National Dairy Council
National Farmers Union
National Federation of Fishermen's Organisations
National Federation of Fishmongers Ltd
National Federation of Meat and Food Traders
National Federation of Women's Institutes
National Game Dealers Association
National Gamekeepers Association
National Pig Association
National Sheep Association
Neville Craddock Associates
Port of Felixstowe
Provision Trade Federation
Rachel's Dairy
Romford Wholesale Meats
Royal Association of British Dairy Farmers
Royal College of Veterinary Surgeons
Royal Institute of Public Health And Hygiene
Royal Society for the Promotion of Health
RSPCA
Rural Payments Agency
Sainsbury's
Salmon and Trout Association
Sea Fish Industry Authority
Seafood Processors Association
Shellfish Association of Great Britain
Small Abattoir Federation
Smithfield Tenants' Association

Soil Association
Somerfield Stores
Specialist Cheese Makers Association
State Veterinary Service
Stilton Cheese Makers Association
Sustain
Tenant Farmers Association
Tesco
Townswomen’s Guild
Trading Standards Institute
Traditional Farm Fresh Turkey Association
UNISON
VEGA
Veterinary Public Health Association
Which?
Worshipful Company of Fishmongers

S T A T U T O R Y I N S T R U M E N T S

2012 No.

FOOD, ENGLAND

The Food Hygiene (England) (Amendment) Regulations 2012

Made - - - -	*2012*
Laid before Parliament	*2012*
Coming into force - -	*2012*

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972(**a**).

The Secretary of State has been designated for the purposes of that section in relation to measures relating to food (including drink) including the primary production of food(**b**).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for any reference to an EU instrument defined in Schedule 1 to be construed in accordance with regulation 2(3) as a reference to that instrument as amended from time to time.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**) there has been open and transparent public consultation during the preparation of the following Regulations.

Title and commencement

1. These Regulations may be cited as the Food Hygiene (England) (Amendment) Regulations 2012 and come into force on [ ] 2012.

Amendments to the Food Hygiene (England) Regulations 2006

2.—(1) The Food Hygiene (England) Regulations 2006(**d**) are amended in accordance with paragraphs (2) to (6).

(**a**) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51).
(**b**) S.I. 2003/2901.
(**c**) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny- Part Four (OJ No. L188, 18.7.2009, p.14).
(**d**) S.I. 2006/14, amended by S.I. 2007/56 and S.I. 2010/534.

(2) In paragraph (1) of regulation 2 (interpretation) for the references to the EU instruments appearing immediately after the definition of "the Community Regulations" substitute the following references —

> ""Decision 2006/766", "Decision 2009/951", "Directive 2004/41", "Regulation 178/2002", "Regulation 852/2004", "Regulation 853/2004", "Regulation 854/2004", "Regulation 882/2004", "Regulation 1688/2005", "Regulation 2073/2005", "Regulation 2074/2005", "Regulation 2075/2005", "Regulation 2076/2005", "Regulation 1020/2008", "Regulation 1021/2008", "Regulation 1029/2008", "Regulation 146/2009", "Regulation 219/2009", "Regulation 596/2009", "Regulation 669/2009", "Regulation 1162/2009", "Regulation 15/2011", "Regulation 150/2011", "Regulation 739/2011", "Regulation 1086/2011" and "Regulation 1109/2011" have the meanings respectively given to them in Schedule 1;".

(3) Immediately after paragraph (5) of regulation 2 insert the following paragraph —

> "(6) In these Regulations, any reference to an EU instrument defined in Schedule 1 is a reference to that instrument as any annex to it may be amended from time to time.".

(4) Immediately after regulation 32 (restrictions on the sale of raw milk intended for direct human consumption) insert the following regulation —

"Special health mark

32A.—(1) The special health mark referred to in paragraph 9 of Chapter VI of Section I of Annex III to Regulation 853/2004 and paragraph 7 of Chapter III of Section I of Annex I to Regulation 854/2004 shall conform with Schedule 6A.

(2) No person shall place on the market minced meat, meat preparations, mechanically separated meat or meat products prepared or produced from meat derived from animals that have undergone emergency slaughter outside the slaughterhouse unless they have an identification mark which conforms with Schedule 6A and has been applied in accordance with Section I of Annex II to Regulation 853/2004.

(3) No person shall export or offer to export to other member States or to third countries minced meat, meat preparations, mechanically separated meat or meat products prepared or produced from meat derived from animals that have undergone emergency slaughter outside the slaughterhouse.

(4) No person shall place on the market minced meat, meat preparations, mechanically separated meat or meat products prepared or produced from meat derived from animals that have undergone emergency slaughter outside the slaughterhouse outside the United Kingdom.

(5) A person who contravenes or fails to comply with paragraph (2), (3) or (4) shall be guilty of an offence.".

(5) For Schedule 1 (definitions of Community legislation) substitute the Schedule set out in Schedule 1 to these Regulations.

(6) Immediately after Schedule 6 (restrictions on the sale of raw milk intended for direct human consumption) insert the Schedule set out in Schedule 2 to these Regulations.

Review

3.—(1) The Agency must from time to time —

(a) carry out a review of regulation 2;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Agency must, so far as is reasonable, have regard to how the EU instruments mentioned in paragraphs (2) and (3) of regulation 2 are executed and enforced in other Member States.

(3) The report must in particular —

(a) set out the objectives intended to be achieved by the regulatory system established by the Food Hygiene (England) Regulations 2006 as amended by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Signed by authority of the Secretary of State for Health

Name
Parliamentary Under Secretary of State,
Date Department of Health

SCHEDULE 1 Regulation 2(5)

SCHEDULE SUBSTITUTED FOR SCHEDULE 1 TO THE FOOD HYGIENE (ENGLAND) REGULATIONS 2006

"SCHEDULE 1 Regulation 2(1)

DEFINITIONS OF COMMUNITY LEGISLATION

"Decision 2006/766" means Commission Decision 2006/766/EC establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted(**a**) as last amended by Decision 2009/951;
"Decision 2009/951" means Commission Decision 2009/951/EU amending Annexes I and II to Decision 2006/766/EC establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted(**b**);
"Directive 2004/41" means Directive 2004/41/EC of the European Parliament and of the Council repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC(**c**);
"Regulation 178/2002" means Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety as last amended by Regulation 596/2009;
"Regulation 852/2004" means Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs(**d**) as last amended by Regulation 219/2009 and as read with Regulation 2073/2005;
"Regulation 853/2004" means Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin(**a**) as last amended by

(**a**) OJ No. L320, 18.11.2006, p.53.
(**b**) OJ No. L328, 15.12.2009, p.70.
(**c**) OJ No. L157, 30.4.2004, p.33. The revised text of Directive 2004/41/EC is now set out in a Corrigendum (OJ No. L195, 2.6.2004, p.12).
(**d**) OJ No. L139, 30.4.2004, p.1. The revised text of Regulation (EC) No. 852/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.3) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.26).

Regulation 150/2011 and as read with Directive 2004/41, Regulation 1688/2005, Regulation 2074/2005, Regulation 2076/2005, Regulation 1020/2008 and Regulation 1162/2009;
"Regulation 854/2004" means Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption(**b**) as last amended by Regulation 739/2011 and as read with Directive 2004/41, Regulation 2074/2005, Regulation 2075/2005, Regulation 2076/2005, Decision 2006/766, Regulation 1021/2008 and Regulation 1162/2009;
"Regulation 882/2004" means Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules(**c**) as last amended by Regulation 1029/2008 and as read with Regulation 2074/2005, Regulation 2076/2005, Regulation 669/2009 and Regulation 1162/2009;
"Regulation 1688/2005" means Commission Regulation (EC) No. 1688/2005 implementing Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs(**d**);
"Regulation 2073/2005" means Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs(**e**) as last amended by Regulation 1086/2011;
"Regulation 2074/2005" means Commission Regulation (EC) No. 2074/2005 laying down implementing measures for certain products under Regulation (EC) No. 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No. 854/2004 of the European Parliament and of the Council and Regulation (EC) No. 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No. 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004(**f**) as last amended by Regulation 15/2011;
"Regulation 2075/2005" means Commission Regulation (EC) No. 2075/2005 laying down specific rules on official controls for *Trichinella* in meat(**g**) as last amended by Regulation 1109/2011;
"Regulation 2076/2005" means Commission Regulation (EC) No. 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004(**h**) as last amended by Regulation 146/2009;
"Regulation 1020/2008" means Commission Regulation (EC) No. 1020/2008 amending Annexes II and III to Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No. 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products(**i**);
"Regulation 1021/2008" means Commission Regulation (EC) No. 1021/2008 amending Annexes I, II and III to Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption and Regulation (EC) No. 2076/2005 as regards live bivalve molluscs, certain fishery products and staff assisting with official controls in slaughterhouses(**j**);

(**a**) OJ No. L139, 30.4.2004, p.55. The revised text of Regulation (EC) No. 853/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.22) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.26).
(**b**) OJ No. L139, 30.4.2004, p.206. The revised text of Regulation (EC) No. 854/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.83) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.26).
(**c**) OJ No. L165, 30.4.2004, p.1. The revised text of Regulation (EC) No. 882/2004 is now set out in a Corrigendum (OJ No. L191, 28.5.2004, p.1) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.29).
(**d**) OJ No. L271, 15.10.2005, p.17.
(**e**) OJ No. L338, 22.12.2005, p.1, as read with the Corrigenda at OJ No. L278, 10.10.2006, p.32 and OJ No. L283, 14.10.2006, p.62.
(**f**) OJ No. L338, 22.12.2005, p.27.
(**g**) OJ No. L338, 22.12.2005, p.60.
(**h**) OJ No. L338, 22.12.2005, p.83.
(**i**) OJ No. L277, 18.10.2008, p.8.
(**j**) OJ No. L277, 18.10.2008, p.15.

"Regulation 1029/2008" means Commission Regulation (EC) No. 1029/2008 amending Regulation (EC) No. 882/2004 of the European Parliament and of the Council to update a reference to certain European standards(**a**);
"Regulation 146/2009" means Commission Regulation (EC) No. 146/2009 amending Annex II to Regulation (EC) No. 2076/2005 as regards imports of fishery products from Cameroon(**b**)
"Regulation 219/2009" means Regulation (EC) No. 219/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Two(**c**);
"Regulation 596/2009" means Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four(**d**);
"Regulation 669/2009" means Commission Regulation (EC) No. 669/2009 implementing Regulation (EC) No. 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC(**e**);
"Regulation 1162/2009" means Commission Regulation (EC) No. 1162/2009 laying down transitional measures for the implementation of Regulations (EC) No. 853/2004, (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council(**f**) as read with the second sub-paragraph of Article 54(3) of Regulation (EU) No. XXXX/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004(**g**);
"Regulation 15/2011" means Commission Regulation (EU) No. 15/2011 amending Regulation (EC) No. 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs(**h**);
"Regulation 150/2011" means Commission Regulation (EU) No. 150/2011 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards farmed and wild game and farmed and wild game meat(**i**);
"Regulation 739/2011" means Commission Implementing Regulation (EU) No. 739/2011 amending Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption(**j**);".
"Regulation 1086/2011" means Commission Regulation (EU) No. 1086/2011 amending Annex II to Regulation (EC) No. 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No. 2073/2005 as regards *salmonella* in fresh poultry meat(**k**);
"Regulation 1109/2011" means Commission Implementing Regulation (EU) No. 1109/2011 amending Annex I to Regulation (EC) No. 2075/2005 as regards the equivalent methods for *Trichinella* testing(**l**);

(**a**) OJ No. L278, 21.10.2008, p.6.
(**b**) OJ No. L50, 21.2.2009, p.3.
(**c**) OJ No. L87, 31.3.2009, p.109.
(**d**) OJ No. L188, 18.7.2009, p.14.
(**e**) OJ No. L194, 25.7.2009, p.11.
(**f**) OJ No. L314, 1.12.2009, p.10.
(**g**) OJ No. L *insert when published*
(**h**) OJ No. L6, 11.1.2011, p.3.
(**i**) OJ No. L46, 19.2.2011, p.14.
(**j**) OJ No. 196, 28.7.2011, p.3.
(**k**) OJ No. L281, 28.10.2011, p.7.
(**l**) OJ No. L287, 4.11.2011, p.23.

SCHEDULE 2

Regulation 2(6)

SCHEDULE TO BE INSERTED IMMEDIATELY AFTER SCHEDULE 6 TO THE FOOD HYGIENE (ENGLAND) REGULATIONS 2006

"SCHEDULE 6A

Regulation 32A

THE SPECIAL HEALTH MARK

1. The special health mark shall consist of a square mark containing in legible form the following characters:

— on the upper part, the letters "UK";

— in the centre, the approval number of the premises; and

— on the lower part, the letter "N".

2. When applied to carcases, the special health mark shall measure 5.5 cm by 5.5 cm and contain letters 0.8 cm high and figures 1 cm high. The dimensions and characters of the mark may be reduced for health marking of lamb, kids and piglets."

EXPLANATORY NOTE

(This note is not part of the Regulations)

Annexe E

For information, below is a list of the *principal* EU Regulations covering food hygiene (Regulations 852/2004, 853/2004 and 854/2004) as well the related Regulations dealing with microbiological criteria, implementing rules, trichinella in meat and the transitional measures

For information to interested parties. The Regulations listed in Annexe F – those being provided with enforcement powers by the Food Hygiene (England) (Amendment) Regulations 2012 - amend Regulations in Annexe E.

Links to copies of the documents listed below, as well as other related Regulations, can be found on the European Commission's web site at:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/dvd/content/en/documents.html

- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
- Regulation (EC) no 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
- Regulation (EC) no 2074/2005 of 5 December 2005 laying down implementing measures for certain products under regulation (EC) no 853/2004 of the European parliament and of the council and for the organisation of official controls under Regulation (EC) no 854/2004 of the European parliament and of the council and Regulation (EC) no 882/2004 of the European parliament and of the council, derogating from Regulation (EC) no 852/2004 of the European parliament and of the council and amending Regulations (EC) no 853/2004 and (EC) no 854/2004
- Regulation (EC) no 2075/2005 of 5 December 2005 laying down specific rules on official controls for trichinella in meat
- Regulation (EC) no 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) no 853/2004, (EC) no 854/2004 and (EC) no 882/2004 of the European Parliament and of the Council and amending Regulations (EC) no 853/2004 and (EC) no 854/2004
- Regulation (EC) no 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Annexe F

List of EU Regulations for which the Food Hygiene (England) Regulations 2012 will provide enforcement powers in English law

These EU Regulations are the last amendments to the Regulations they amend - reflecting the amendments to Schedule 1 of the Food Hygiene (England)(Amendment) Regulations 2012:

1) Commission Regulation (EC) 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0010:0012:EN:PDF

2) Commission Regulation (EU) No 15/2011 of 10 January 2011 amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:006:0003:0006:EN:PDF

3) Commission Regulation (EU) 150/2011 of 18 February 2011 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards farmed and wild game and farmed and wild game meat
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:046:0014:0016:EN:PDF

4) Commission Regulation (EU) 739/2011 of 27 July 2011 amending Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of officials controls on products of animal origin intended for human consumption
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:196:0003:0005:EN:PDF

5) Commission Regulation (EU) 1086/2011 of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No 2073/2005 as regards *salmonella* in fresh poultry meat
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:281:0007:0011:EN:PDF

6) Commission Implementing Regulation (EU) No 1109/2011 of 3 November 2011 amending Annex I to Regulation (EC) No 2075/2005 as regards the equivalent methods for *Trichinella* testing
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:287:0023:0026:EN:PDF

A full list of all amending, transitional or implementing EU Regulations can be found on the FSA's web site at this address:

http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/foodhygimptrans

EUROPEAN COMMISSION

Brussels, XXX
SANCO/10492/2010 Rev. 4
(POOL/E2/2010/10492/10492R4-EN.doc) D010252/08
[...](2011) XXX draft

COMMISSION REGULATION (EU) No .../..

of XXX

laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009

(Text with EEA relevance)

(1) Directive 97/78/EC provides that veterinary checks on products from third countries introduced into the Union are to be carried out by Member States in accordance with that Directive and with Regulation (EC) No 882/2004.

(2) Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment.

(3) Directive 2002/99/EC lays down the general animal health rules governing all stages of the production, processing and distribution within the Union and the introduction from third countries of products of animal origin and products obtained intended for human consumption.

(4) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. Article 6(4) of that Regulation provides that food business operators importing food containing both products of plant origin and processed products of animal origin (composite products) are to ensure that the processed products of animal origin contained in such food satisfy certain public health requirements laid down therein. In addition, Regulation (EC) No 853/2004 provides that food business operators must be able to demonstrate that they have done so, for example through appropriate documentation or certification.

(5) Regulation (EC) No 853/2004 applies from 1 January 2006. However, the application of a number of measures laid down therein with immediate effect from that date would have presented practical difficulties in certain cases.

(6) Commission Regulation (EC) No 2076/2005[7] therefore provided that, by way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing composite products were to be exempt from the obligation provided for in that Article.

(7) Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council[8] repealed and replaced Regulation (EC) No 2076/2005. Regulation (EC) No 1162/2009 contains the same derogation from Article 6(4) of Regulation (EC) No 853/2004 as did Regulation (EC) No 2076/2005.

(8) In addition, Regulation (EC) No 1162/2009 provides that imports of composite products are to comply with the harmonised Union rules, where applicable, and with the national rules implemented by the Member States in other cases.

(9) Regulation (EC) No 1162/2009 applies until 31 December 2013.

(10) Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives

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7 OJ L 338, 22.12.2005, p. 83.

8 OJ L 314, 1.12.2009, p. 10.

91/496/EEC and 97/78/EC[9] provides that certain composite products are to be subject to veterinary checks, when imported into the Union. Pursuant to that Decision, the composite products subjected to veterinary checks are all those containing processed meat products, those containing half or more of their substance of any one processed product of animal origin other than processed meat products and those containing no processed meat products and less than half of their substance of processed milk product where the final products do not meet certain requirements laid down in Decision 2007/275/EC.

(11) In addition, Decision 2007/275/EC lays down certain certification requirements regarding the composite products subject to veterinary checks. It provides that composite products containing processed meat products are to be accompanied at introduction into the Union by the relevant certificate for meat products laid down in Union legislation. Composite products containing processed milk products, which are to be subjected to veterinary checks, are to be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation. In addition, composite products containing only processed fishery or egg products which are to be subjected to veterinary checks are to be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation or a commercial document where there is no certificate so required.

(12) The composite products subjected to veterinary checks pursuant to Decision 2007/275/EC are, by their very nature, the ones that may present also a higher public health risk. The levels of potential public health risk vary depending on the product of animal origin which is included in the composite product, the percentage in which that product of animal origin is present in the composite product and the treatments applied to it as well as the shelf stability of the composite product.

(13) It is therefore appropriate that the public health requirements laid down in Regulation (EC) No 853/2004 apply to those composite products even before the expiry of the derogation provided for in Regulation (EC) No 1162/2009.

(14) In particular, the certification of compliance with public health requirements as laid down in Regulation (EC) No 853/2004 should be provided for in this Regulation for the importation of the composite products containing processed meat products, of those composite products containing half or more of their substance of milk products or of processed fishery or egg products and of those composite products containing no processed meat products and less than half of their substance of processed milk products where the final products are not shelf-stable at ambient temperature or where they have not clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance, so that any raw product is not denatured.

(15) As a consequence, the derogation laid down in Regulation (EC) No 1162/2009 should no longer apply for those composite products.

(16) The animal health requirements concerning those composite products are already laid down in Union legislation. Pursuant to those requirements, those composite products should in particular only be imported from approved third countries.

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9 OJ L 116, 4.5.2007, p. 9.

(17) A specific model health certificate attesting that such composite products imported into the Union comply with those public and animal health requirements should be laid down in this Regulation. As a consequence, the certification requirements laid down in Decision 2007/275/EC should no longer apply for those composite products.

(18) For the other composite products containing half or more of their substance of products of animal origin other than milk products or fishery or egg products, the certification requirements laid down in Decision 2007/275/EC should continue to apply. However, for reasons of simplification and clarity of Union legislation, it is appropriate to include those certification requirements in this Regulation, so that the main rules on the certification of composite products be laid down in only one act.

(19) Decision 2007/275/EC and Regulation (EC) No 1162/2009 should therefore be amended accordingly.

(20) Due to animal health reasons, a certificate and specific conditions for transit via the Union should be provided for. However these conditions should be applicable only to composite products containing processed meat products or processed dairy products.

(21) Specific conditions for transit via the Union of consignments to and from Russia should be provided for, owing to the geographical situation of Kaliningrad, which only concerns Latvia, Lithuania and Poland.

(22) To avoid any disruption of trade, the use of certificates issued in accordance with Decision 2007/275/EC prior to the date of application of this Regulation should be authorised for a transitional period.

(23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down rules on the certification of consignments of certain composite products introduced into the Union from third countries.

Article 2
Definitions

For the purposes of this Regulation, the definitions in Article 2 of Decision 2007/275/EC shall apply.

Article 3
Imports of certain composite products

1. Consignments of the following composite products introduced into the Union shall come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and the products of animal origin used for the production of such composite products shall originate from establishments in compliance with Article 6.1(b) of Regulation (EC) No 853/2004:

   (a) composite products containing processed meat products, as referred to in Article 4(a) of Decision 2007/275/EC;

   (b) composite products containing processed milk products and covered by Article 4(b) and (c) of Decision 2007/275/EC;

   (c) composite products containing half or more of their substance of processed fishery or egg products and covered by Article 4(b) of Decision 2007/275/EC.

2. Consignments of composite products referred to in paragraph 1 shall be accompanied by a health certificate in accordance with the model health certificate set out in Annex I and comply with the conditions established in such certificates.

3. Consignments of composite products containing half or more of their substance of products of animal origin other than those referred to in paragraph 1 shall come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and shall be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation for those products of animal origin or by a commercial document where there is no certificate so required.

Article 4
Transit and storage of certain composite products

The introduction into the Union of consignments of composite products referred to in Article 3(1) (a) and (b) not intended for importation into the Union but destined for a third country either by immediate transit or after storage in the Union, in accordance with Articles 11, 12 or 13 of Council Directive 97/78/EC, shall only be authorised if the consignments comply with the following conditions:

(a) they come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and comply with the appropriate treatment conditions for such products, as provided for in Commission Decision 2007/777/EC[10] and Commission Regulation (EU) No 605/2010[11] for the product of animal origin concerned;

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[10] OJ L 312, 30.11.2007, p. 49.
[11] OJ L 175, 10.7.2010, p. 1.

(b) they are accompanied by a health certificate drawn up in accordance with the model health certificate set out in Annex II;

(c) they comply with the specific animal health requirements for the importation into the Union of the products of animal origin contained in the composite products concerned, as set out in the animal health attestation in the model health certificate referred to in point (b);

(d) they are certified as acceptable for transit, including for storage as appropriate, on the common veterinary entry document referred to in Article 2(1) of Commission Regulation (EC) No 136/2004[12], signed by the official veterinarian of the border inspection post of introduction into the Union.

Article 5

Derogation for transit of consignments coming from and destined to Russia

1. By way of derogation from Article 4, the transit by road or by rail through the Union, between designated border inspection posts in Latvia, Lithuania and Poland, listed in Commission Decision 2009/821/EC[13], of consignments of composite products referred to Article 3 coming from and destined to Russia directly or via another third country shall be authorised provided that the following conditions are complied with:

   (a) the consignment is sealed with a serially numbered seal at the border inspection post of introduction into the Union by the veterinary services of the competent authority;

   (b) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC are stamped "ONLY FOR TRANSIT TO RUSSIA VIA THE EU" on each page by the official veterinarian of the competent authority responsible for the border inspection post of introduction into the Union;

   (c) the procedural requirements provided for in Article 11 of Directive 97/78/EC are complied with;

   (d) the consignment is certified as acceptable for transit on the common veterinary entry document by the official veterinarian of the border inspection post of introduction into the Union.

2. Unloading or storage, as defined in Article 12(4) or in Article 13 of Directive 97/78/EC, of such consignments on Union territory shall not be allowed.

3. Regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the Union territory matches the number and quantities entering the Union.

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12 OJ L 21, 28.1.2004, p. 11.

13 OJ L 296, 12.11.2009, p. 1.

Article 6
Amendment to Decision 2007/275/EC

Article 5 of Decision 2007/275/EC is deleted.

Article 7
Amendment to Regulation (EC) No 1162/2009

In Regulation (EC) No 1162/2009, the first subparagraph of Article 3(2) is replaced by the following:

"2. By way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing both products of plant origin and processed products of animal origin, other than those referred to in Article 3(1) of Regulation (EU) No XXX/2011, shall be exempt from the obligation provided for in that Article."

Article 8
Transitional provision

For a transitional period until 30 September 2012, consignments of composite products in respect of which the relevant certificates have been issued in accordance with Article 5 of Decision 2007/275/EC before 1 March 2012 may continue to be introduced into the Union.

Article 9
Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 March 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
José Manuel BARROSO
The President

ANNEX I

Model Health Certificate for import into the European Union of composite products intended for human consumption

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference No / I.2.a. I.3. Central competent authority I.4. Local competent authority
I.5. Consignee Name Address Postcode Tel.	I.6.
I.7. Country of origin / ISO code / I.8. Region of origin / Code	I.9. Country of destination / ISO code / I.10.
I.11. Place of origin Name / Approval number Address Name / Approval number Address Name / Approval number Address	I.12.
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references	I.16. Entry BIP in EU I.17.
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Seal/Container No	I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐	
I.26.	I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Manufacturing plant	Number of packages	Nature of commodity	Net weight	Batch number

COUNTRY **Composite products intended for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian/official inspector hereby certify that

II.1 I am aware of the relevant provisions of Regulations (EC) 178/2002, (EC) No 852/2004 and (EC) No 853/2004, in particular Article 6.1(b) on the origin of the products of animal origin used in the production of the composite products described above and certify that the composite products described above were produced in accordance with those requirements, in particular that they come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

II.2 the composite products described above contain :

(1)*either* **[II.2.A Meat products, treated stomachs, bladders and intestines**(2) in any quantity which meet the animal health requirements in Commission Decision 2007/777/EC and contain the following meat constituents which meet the criteria indicated below:

Species (A)	Treatment (B)	Origin (C)	Approved Establishment(s) (D)

(A) Insert the code for the relevant species of meat product, treated stomachs, bladders and intestines where BOV = domestic bovine animals (Bos taurus, Bison bison, Bubalus bubalis and their crossbreds); OVI = domestic sheep (Ovis aries) and goats (Capra hircus); EQI = domestic equine animals (Equus caballus, Equus asinus and their crossbreds), POR = domestic porcine animals (Sus scrofa); RM = domestic rabbits, PFG = domestic poultry and farmed feathered game, RUF farmed non-domestic animals other than suidae and solipeds; RUW = wild non-domestic animals other than suidae and solipeds; SUW = wild non-domestic suidae: EQW = wild non-domestic solipeds, WL = wild lagomorphs, WGB = wild game birds.

(B) Insert A, B, C, D, E or F for the required treatment as specified and defined in Parts 2, 3 and 4 of Annex II to Decision 2007/777/EC.

(C) Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and, in the case of regionalization by Union legislation for the relevant meat constituents, the region as indicated in Part 1 of Annex II to Decision 2007/777/EC. The country of origin of the meat products must be the same as the country of export in box 1.7.

(D) Insert EU approval number of the establishments of origin of the meat products, treated stomachs, bladders and intestines contained in the composite product.

(E) If containing material from bovine, ovine or caprine animals, the fresh meat and/or intestines used in the preparation of the meat products and/or treated intestines shall be subject to the following conditions depending on the BSE risk category of the country of origin:

(1) (E.1) for imports from a country or a region with a negligible BSE risk as listed in Annex to Commission Decision 2007/453/EC as amended:

(1) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country with negligible BSE risk and passed ante-mortem and post-mortem inspections;

(1) (3) if in the country or region there have been BSE indigenous cases:

(1) (a) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced, or

(1) (b) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

(1) (E.2) for imports from a country or a region with a controlled BSE risk as listed in

II. **Health information**	II.a. Certificate reference No	II.b.

Annex to Commission Decision 2007/453/EC as amended:

(1) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived passed ante-mortem and post-mortem inspections;

(3) animals from which the products of bovine, ovine and caprine animal origin destined for export were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

[1][3] (4) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

[1][4] (5) in the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the following conditions:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed ante-mortem and post-mortem inspections;

[1] (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

[1] (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

[1] (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001.

[1] (E.3) for imports from a country or a region with an undetermined BSE risk as listed in Annex to Commission Decision 2007/453/EC:

(1) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

[1][5] (3) the products of bovine, ovine and caprine animal origin are not derived from:

(i) specified risk material as defined in Annex V to Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

[1][4] (4) in the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the following conditions:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing an

II. Health information	II.a. Certificate reference No	II.b.

undetermined BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed ante-mortem and post-mortem inspections;

(1) (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(1) (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

(1) (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001.]

(1) *and/or* [II.2.B **Processed dairy products**[6] in an amount of half or more of the substance of the composite product or not shelf stable dairy products in any quantity that

(a) have been produced in the establishment ..... (approval number of the establishments of origin of the dairy products contained in the composite product authorised at the time of production for export of dairy products to the EU. The country of origin of the dairy products must be the same as the country of export in box I.7)

The country of origin indicated in box I.7 must be listed in Annex I to Regulation (EU) No 605/2010 and the treatment applied is conform to the treatment provided for in that list for the relevant country.

(b) have been produced from milk obtained from animals:

(i) under the control of the official veterinary service,

(ii) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,

(iii) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Directive 2002/99/EC,

(c) are dairy products made from raw milk obtained from

(1) *either* [cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

(1) *either* [a pasteurisation treatment involving a single heat treatment with a heating effect at least equivalent to that achieved by a pasteurisation process of at least 72°C for at 15 seconds and where applicable, sufficient to ensure a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment]

(1) *or* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied to milk with a pH lower than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied twice to milk with a pH equal to or greater than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, immediately followed by

(1) *either* [lowering the pH below 6 for one hour;]

(1) *or* [additional heating equal to or greater than 72°C , combined with desiccation;]]

II. Health information	II.a. Certificate reference No	II.b.

[1] *or* [animals other than cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

[1] *either* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

[1] *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]]

(d) were produced on ..... or between ..... and .....[7].]

[1]*and/or* [**II.2.C** **Processed fishery products** that originate from the approved establishment N°[8].....situated in the country[9] .....]

[1]*and/or* [**II.2.D** **Processed egg products** that originate from the approved country[9].....]

Notes

Part I :

- Box reference I.7: Insert the ISO code of the country of origin of the composite product containing meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and/or for processed dairy products in Annex I to Commission Regulation (EU) No 605/2010 and/or for processed fishery products in Annex I and II to Commission Decision 2006/766/EC and/or for processed egg products in Annex I part 1 to Commission Regulation (EC) No 798/2008.
- Box reference I.11: Name, address and registration/approval number if available of the establishments of production of the composite product(s). Name of the country of origin which must be the same as the country of origin in box 1.7.
- Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (ship). In the case of transport in containers, the total number of containers and their registration number and where there is a serial number of the seal it must be indicated in box I.23. In case of unloading and reloading, the consignor must inform the border inspection post of introduction into the European Union.
- Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: codes of the following headings: 16.01; 16.02; 16.03; 16.04; 16.05; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.06.
- Box reference I.20: Indicate total gross weight and total net weight.
- Box reference I.23: for containers or boxes, the container number and the seal number (if applicable) must be included.
- Box reference I.28: manufacturing plant: insert the name and approval number if available of the establishments of production of the composite product(s). Nature of commodity: in case of composite products containing meat products, treated stomachs, bladders and intestines indicate 'meat product', 'treated stomachs', 'bladders' or 'intestines'. In case of composite product containing dairy products indicate 'dairy product'. In case of composite product containing processed fishery products specify whether aquaculture or wild origin. In case of composite product containing egg products specify the egg content percentage.

Part II:

(1) Keep as appropriate.

(2) Meat products as laid down in point 7.1 of Annex I to Regulation (EC) No 853/2004 and treated stomachs, bladders and intestines as laid down in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have undergone one of the treatments laid down in Annex II part 4 to Decision 2007/777/EC.

(3) By way of derogation from point 4, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000.

The number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required shall be

II.	**Health information**	II.a. Certificate reference No	II.b.

added to the document referred to in Article 2 (1) of Regulation (EC) No 136/2004 in case of imports.

(4) Only applicable to imports of treated intestines.

(5) By way of derogation from point 3, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000.

Specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required and from which removal of the vertebral column is not required shall be added to the document referred to in Article 2 (1) of Regulation (EC) No 136/2004 in case of imports.

(6) Raw milk and dairy products means, raw milk and dairy products for human consumption as defined in in point 7.2 of Annex I to Regulation (EC) No 853/2004.

(7) Date or dates of production. Imports of raw milk and dairy products shall not be allowed when obtained either prior to the date of authorisation for exportation to the European Union of the third country or part thereof mentioned under I.7 and I.8, or during a period where restrictive measures have been adopted by the European Union against imports of raw milk and dairy products from this third country or part thereof.

(8) Number of the fishery product establishment authorised to export to the EU.

(9) Country of origin authorised to export to the EU.

(10) In case of composite products containing only egg or fishery products the signature of an official Inspector can be accepted.

- The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

Official veterinarian/Official inspector(10)

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

ANNEX II

Model Health Certificate for transit through or storage in the European Union of composite products intended for human consumption

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference No / I.2.a. I.3. Central competent authority I.4. Local competent authority
I.5. Consignee Name Address Postcode Tel.	I.6. Person responsible for the load in EU Name Address Postcode Tel.
I.7. Country of origin ISO code / I.8. Region of origin Code	I.9. Country of destination ISO code / I.10.
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address	I.12. Place of destination Custom warehouse ☐ Ship supplier ☐ Name Approval number Address Postcode
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references	I.16. Entry BIP in EU I.17.
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Seal/Container No	I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐	
I.26. For transit through EU to third country ☐ Third country ISO code	I.27.
I.28. Identification of the commodities Manufacturing plant / Number of packages / Nature of commodity / Net weight / Batch number	

COUNTRY **Composite products intended for human consumption**

Transit/Storage

Part II: Certification

II.	Health information	II.a.	Certificate reference number	II.b.

I, the undersigned official veterinarian/official inspector hereby certify that the composite products described above contain :

(1) *either* **[II.1.A Meat products, treated stomachs, bladders and intestines**(2) in any quantity and such meat products, treated stomachs, bladders and intestines have been produced according to Commission Decision 2007/777/EC and contain the following meat constituents and meet the criteria indicated below:

Species (A)	Treatment (B)	Origin (C)

(A) Insert the code for the relevant species of meat product, treated stomachs, bladders and intestines where BOV = domestic bovine animals (Bos taurus, Bison bison, Bubalus bubalis and their crossbreds); OVI = domestic sheep (Ovis aries) and goats (Capra hircus); EQI = domestic equine animals (Equus caballus, Equus asinus and their crossbreds), POR = domestic porcine animals (Sus scrofa); RM = domestic rabbits, PFG = domestic poultry and farmed feathered game, RUF farmed non-domestic animals other than suidae and solipeds; RUW = wild non-domestic animals other than suidae and solipeds; SUW = wild non-domestic suidae: EQW = wild non-domestic solipeds, WL = wild lagomorphs, WGB = wild game birds.

(B) Insert A, B, C, D, E or F for the required treatment as specified and defined in Parts 2, 3 and 4 of Annex II to Decision 2007/777/EC.

(C) Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and, in the case of regionalization by Union legislation for the relevant meat constituents, the region as indicated in Part 1 of Annex II to Decision 2007/777/EC. The country of origin of the meat products must be the same as the country of export in box 1.7.]

(1) *and/or* **[II.1.B Processed dairy products**(3) in an amount of half or more of the substance of the composite product or not shelf stable dairy products in any quantity that

(a) originate in the country indicated in box I.7 which is listed in Annex I to Regulation (EU) No 605/2010 and the treatment applied is conform to the treatment provided for in that list for the relevant country. The country of origin of the dairy products must be the same as the country of export in box 1.7;

(b) have been produced from milk obtained from animals:

(i) under the control of the official veterinary service,

(ii) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,

(iii) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Directive 2002/99/EC,

(c) are dairy products made from raw milk obtained from

(1) *either* [cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

(1) *either* [a pasteurisation treatment involving a single heat treatment with a heating effect at least equivalent to that achieved by a pasteurisation process of at least 72°C for at 15 seconds and where applicable, sufficient to ensure a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment]

(1) *or* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at

II. Health information	II.a. Certificate reference number	II.b.

72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied to milk with a pH lower than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test];

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied twice to milk with a pH equal to or greater than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, immediately followed by

(1) *either* [lowering the pH below 6 for one hour;]

(1) *or* [additional heating equal to or greater than 72 °C, combined with desiccation;]]

(1) *or* [animals other than cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

(1) *either* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]]

(d) were produced on ..... or between ..... and .....(4).]

Notes

Part I :

- Box reference I.7: Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and/or for processed dairy product in Annex I to Commission Regulation (EU) No 605/2010.
- Box reference I.11: Name, address of the establishments of production of the composite product(s). Name of the country of origin which must be the same as the country of origin in box 1.7. Approval number is not applicable.
- Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (ship). In the case of transport in containers, the total number of containers and their registration number and where there is a serial number of the seal it must be indicated in box I.23 In case of unloading and reloading, the consignor must inform the border inspection post of introduction into the European Union.
- Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: codes of the following headings: 16.01; 16.02; 16.03; 16.04; 16.05; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.06.
- Box reference I.20: Indicate total gross weight and total net weight.
- Box reference I.23: for containers or boxes, the container number and the seal number (if applicable) must be included.
- Box reference I.28: manufacturing plant: insert the name and approval number if available of the establishments of production of the composite product(s). Nature of commodity: in case of composite products containing meat products, treated stomachs, bladders and intestines indicate 'meat product', 'treated stomachs', 'bladders' or 'intestines'. In case of composite product containing dairy products indicate 'dairy product'.

Part II:

(1) Keep as appropriate.

(2) Meat products as laid down in point 7.1 of Annex I to Regulation (EC) No 853/2004 and treated stomachs, bladders and intestines as laid down in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have undergone one of the treatments laid down in Annex II part 4 to Decision 2007/777/EC.

(3) Raw milk and dairy products means, raw milk and dairy products for human consumption as defined in in point 7.2 of Annex I to Regulation (EC) No 853/2004.

(4) Date or dates of production. Imports of raw milk and dairy products shall not be allowed when obtained either prior to the date of authorisation for exportation to the European Union of the third country or part thereof mentioned under I.7 and I.8, or during a period where restrictive measures have been adopted by

COUNTRY **Composite products intended for human consumption**

Transit/Storage

II. Health information	II.a. Certificate reference number	II.b.

the European Union against imports of raw milk and dairy products from this third country or part thereof.

- The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

Official veterinarian/ Official inspector

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

EUROPEAN COMMISSION

Brussels, XXX
SANCO/10492/2010 Rev. 4
(POOL/E2/2010/10492/10492R4-EN.doc) D010252/08
[...](2011) XXX draft

COMMISSION REGULATION (EU) No .../..

of XXX

laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009

(Text with EEA relevance)

(1) Directive 97/78/EC provides that veterinary checks on products from third countries introduced into the Union are to be carried out by Member States in accordance with that Directive and with Regulation (EC) No 882/2004.

(2) Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment.

(3) Directive 2002/99/EC lays down the general animal health rules governing all stages of the production, processing and distribution within the Union and the introduction from third countries of products of animal origin and products obtained intended for human consumption.

(4) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. Article 6(4) of that Regulation provides that food business operators importing food containing both products of plant origin and processed products of animal origin (composite products) are to ensure that the processed products of animal origin contained in such food satisfy certain public health requirements laid down therein. In addition, Regulation (EC) No 853/2004 provides that food business operators must be able to demonstrate that they have done so, for example through appropriate documentation or certification.

(5) Regulation (EC) No 853/2004 applies from 1 January 2006. However, the application of a number of measures laid down therein with immediate effect from that date would have presented practical difficulties in certain cases.

(6) Commission Regulation (EC) No 2076/2005[7] therefore provided that, by way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing composite products were to be exempt from the obligation provided for in that Article.

(7) Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council[8] repealed and replaced Regulation (EC) No 2076/2005. Regulation (EC) No 1162/2009 contains the same derogation from Article 6(4) of Regulation (EC) No 853/2004 as did Regulation (EC) No 2076/2005.

(8) In addition, Regulation (EC) No 1162/2009 provides that imports of composite products are to comply with the harmonised Union rules, where applicable, and with the national rules implemented by the Member States in other cases.

(9) Regulation (EC) No 1162/2009 applies until 31 December 2013.

(10) Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives

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7 OJ L 338, 22.12.2005, p. 83.

8 OJ L 314, 1.12.2009, p. 10.

91/496/EEC and 97/78/EC[9] provides that certain composite products are to be subject to veterinary checks, when imported into the Union. Pursuant to that Decision, the composite products subjected to veterinary checks are all those containing processed meat products, those containing half or more of their substance of any one processed product of animal origin other than processed meat products and those containing no processed meat products and less than half of their substance of processed milk product where the final products do not meet certain requirements laid down in Decision 2007/275/EC.

(11) In addition, Decision 2007/275/EC lays down certain certification requirements regarding the composite products subject to veterinary checks. It provides that composite products containing processed meat products are to be accompanied at introduction into the Union by the relevant certificate for meat products laid down in Union legislation. Composite products containing processed milk products, which are to be subjected to veterinary checks, are to be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation. In addition, composite products containing only processed fishery or egg products which are to be subjected to veterinary checks are to be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation or a commercial document where there is no certificate so required.

(12) The composite products subjected to veterinary checks pursuant to Decision 2007/275/EC are, by their very nature, the ones that may present also a higher public health risk. The levels of potential public health risk vary depending on the product of animal origin which is included in the composite product, the percentage in which that product of animal origin is present in the composite product and the treatments applied to it as well as the shelf stability of the composite product.

(13) It is therefore appropriate that the public health requirements laid down in Regulation (EC) No 853/2004 apply to those composite products even before the expiry of the derogation provided for in Regulation (EC) No 1162/2009.

(14) In particular, the certification of compliance with public health requirements as laid down in Regulation (EC) No 853/2004 should be provided for in this Regulation for the importation of the composite products containing processed meat products, of those composite products containing half or more of their substance of milk products or of processed fishery or egg products and of those composite products containing no processed meat products and less than half of their substance of processed milk products where the final products are not shelf-stable at ambient temperature or where they have not clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance, so that any raw product is not denatured.

(15) As a consequence, the derogation laid down in Regulation (EC) No 1162/2009 should no longer apply for those composite products.

(16) The animal health requirements concerning those composite products are already laid down in Union legislation. Pursuant to those requirements, those composite products should in particular only be imported from approved third countries.

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9 OJ L 116, 4.5.2007, p. 9.

(17) A specific model health certificate attesting that such composite products imported into the Union comply with those public and animal health requirements should be laid down in this Regulation. As a consequence, the certification requirements laid down in Decision 2007/275/EC should no longer apply for those composite products.

(18) For the other composite products containing half or more of their substance of products of animal origin other than milk products or fishery or egg products, the certification requirements laid down in Decision 2007/275/EC should continue to apply. However, for reasons of simplification and clarity of Union legislation, it is appropriate to include those certification requirements in this Regulation, so that the main rules on the certification of composite products be laid down in only one act.

(19) Decision 2007/275/EC and Regulation (EC) No 1162/2009 should therefore be amended accordingly.

(20) Due to animal health reasons, a certificate and specific conditions for transit via the Union should be provided for. However these conditions should be applicable only to composite products containing processed meat products or processed dairy products.

(21) Specific conditions for transit via the Union of consignments to and from Russia should be provided for, owing to the geographical situation of Kaliningrad, which only concerns Latvia, Lithuania and Poland.

(22) To avoid any disruption of trade, the use of certificates issued in accordance with Decision 2007/275/EC prior to the date of application of this Regulation should be authorised for a transitional period.

(23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down rules on the certification of consignments of certain composite products introduced into the Union from third countries.

Article 2
Definitions

For the purposes of this Regulation, the definitions in Article 2 of Decision 2007/275/EC shall apply.

Article 3
Imports of certain composite products

1. Consignments of the following composite products introduced into the Union shall come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and the products of animal origin used for the production of such composite products shall originate from establishments in compliance with Article 6.1(b) of Regulation (EC) No 853/2004:

   (a) composite products containing processed meat products, as referred to in Article 4(a) of Decision 2007/275/EC;

   (b) composite products containing processed milk products and covered by Article 4(b) and (c) of Decision 2007/275/EC;

   (c) composite products containing half or more of their substance of processed fishery or egg products and covered by Article 4(b) of Decision 2007/275/EC.

2. Consignments of composite products referred to in paragraph 1 shall be accompanied by a health certificate in accordance with the model health certificate set out in Annex I and comply with the conditions established in such certificates.

3. Consignments of composite products containing half or more of their substance of products of animal origin other than those referred to in paragraph 1 shall come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and shall be accompanied at introduction into the Union by the relevant certificate laid down in Union legislation for those products of animal origin or by a commercial document where there is no certificate so required.

Article 4
Transit and storage of certain composite products

The introduction into the Union of consignments of composite products referred to in Article 3(1) (a) and (b) not intended for importation into the Union but destined for a third country either by immediate transit or after storage in the Union, in accordance with Articles 11, 12 or 13 of Council Directive 97/78/EC, shall only be authorised if the consignments comply with the following conditions:

(a) they come from a third country or part thereof authorised for the introduction into the Union of consignments of the products of animal origin contained in those composite products and comply with the appropriate treatment conditions for such products, as provided for in Commission Decision 2007/777/EC[10] and Commission Regulation (EU) No 605/2010[11] for the product of animal origin concerned;

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[10] OJ L 312, 30.11.2007, p. 49.
[11] OJ L 175, 10.7.2010, p. 1.

(b) they are accompanied by a health certificate drawn up in accordance with the model health certificate set out in Annex II;

(c) they comply with the specific animal health requirements for the importation into the Union of the products of animal origin contained in the composite products concerned, as set out in the animal health attestation in the model health certificate referred to in point (b);

(d) they are certified as acceptable for transit, including for storage as appropriate, on the common veterinary entry document referred to in Article 2(1) of Commission Regulation (EC) No 136/2004[12], signed by the official veterinarian of the border inspection post of introduction into the Union.

Article 5

Derogation for transit of consignments coming from and destined to Russia

1. By way of derogation from Article 4, the transit by road or by rail through the Union, between designated border inspection posts in Latvia, Lithuania and Poland, listed in Commission Decision 2009/821/EC[13], of consignments of composite products referred to Article 3 coming from and destined to Russia directly or via another third country shall be authorised provided that the following conditions are complied with:

   (a) the consignment is sealed with a serially numbered seal at the border inspection post of introduction into the Union by the veterinary services of the competent authority;

   (b) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC are stamped "ONLY FOR TRANSIT TO RUSSIA VIA THE EU" on each page by the official veterinarian of the competent authority responsible for the border inspection post of introduction into the Union;

   (c) the procedural requirements provided for in Article 11 of Directive 97/78/EC are complied with;

   (d) the consignment is certified as acceptable for transit on the common veterinary entry document by the official veterinarian of the border inspection post of introduction into the Union.

2. Unloading or storage, as defined in Article 12(4) or in Article 13 of Directive 97/78/EC, of such consignments on Union territory shall not be allowed.

3. Regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the Union territory matches the number and quantities entering the Union.

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12 OJ L 21, 28.1.2004, p. 11.

13 OJ L 296, 12.11.2009, p. 1.

Article 6
Amendment to Decision 2007/275/EC

Article 5 of Decision 2007/275/EC is deleted.

Article 7
Amendment to Regulation (EC) No 1162/2009

In Regulation (EC) No 1162/2009, the first subparagraph of Article 3(2) is replaced by the following:

"2. By way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing both products of plant origin and processed products of animal origin, other than those referred to in Article 3(1) of Regulation (EU) No XXX/2011, shall be exempt from the obligation provided for in that Article."

Article 8
Transitional provision

For a transitional period until 30 September 2012, consignments of composite products in respect of which the relevant certificates have been issued in accordance with Article 5 of Decision 2007/275/EC before 1 March 2012 may continue to be introduced into the Union.

Article 9
Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 March 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
José Manuel BARROSO
The President

ANNEX I

Model Health Certificate for import into the European Union of composite products intended for human consumption

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference No / I.2.a. I.3. Central competent authority I.4. Local competent authority
I.5. Consignee Name Address Postcode Tel.	I.6.
I.7. Country of origin / ISO code / I.8. Region of origin / Code	I.9. Country of destination / ISO code / I.10.
I.11. Place of origin Name / Approval number Address Name / Approval number Address Name / Approval number Address	I.12.
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references	I.16. Entry BIP in EU I.17.
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Seal/Container No	I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐	
I.26.	I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Manufacturing plant	Number of packages	Nature of commodity	Net weight	Batch number

COUNTRY **Composite products intended for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian/official inspector hereby certify that

II.1 I am aware of the relevant provisions of Regulations (EC) 178/2002, (EC) No 852/2004 and (EC) No 853/2004, in particular Article 6.1(b) on the origin of the products of animal origin used in the production of the composite products described above and certify that the composite products described above were produced in accordance with those requirements, in particular that they come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;

II.2 the composite products described above contain :

(1)*either* **[II.2.A Meat products, treated stomachs, bladders and intestines**(2) in any quantity which meet the animal health requirements in Commission Decision 2007/777/EC and contain the following meat constituents which meet the criteria indicated below:

Species (A)	Treatment (B)	Origin (C)	Approved Establishment(s) (D)

(A) Insert the code for the relevant species of meat product, treated stomachs, bladders and intestines where BOV = domestic bovine animals (Bos taurus, Bison bison, Bubalus bubalis and their crossbreds); OVI = domestic sheep (Ovis aries) and goats (Capra hircus); EQI = domestic equine animals (Equus caballus, Equus asinus and their crossbreds), POR = domestic porcine animals (Sus scrofa); RM = domestic rabbits, PFG = domestic poultry and farmed feathered game, RUF farmed non-domestic animals other than suidae and solipeds; RUW = wild non-domestic animals other than suidae and solipeds; SUW = wild non-domestic suidae: EQW = wild non-domestic solipeds, WL = wild lagomorphs, WGB = wild game birds.

(B) Insert A, B, C, D, E or F for the required treatment as specified and defined in Parts 2, 3 and 4 of Annex II to Decision 2007/777/EC.

(C) Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and, in the case of regionalization by Union legislation for the relevant meat constituents, the region as indicated in Part 1 of Annex II to Decision 2007/777/EC. The country of origin of the meat products must be the same as the country of export in box 1.7.

(D) Insert EU approval number of the establishments of origin of the meat products, treated stomachs, bladders and intestines contained in the composite product.

(E) If containing material from bovine, ovine or caprine animals, the fresh meat and/or intestines used in the preparation of the meat products and/or treated intestines shall be subject to the following conditions depending on the BSE risk category of the country of origin:

(1) (E.1) for imports from a country or a region with a negligible BSE risk as listed in Annex to Commission Decision 2007/453/EC as amended:

(1) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country with negligible BSE risk and passed ante-mortem and post-mortem inspections;

(1) (3) if in the country or region there have been BSE indigenous cases:

(1) (a) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced, or

(1) (b) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

(1) (E.2) for imports from a country or a region with a controlled BSE risk as listed in

II. **Health information**	II.a. Certificate reference No	II.b.

Annex to Commission Decision 2007/453/EC as amended:

(1) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived passed ante-mortem and post-mortem inspections;

(3) animals from which the products of bovine, ovine and caprine animal origin destined for export were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

[1][3] (4) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

[1][4] (5) in the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the following conditions:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed ante-mortem and post-mortem inspections;

[1] (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

[1] (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

[1] (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001.

[1] (E.3) for imports from a country or a region with an undetermined BSE risk as listed in Annex to Commission Decision 2007/453/EC:

(1) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;

(2) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

[1][5] (3) the products of bovine, ovine and caprine animal origin are not derived from:

(i) specified risk material as defined in Annex V to Regulation (EC) No 999/2001;

(ii) nervous and lymphatic tissues exposed during the deboning process;

(iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

[1][4] (4) in the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the following conditions:

(a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing an

II. Health information	II.a. Certificate reference No	II.b.

undetermined BSE risk;

(b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed ante-mortem and post-mortem inspections;

(1) (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:

(1) (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

(1) (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001.]

(1) *and/or* [II.2.B **Processed dairy products**[6] in an amount of half or more of the substance of the composite product or not shelf stable dairy products in any quantity that

(a) have been produced in the establishment ..... (approval number of the establishments of origin of the dairy products contained in the composite product authorised at the time of production for export of dairy products to the EU. The country of origin of the dairy products must be the same as the country of export in box I.7)

The country of origin indicated in box I.7 must be listed in Annex I to Regulation (EU) No 605/2010 and the treatment applied is conform to the treatment provided for in that list for the relevant country.

(b) have been produced from milk obtained from animals:

(i) under the control of the official veterinary service,

(ii) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,

(iii) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Directive 2002/99/EC,

(c) are dairy products made from raw milk obtained from

(1) *either* [cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

(1) *either* [a pasteurisation treatment involving a single heat treatment with a heating effect at least equivalent to that achieved by a pasteurisation process of at least 72°C for at 15 seconds and where applicable, sufficient to ensure a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment]

(1) *or* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied to milk with a pH lower than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied twice to milk with a pH equal to or greater than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, immediately followed by

(1) *either* [lowering the pH below 6 for one hour;]

(1) *or* [additional heating equal to or greater than 72°C , combined with desiccation;]]

II. Health information	II.a. Certificate reference No	II.b.

[1] *or* [animals other than cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

[1] *either* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

[1] *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]]

(d) were produced on ..... or between ..... and .....[7].]

[1]*and/or* [**II.2.C** **Processed fishery products** that originate from the approved establishment N°[8].....situated in the country[9] .....]

[1]*and/or* [**II.2.D** **Processed egg products** that originate from the approved country[9].....]

Notes

Part I :

- Box reference I.7: Insert the ISO code of the country of origin of the composite product containing meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and/or for processed dairy products in Annex I to Commission Regulation (EU) No 605/2010 and/or for processed fishery products in Annex I and II to Commission Decision 2006/766/EC and/or for processed egg products in Annex I part 1 to Commission Regulation (EC) No 798/2008.
- Box reference I.11: Name, address and registration/approval number if available of the establishments of production of the composite product(s). Name of the country of origin which must be the same as the country of origin in box 1.7.
- Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (ship). In the case of transport in containers, the total number of containers and their registration number and where there is a serial number of the seal it must be indicated in box I.23. In case of unloading and reloading, the consignor must inform the border inspection post of introduction into the European Union.
- Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: codes of the following headings: 16.01; 16.02; 16.03; 16.04; 16.05; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.06.
- Box reference I.20: Indicate total gross weight and total net weight.
- Box reference I.23: for containers or boxes, the container number and the seal number (if applicable) must be included.
- Box reference I.28: manufacturing plant: insert the name and approval number if available of the establishments of production of the composite product(s). Nature of commodity: in case of composite products containing meat products, treated stomachs, bladders and intestines indicate 'meat product', 'treated stomachs', 'bladders' or 'intestines'. In case of composite product containing dairy products indicate 'dairy product'. In case of composite product containing processed fishery products specify whether aquaculture or wild origin. In case of composite product containing egg products specify the egg content percentage.

Part II:

(1) Keep as appropriate.

(2) Meat products as laid down in point 7.1 of Annex I to Regulation (EC) No 853/2004 and treated stomachs, bladders and intestines as laid down in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have undergone one of the treatments laid down in Annex II part 4 to Decision 2007/777/EC.

(3) By way of derogation from point 4, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000.

The number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required shall be

II.	**Health information**	II.a. Certificate reference No	II.b.

added to the document referred to in Article 2 (1) of Regulation (EC) No 136/2004 in case of imports.

(4) Only applicable to imports of treated intestines.

(5) By way of derogation from point 3, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000.

Specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required and from which removal of the vertebral column is not required shall be added to the document referred to in Article 2 (1) of Regulation (EC) No 136/2004 in case of imports.

(6) Raw milk and dairy products means, raw milk and dairy products for human consumption as defined in in point 7.2 of Annex I to Regulation (EC) No 853/2004.

(7) Date or dates of production. Imports of raw milk and dairy products shall not be allowed when obtained either prior to the date of authorisation for exportation to the European Union of the third country or part thereof mentioned under I.7 and I.8, or during a period where restrictive measures have been adopted by the European Union against imports of raw milk and dairy products from this third country or part thereof.

(8) Number of the fishery product establishment authorised to export to the EU.

(9) Country of origin authorised to export to the EU.

(10) In case of composite products containing only egg or fishery products the signature of an official Inspector can be accepted.

- The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

Official veterinarian/Official inspector(10)

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

ANNEX II

Model Health Certificate for transit through or storage in the European Union of composite products intended for human consumption

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference No / I.2.a. I.3. Central competent authority I.4. Local competent authority
I.5. Consignee Name Address Postcode Tel.	I.6. Person responsible for the load in EU Name Address Postcode Tel.
I.7. Country of origin ISO code / I.8. Region of origin Code	I.9. Country of destination ISO code / I.10.
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address	I.12. Place of destination Custom warehouse ☐ Ship supplier ☐ Name Approval number Address Postcode
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references	I.16. Entry BIP in EU I.17.
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Seal/Container No	I.24. Type of packaging
I.25. Commodities certified for: Human consumption ☐	
I.26. For transit through EU to third country ☐ Third country ISO code	I.27.
I.28. Identification of the commodities Manufacturing plant / Number of packages / Nature of commodity / Net weight / Batch number	

COUNTRY **Composite products intended for human consumption**

Transit/Storage

Part II: Certification

II.	Health information	II.a.	Certificate reference number	II.b.

I, the undersigned official veterinarian/official inspector hereby certify that the composite products described above contain :

(1) *either* **[II.1.A Meat products, treated stomachs, bladders and intestines**(2) in any quantity and such meat products, treated stomachs, bladders and intestines have been produced according to Commission Decision 2007/777/EC and contain the following meat constituents and meet the criteria indicated below:

Species (A)	Treatment (B)	Origin (C)

(A) Insert the code for the relevant species of meat product, treated stomachs, bladders and intestines where BOV = domestic bovine animals (Bos taurus, Bison bison, Bubalus bubalis and their crossbreds); OVI = domestic sheep (Ovis aries) and goats (Capra hircus); EQI = domestic equine animals (Equus caballus, Equus asinus and their crossbreds), POR = domestic porcine animals (Sus scrofa); RM = domestic rabbits, PFG = domestic poultry and farmed feathered game, RUF farmed non-domestic animals other than suidae and solipeds; RUW = wild non-domestic animals other than suidae and solipeds; SUW = wild non-domestic suidae: EQW = wild non-domestic solipeds, WL = wild lagomorphs, WGB = wild game birds.

(B) Insert A, B, C, D, E or F for the required treatment as specified and defined in Parts 2, 3 and 4 of Annex II to Decision 2007/777/EC.

(C) Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and, in the case of regionalization by Union legislation for the relevant meat constituents, the region as indicated in Part 1 of Annex II to Decision 2007/777/EC. The country of origin of the meat products must be the same as the country of export in box 1.7.]

(1) *and/or* **[II.1.B Processed dairy products**(3) in an amount of half or more of the substance of the composite product or not shelf stable dairy products in any quantity that

(a) originate in the country indicated in box I.7 which is listed in Annex I to Regulation (EU) No 605/2010 and the treatment applied is conform to the treatment provided for in that list for the relevant country. The country of origin of the dairy products must be the same as the country of export in box 1.7;

(b) have been produced from milk obtained from animals:

(i) under the control of the official veterinary service,

(ii) belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest, and,

(iii) subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Directive 2002/99/EC,

(c) are dairy products made from raw milk obtained from

(1) *either* [cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

(1) *either* [a pasteurisation treatment involving a single heat treatment with a heating effect at least equivalent to that achieved by a pasteurisation process of at least 72°C for at 15 seconds and where applicable, sufficient to ensure a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment]

(1) *or* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at

II. Health information	II.a. Certificate reference number	II.b.

72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied to milk with a pH lower than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test];

(1) *or* [a high temperature short time pasteurisation treatment (HTST) at 72°C for 15 seconds, or a treatment with an equivalent pasteurisation effect, applied twice to milk with a pH equal to or greater than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, immediately followed by

(1) *either* [lowering the pH below 6 for one hour;]

(1) *or* [additional heating equal to or greater than 72 °C, combined with desiccation;]]

(1) *or* [animals other than cows, ewes, goats or buffaloes and prior to import into the territory of the European Union have undergone or been produced from raw milk which has undergone

(1) *either* [a sterilisation process, to achieve an F_0 value equal to or greater than three;]

(1) *or* [an ultra high temperature (UHT) treatment at not less than 135°C in combination with a suitable holding time;]]

(d) were produced on ..... or between ..... and .....(4).]

Notes

Part I :

- Box reference I.7: Insert the ISO code of the country of origin of the meat product, treated stomachs, bladders and intestines as listed in Annex II, Part 2 to Decision 2007/777/EC and/or for processed dairy product in Annex I to Commission Regulation (EU) No 605/2010.
- Box reference I.11: Name, address of the establishments of production of the composite product(s). Name of the country of origin which must be the same as the country of origin in box 1.7. Approval number is not applicable.
- Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (ship). In the case of transport in containers, the total number of containers and their registration number and where there is a serial number of the seal it must be indicated in box I.23 In case of unloading and reloading, the consignor must inform the border inspection post of introduction into the European Union.
- Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: codes of the following headings: 16.01; 16.02; 16.03; 16.04; 16.05; 19.01; 19.02; 19.05; 20.04; 20.05; 21.03; 21.04; 21.05; 21.06.
- Box reference I.20: Indicate total gross weight and total net weight.
- Box reference I.23: for containers or boxes, the container number and the seal number (if applicable) must be included.
- Box reference I.28: manufacturing plant: insert the name and approval number if available of the establishments of production of the composite product(s). Nature of commodity: in case of composite products containing meat products, treated stomachs, bladders and intestines indicate 'meat product', 'treated stomachs', 'bladders' or 'intestines'. In case of composite product containing dairy products indicate 'dairy product'.

Part II:

(1) Keep as appropriate.

(2) Meat products as laid down in point 7.1 of Annex I to Regulation (EC) No 853/2004 and treated stomachs, bladders and intestines as laid down in point 7.9 of Annex I to Regulation (EC) No 853/2004 that have undergone one of the treatments laid down in Annex II part 4 to Decision 2007/777/EC.

(3) Raw milk and dairy products means, raw milk and dairy products for human consumption as defined in in point 7.2 of Annex I to Regulation (EC) No 853/2004.

(4) Date or dates of production. Imports of raw milk and dairy products shall not be allowed when obtained either prior to the date of authorisation for exportation to the European Union of the third country or part thereof mentioned under I.7 and I.8, or during a period where restrictive measures have been adopted by

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the European Union against imports of raw milk and dairy products from this third country or part thereof.

- The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

Official veterinarian/ Official inspector

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp: