

## **JULY 2008 UPDATE ON EU REGULATION 882/2004 ON OFFICIAL CONTROLS – IMPLEMENTING RULES FOR IMPORT CONTROLS FOR 'HIGH-RISK' FEED AND FOOD OF NON-ANIMAL ORIGIN**

Further views from stakeholders are requested by 15 August 2008 and should be sent to:

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### **Introduction**

1. This update highlights a forthcoming consultation by the Commission on the above proposals, seeks your views on the draft list of 'high-risk' products that will be subject to the proposals, and requests information to assist us in the further development of the associated Regulatory Impact Assessment. .

### **Commission consultation**

2. The Commission has indicated its intention to consult with stakeholders on its proposals for implementing rules during 2008. The precise timing and scope of this exercise is not yet clear but we will update you if any further details become available. In the meantime, more information on the Commission's plans is available at:

[http://ec.europa.eu/dgs/health\\_consumer/sdg/docs/comitology\\_planner.pdf](http://ec.europa.eu/dgs/health_consumer/sdg/docs/comitology_planner.pdf)

### **List of 'high-risk' products - Annex 1**

3. As highlighted in the last update letter,<sup>1</sup> there was no substantial discussion at the last EU meeting as regards the list of 'high-risk' products at Annex 1 of the draft Regulation. It was, however, agreed that this list should specify the frequency of both identity and physical checks and specify the type of physical check (e.g. chemical analysis or temperature check etc.) and any maximum values that apply. We would welcome your views on this and, in particular, on the products included in the list, the draft of which is at Appendix 1 to this note.

4. We would also welcome your views on whether any other products should be included in the list and would be grateful for details of the evidence to support any such proposals. If so, it would be helpful to us if you could also indicate a proposed frequency for identity and physical checks and any maximum values that would be appropriate in these cases.

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<sup>1</sup> Copies are available at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/> or on request from the contact details at the foot of this letter

## **Development of Regulatory Impact Assessment (RIA)**

5. The FSA carried out a full public consultation on the Commission Working Document for the proposals between 1 March and 24 May last year. Full details of the consultation, including a summary of responses can be found on the Agency's website at: <http://www.food.gov.uk/consultations/ukwideconsults/2007/nonpoaoimports>.

6. This consultation included a partial RIA to assess and record the likely costs and benefits for enforcement authorities, businesses and consumers of the proposed measures. At that time, however, the Commission had not developed the draft list of 'high-risk' products that will be subject to the proposed implementing rules such that it was not possible to undertake a full assessment. Now that a draft list has been prepared we are taking this opportunity to further develop the RIA and include an estimate of the costs and benefits likely to arise from the proposed measures when applied to these products. To assist us in this, industry and enforcement stakeholders are invited, in particular, to provide any information and views in response to the questions set out in the partial RIA at [Appendix 2](#). Copies of the latest drafts of the Regulation and the Common Entry Document (CED) are provided for reference at [Appendix 3](#) and [Appendix 4](#) respectively.

### **Further information**

7. We will keep you informed of further developments but, in the meantime, please get in touch with Rufina Acheampong (contact details given above) or David Millis on 020 7276 8424 (email: [david.millis@foodstandards.gsi.gov.uk](mailto:david.millis@foodstandards.gsi.gov.uk)) if you wish to discuss any of the above issues.

## Appendix 1 to FSA letter

### ANNEX I

#### **FEED AND FOOD OF NON-ANIMAL ORIGIN WITH KNOWN OR EMERGING RISK**

**TARIC CODE VALID ON 01/01/2008 – ACCORDING REGULATION (EC) NO 1214/2007 OF 20 SEPTEMBER 2007 (OJ L 286 OF 31.10.2007)**

<i>Feed-/ foodstuff</i>	<i>CN code</i>	<i>Country of origin</i>	<i>Hazard</i>	<i>Frequency of physical checks (%)</i>
Groundnuts (peanuts) and derived products	1202 10 90; 1202 20 00; 2008 11 10; 2008 11 91;	<b>Argentina</b>	Aflatoxins	10
Groundnuts (peanuts) and derived products <sup>1</sup>	1202 10 90; 1202 20 00; 2008 11 10; 2008 11 91;	<b>Brazil</b>	Aflatoxins	50
Zinc sulphate Manganese oxide intended for food and feed	2833 29 20; 2820	<b>China</b>	Cadmium and lead	100
Groundnuts (peanuts) and derived products, in particular peanut butter	1202 10 90; 1202 20 00; 2008 11 10; 2008 11 91;	<b>Ghana</b>	Aflatoxins	100
Spices <sup>2</sup>	0904 20; 0908 10; 0908 20; 0910 10; 0910 30;	<b>India</b>	Aflatoxins	50
Groundnuts (peanuts) and derived products	1202 10 90; 1202 20 00; 2008 11 10; 2008 11 91;	<b>India</b>	Aflatoxins	10
Melon (egusi) seeds and derived products <sup>3</sup>	1207 99;	<b>Nigeria</b>	Aflatoxins	50
Dried vine fruit	0806 20;	<b>Uzbekistan</b>	Ochratoxin A	50
Hazelnuts and derived products	0802 21 00; 0802 22 00; 2007 99 97 90; 2008 19; 1106 30 90;	<b>Azerbaijan</b>	Aflatoxins	20

<sup>1</sup> With the entry into application of this Regulation, Commission Decision 2007/759/EC of 19 November 2007 amending Decision 2006/504/EC as regards frequency of controls on peanuts and derived products originating in or consigned from Brazil due to contamination risks of these products by aflatoxins (OJ L305, 23.11.2007, p. 56) will be repealed.

<sup>2</sup> *Capsicum spp* (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika)  
*Myristica fragrans* (nutmeg)  
*Zingiber officinale* (ginger)  
*Curcuma longa* (turmeric)

<sup>3</sup> The maximum levels established for aflatoxins in groundnuts and derived products in Regulation (EC) 1881/2006 are the reference points for action

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Sunflower seeds	1206 00 91;	<b>Egypt</b>	Aflatoxins	50
Chilli, chilli products curcuma and palm oil <sup>4,5</sup>	0904 20 90; 0910 99 60; 0910 30; 1511 10 90;	<b>All Third countries</b>	Sudan dyes <sup>6</sup>	25
Vegetables, fresh, chilled or frozen  - beans - aubergines - Brassica vegetables .	0708 20; 0709 30; 0704;	<b>Thailand</b>	Organo- phosphorus pesticide residues	50
Groundnuts (peanuts) and derived products	1202 10 90; 1202 20 00; 2008 11 10; 2008 11 91;	<b>Vietnam</b>	Aflatoxins	10
Dried vine fruit	0806 20;	<b>Afghanistan</b>	Ochratoxin A	10
Basmati rice	1006 20 17 13; 1006 20 98 13;	<b>India and Pakistan</b>	Aflatoxins	5

<sup>4</sup> For the purpose of the application of this Regulation

- 'chilli' means fruits of the genus *Capsicum*, dried and crushed or ground within CN Code 0904 20 90, in whatever form, intended for human consumption and
- 'chilli products' means curry powder within CN Code 0910 50, in whatever form, intended for human consumption and
- 'curcuma', means curcuma dried and crushed or ground within CN Code 0910 30, in whatever form, intended for human consumption and
- 'palm oil', means palm oil within CN Code 1511 10 90, intended for direct human consumption.

<sup>5</sup> With the entry into application of this Regulation, Commission Decision 2005/402/EC of 23 May 2005 on emergency measures regarding chilli, chilli products and palm oil (OJ L135, 28.5..2005, p. 34) will be repealed

<sup>6</sup> "Sudan dyes" refer to following chemical substances: Sudan I (CAS Number 842-07-9), Sudan II (CAS Number 3118-97-6), Sudan III (CAS Number 85-86-9), Scarlet Red or Sudan IV (CAS Number 85-83-6).

## APPENDIX 2

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### **PARTIAL REGULATORY IMPACT ASSESSMENT – COMMISSION REGULATION ON AN INCREASED LEVEL OF OFFICIAL CONTROLS AT THE DESIGNATED POINT OF FIRST ARRIVAL OR AT THE DESIGNATED POINT OF IMPORT INTO THE COMMUNITY OF FEED AND FOOD OF NON-ANIMAL ORIGIN DUE TO KNOWN OR EMERGING RISK AS FORESEEN IN ARTICLE 15(5) OF REGULATION 882/2004**

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**Important note** - The proposed measures set out in the draft Commission Regulation that is the subject of this partial Regulatory Impact Assessment (RIA) are for implementing rules being made under Regulation (EC) No 882/2004 on official controls. The framework on which the rules are based was considered as part of the RIA that was prepared for that Regulation. This is available on the website of the Food Standards Agency at: <http://www.food.gov.uk/multimedia/pdfs/offcraapr04.pdf>. The current RIA, therefore, aims to update the general assessment that was made at that time and reconsider the likely costs and benefits for enforcement authorities, businesses and consumers in light of that.

#### **1. Title of proposal**

1.1 The proposal is for a European Commission Regulation on an increased level of official controls at the designated point of first arrival or at the designated point of import into the Community of feed and food of non-animal origin due to known or emerging risk as foreseen in Article 15(5) of Regulation 882/2004.

#### **2. Purpose and intended effect**

##### **Objectives**

2.1 The proposal is to establish detailed implementing rules under Regulation (EC) No 882/2004 on official controls<sup>1</sup> for feed and food products of non-animal origin (non-POAO) where there is a known or emerging risk ('high-risk') being imported from outside the Community. Products that fall within the scope of the Commission Regulation will be subject to an increased level of checks at designated ports, and fees will be imposed for the controls undertaken. The main purpose is to bring the rules for 'high-risk' non-POAO into line with those for products of animal origin (POAO) which are similarly considered to be 'high-risk'.

##### **Devolution**

2.2 The proposed implementing rules will be directly applicable throughout the UK. Separate but parallel legislation in each of the four countries of the UK will be needed to give effect to them once they have been adopted.

##### **Background**

###### Regulation (EC) No 882/2004 on official controls

2.3 Regulation 882/2004 on official feed and food, animal health and animal welfare controls was adopted in April 2004. Most of its provisions applied from 1 January 2006 and others from 1 January 2007. Detailed information on the feed and food elements of the Regulation is provided in the RIA for the Regulation and in Q&A Notes published by the

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<sup>1</sup> Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules. Official Journal L191, 28.5.2004, 1-52.

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Food Standards Agency (FSA).<sup>2</sup> As regards this RIA, the following detailed information is relevant.

### Official controls on non-POAO imported from outside the Community

2.4 Regulation 882/2004 introduced new rules for official controls of non-POAO imported from outside the Community, i.e. from third countries. These are set out at Articles 15 to 25. In general, these require that there should be systematic checks of documentation with additional random identity and physical checks. The frequency of physical checks should take into account the risks associated with the product, the history of compliance, controls applied by the importer, and any guarantees given by the competent authority of the third country (i.e. information about the organisation and management of control systems operated by that country and assessed by the Commission). These checks may take place at any appropriate place but will usually be at the point of entry to the UK.<sup>3</sup>

2.5 For those products that represent a known or emerging risk to human or animal health - 'high-risk' products - a framework is established at Articles 15(5) and 17 of the Regulation which, when given effect by the new implementing rules, will bring arrangements into line with those for POAO. Importers will have to pre-notify the relevant authorities of the arrival of 'high-risk' non-POAO. In addition, they will have to present these products at specific ports that have been designated specially to deal with particular 'high-risk' products. The products themselves will be subject to an increased frequency of checks in much the same way as products covered by Commission emergency safeguard measures made under Article 53 of Regulation (EC) No 178/2002<sup>4</sup> are at present. The framework also allows for the possibility of establishing a system of fees for these controls.

### Commission implementing rules

2.6 A draft Regulation setting out proposals for these implementing rules has been issued by the Commission. It should be noted that this draft does not necessarily represent the view of the Commission and the document that is presented for formal adoption may differ. The main elements of the proposals are:

- **Standard documentation for prior notification** – It is proposed that the prior notification requirement will be facilitated by means of standard documentation using a Common Entry Document (CED). This would bring procedures into line with those for POAO imports for which a Common Veterinary Entry Document (CVED) is used.
- **Designated points at which controls should be undertaken** – It is proposed that the requirement that 'high-risk' non-POAO be imported via points of entry designated by Member States will be put into practice by means of a flexible system. Documentary checks must be carried out at a designated 'point of first arrival' but Member States may also designate 'points for identity and physical checks', which may be inland, where identity and, as appropriate physical, checks may be carried out before release into free circulation.
- **List of 'high-risk' products** – Annex I of the draft Regulation lists the 'high-risk' non-POAO that will be subject to the implementing rules. It also specifies the frequency and nature of the checks that must be carried out. It is proposed that evidence from

<sup>2</sup> Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules - Q&A Notes for enforcement authorities on the feed and food elements (Revision 1, January 2006) - available on the FSA website at: <http://www.food.gov.uk/multimedia/pdfs/offcqaquidancenotes.pdf>

<sup>3</sup> These provisions are given effect in England by the Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15) and separate but parallel legislation in Scotland, Wales and Northern Ireland.

<sup>4</sup> Regulation EC 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. Official Journal L31, 1.2.2002, 1-24.

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RASFF notifications,<sup>5</sup> the outcome of Commission controls in third countries, reports and intelligence from the Member States and, where appropriate, scientific assessment will be considered in identifying products for inclusion in the list.

- **Fees** – The proposal includes mandatory fees for official controls of 'high-risk' non-POAO. A minimum fee is to be set but the relevant competent authority may recover up to full costs. Again, this is in line with the system of fees for POAO imports.

### Rationale for Government intervention

2.7 A risk assessment for Regulation 882/2004 as a whole was included in the associated RIA. This concluded that the new arrangements would contribute towards a reduction in food-borne disease, a reduction in contamination incidents and to increased consumer protection, and to a reduction in the costs associated with these. It would also lead, in turn, to increased consumer confidence in food produced within the Community and in imported food. With regard to the provisions on imports of non-POAO, by filling a gap in the current EU harmonised legislation, it was considered that these would help to improve public health protection by ensuring better targeting of controls and more effective management of risks.

2.8 The risk of no Government intervention is that Regulation 882/2004 will not be applied fully in the UK. There would then be a risk of challenge from the European Commission following inspection by its Food and Veterinary Office of UK arrangements and their compliance with the requirements of Regulation 882/2004.

## 3 Consultation

### Within Government

3.1 Consultation at official level and, in particular, with Defra, the Agriculture/Rural Affairs Departments in the Devolved Administrations and with Her Majesty's Revenue and Customs, has also been on-going since the discussions on the detailed implementing rules began in 2006. This will continue as the negotiations proceed.

### Public Consultation

3.2 Following the initial discussions at EU level on the implementing rules, the Agency wrote to over 100 interested parties, including trade associations, enforcement bodies and consumer organisations, seeking initial views on the main issues. The responses from this exercise helped to inform the UK negotiating position during subsequent discussions at EU level. Enforcement stakeholders were, in general terms, very supportive of the proposals whilst industry stakeholders highlighted the need to ensure that proper risk assessments are undertaken and that consideration is given to the economic implications for the trade.

3.3 A full 12 week public consultation on a draft Commission Regulation and this RIA was undertaken between 1 March and 24 May 2007. However, it should be noted that at this time a proposed list of 'high risk' products had not been made available.

3.4 A summary of the responses on the specific issues on which views were sought is provided at Annex A to this RIA. Stakeholders supported using the proposed sources of information as the basis for identifying 'high-risk' products and the level of official controls, but cautioned that the mechanism to add or remove products from the list should be transparent and flexible to avoid creating barriers to trade. The majority of respondents supported use of the Common Entry Document (CED) to facilitate prior

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<sup>5</sup> RASFF (Rapid Alert System for Feed and food) - more information is available at: [http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)

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notification and for the notification to be provided before the physical arrival of consignments into the Community. Views on the application of mandatory fees varied; some stakeholders supported the adoption of a minimum fee whilst others felt that any fees should be restricted to the actual cost incurred from the controls undertaken.

3.5 The FSA has also engaged with stakeholders, and will continue to do so at appropriate stages as the Commission Regulation is developed. This includes publication of regular briefings and updates on the Agency's website; consultation using the Agency's Rapidly Developing Policy system (a web-based consultation tool that can be accessed from the link below), writing to interested parties seeking their views and participation in relevant meetings and seminars.

<http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/>

### 4 **Options**

4.1 Two options have been considered.

- **Option 1** - Do nothing. This would retain the *status quo* in the UK in terms of the import control arrangements for non-POAO, including the current financing arrangements for such controls.
- **Option 2** - Implement the detailed rules set out in the Commission Regulation.

### 5. **Costs and Benefits**

#### **Sectors and groups affected**

##### Competent authorities

5.1 The draft Regulation is principally concerned with the role of the enforcement (competent) authorities responsible for organising and undertaking official feed and food controls on non-POAO imported from outside the Community. In the UK, this responsibility is held centrally but, in practice, day to day responsibility for the official control function is divided between central and local Government. In Great Britain, feed and food law enforcement services of local and port health authorities undertake such controls. In Northern Ireland, district councils are responsible for import controls of non-POAO food whilst the Department of Agriculture and Rural Development has responsibility as regards non-POAO feed.

##### Feed and food businesses

5.2 There are approximately 91,000 feed businesses in the UK. This includes importers as well as producers of feed materials, manufacturers of additives and premixtures, manufacturers of compound feedingstuffs, distributors, retailers and farms. With regard to food, there are approximately 600,000 establishments which again includes importers but also slaughterhouses, cutting plants, manufacturers, processors, packers, distributors and wholesalers, retailers, and restaurants and caterers. As regards these specific proposals it is estimated that approximately 600 importers may be directly affected (this is based on the number of businesses that imported feed and food from outside the Community during 2006 that was subject to emergency safeguard measures under Regulation 178/2002).<sup>6</sup>

##### Consumers

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<sup>6</sup> Source: HM Revenue & Customs uktradeinfo website [www.uktradeinfo.com](http://www.uktradeinfo.com)

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5.3 The measures proposed in the draft Regulation will contribute towards the overall expected benefits of application of Regulation 882/2004, i.e. a reduction in food-borne disease, a reduction in contamination incidents and to increased consumer protection. In addition, the costs for undertaking official controls for non-POAO that present a known or emerging risk to public or animal health that, in effect, currently fall to the taxpayer will fall in future to the feed and food industry.

### Social and environmental impacts

5.4 The Agency believes that the proposed measures will not have any impact on racial equality or on social or environmental sustainability issues.

### Administrative burdens

5.5 The draft Regulation proposes the requirement for feed and food businesses to pre-notify the relevant authorities of the arrival of products of non-POAO identified as presenting a known or emerging risk will be made using a Common Entry Document (CED). Completion of the CED and complying with the resulting inspections will represent an information obligation for industry and there may be additional costs over and above those which a business may incur commercially. It is important to note, however, that this will apply only in cases where there is a known or emerging risk to public health i.e. for 'high-risk' products. It will also be of benefit to industry in that it will help to streamline the process of presenting consignments for official control and to speed up the passage of consignments through the ports.

**Responses to the following questions are invited from industry and enforcement stakeholders:**

**Q1. With reference to the list of 'high-risk' products, can you estimate the number of pre-notifications that may result each year and the costs associated with these? It would be helpful if you could include an estimate of the time required to complete the CED in your answer.**

**Q2. Will there be any savings in costs arising from these requirements, for example improving the efficiency of the passage of consignments through ports? If so, please identify what these may be and provide an estimate of these savings each year.**

**Q3. Are there any other costs or benefits arising from the provisions concerning prior notification and the use of the CED in the proposed Regulation over and above those currently incurred or accrued?**

### **Analysis of costs and benefits**

#### Benefits

##### **Option 1**

5.6 This option will maintain the *status quo* and will, therefore, not generate any incremental benefit. However, to do nothing would leave the UK in breach of an EU obligation to apply a Commission Regulation. There is also a risk of challenge from the European Commission following inspection by its Food and Veterinary Office of UK enforcement arrangements and their compliance with the requirements of Regulation 882/2004. In view of this, the FSA considers that Option 1 is not viable.

##### **Option 2**

5.7 The UK supported the establishment of a new framework for import controls on 'high-risk' non-POAO imports during the negotiations on Regulation 882/2004 as it was considered that this would help to improve public health protection by ensuring better

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targeting of controls and more effective management of risks. The implementing rules will give effect to this framework.

5.8 In addition, the introduction of mandatory fees across the Community for these controls will help to ensure consistency with import controls for POAO and to ensure that trade is not distorted by variations in practices between Member States. The costs of official controls carried out on non-POAO that may be included on the list of 'high-risk' products under the proposed measures are currently funded through general and local taxation. Under the measures proposed in the draft Regulation, these costs will fall in future to the feed and food industry, representing a saving to taxpayers.

### Costs

#### **Option 1**

5.9 As there would be no change to current arrangements for official controls, there would be no compliance costs for the competent authorities or for businesses.

#### **Option 2**

##### **Costs for the competent authorities**

5.10 The competent authorities responsible for official controls on non-POAO imported from outside the Community routinely undertake checks on products that present a known or emerging risk to public or animal health identified through RASFF notification, TRACES<sup>7</sup> or other risk-based assessments or emergency measures. The proposed measures do not, therefore, represent an increase in the control activities currently carried out on these products. There may be some new administrative costs for the competent authorities in terms of receiving prior notification from business operators and processing the CED, but these are expected to be minimal.

**Q4. Will there be any increase or decrease in the current level of identity and physical checks undertaken on the 'high-risk' products based on those, and the frequency of checks specified in the draft list? If so, please provide an estimate of the likely increase or decrease each year.**

**Q5. For those 'high-risk' products included in the draft list, what is the average time taken to undertake identity and physical checks?**

**Q6. What are the average costs of sampling and analysis of those 'high-risk' products included in the draft list for which physical checks are specified?**

**Q7. Do you envisage any other additional costs? If so, what for and what do you estimate these at on an annual basis?**

##### **Costs for businesses**

5.11 Fees - An estimate of the costs for businesses was provided in the RIA for the proposal for Regulation 882/2004. This was based on the cost of around £1 million for carrying out official controls on 'high-risk' non-POAO, providing for the inclusion of non-POAO products subject to specific EU emergency safeguard measures and the expectation that the Commission would designate more products as 'high-risk' than were currently subject to these controls. This provided a total estimated cost, allowing for a doubling of the number of products designated as 'high-risk' of £2 million per annum.

<sup>7</sup> TRACES (Trade Control and Export System). This is internet based system providing information on intra-Community movements and imports of POAO and live animals. More information on TRACES is available at: <http://europa.eu/scadplus/leg/en/lvb/f84009.htm>

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5.12 Designated points of entry - These costs were also considered in the RIA for the proposal for Regulation 882/2004. It was not envisaged that the designation of specific ports for 'high-risk' non-POAO will impose additional costs on businesses. The requirement for importers to present non-POAO for mandatory checks at designated ports (with adequate examination facilities) is already established, and there is a good geographical spread of such seaports in the UK. For example 20 points of entry are currently designated for importation of certain foodstuffs where there is a risk of contamination by aflatoxins.<sup>8</sup> It seems likely that the existing designated points of entry will be appropriate for those non-POAO deemed to be 'high-risk' and there should be no need for shippers to re-route consignments.

5.13 Prior notification - An assessment of the costs associated with prior notification of consignments of 'high-risk' non-POAO is provided at paragraph 5.5 above.

***Q8. What are the average costs associated with detaining consignments (e.g. handling and storage) until the results of checks have been obtained, and what is the total annual cost?***

***Q9. Do you envisage any other costs associated with these provisions? If so, what are these for and what do you estimate these at on an annual basis?***

### Summary of costs and benefits

5.14 The principle costs to businesses resulting from the proposed measures are off-set by an equivalent saving to the taxpayer. [The administrative burden associated with the use of the CED must also be taken into consideration here and so this section will be expanded following the consultation exercise.]

### 6. 'Small Firms' Impact Test

6.1 The proposed measures will apply to all feed/food businesses including small businesses.

6.2 The Small Business Service (SBS) was involved in the development of the RIA for Regulation 882/2004 where the impact of the transfer of costs was considered. The Service has also been involved and will be further involved in the development of this RIA.

6.3 As regards consulting with small business, trade associations representing small business will be targeted. In addition, around 600 individual imported feed and food businesses, identified as having interests in the areas where the proposed measures may have some impact, were informed of the proposed measures and asked for their views.

### 7. Competition Assessment

7.1 On the basis of a Competition Filter Test, the proposals that affect businesses are unlikely to have a negative impact on competition. These provisions apply to all new and existing feed/food businesses. In view of this, any effect on competition will be negligible. The proposed measures will also help to ensure consistency of import controls for non-POAO and to ensure that trade is not distorted by variations in practices between sectors.

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<sup>8</sup> Commission Decision 2006/504/EC on special conditions governing certain foodstuffs imported from certain third countries due to the risk of contamination risks of these products by aflatoxins. Official Journal L199, 21.7.2006, 21-32.

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## **8. Enforcement, sanctions and monitoring**

8.1 The measures proposed in the draft Regulation are to be included in a directly applicable Commission Regulation. This will be given effect through national legislation in the UK. Consideration will be given to the appropriate measures for enforcement and sanctions when this national legislation is drafted and these will be subject to separate public consultation.

## **9. Post implementation review**

9.1 The European Commission will undertake a review of the application of Regulation 882/2004. It is not yet clear when this will take place but it will cover the official controls of non-POAO imports. The UK will feed into this and will review the application measures as part of that.

9.2 It is a requirement under Regulation 882/2004 for each Member State to prepare a multi-annual national control plan<sup>9</sup> setting out the national control structure and the work that the enforcement authorities will undertake, including import controls for 'high-risk' non-POAO, and report annually to the Commission on its implementation. These reports will also provide a more formal means of monitoring the effectiveness of the measures proposed in the draft Regulation.

## **10. Summary and Recommendation**

10.1 The proposed measures will contribute to the protection of public and animal health in relation to feed and food. They will help to deliver a more proportionate and consistent enforcement, to improve the transparency of enforcement arrangements for stakeholders, through the wider implementation of a risk-based system and reduce the level of illegal imports. In particular the proposed measures will increase consistency and effectiveness of enforcement across the Community for businesses.

10.2 The cost to feed/food businesses will be off-set by savings for the competent authorities (and indirectly to the taxpayer).

10.3 [A table summarising costs will be included as the RIA is developed further.]

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<sup>9</sup> The first multi-annual national control plan for the UK was published on 14 December 2006 on the FSA website and can be found at <http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk>

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## Annex A

### **EU REGULATION 882/2004 ON OFFICIAL CONTROLS - EUROPEAN COMMISSION WORKING DOCUMENT ON IMPLEMENTING RULES FOR IMPORT CONTROLS FOR 'HIGH-RISK' FEED AND FOOD OF NON-ANIMAL ORIGIN - SUMMARY OF CONSULTATION RESPONSES**

#### **Background**

This was a UK-wide consultation which took place from 1 March to 24 May 2007. The package was sent to 626 stakeholders. Twelve substantive responses were received and are summarised in the table below. Section A summarises comments on the draft Commission Working Document in terms of the specific questions asked in the consultation. Section B summarises comments made on the partial Regulatory Impact Assessment (RIA).

Copies of individual replies are available in the FSA library.

## Draft - July 2008

### Section A - Summary of comments on implementing rules for import control for 'high risk' feed and food of non-animal origin (non-POAO)

Consultation question	Summary of responses	FSA evaluation/proposed way forward
<p><b><u>List of products representing a known or emerging risk</u></b></p> <p>It is proposed that a list of non-POAO representing a known or emerging risk will be drawn up and included in the Working Document (as Annex I), and that the frequency of checks to be carried out will be specified.</p> <ul style="list-style-type: none"> <li>• What sources of information/intelligence should be used for identifying non-POAO for possible inclusion in the list?</li> <li>• What criteria should be used to assess whether such products should be added to/removed from the list i.e. for determining if they do in fact represent a known or emerging risk, and for determining the frequency of controls that should be undertaken?</li> </ul>	<p>All respondents that commented supported the proposed sources of information as a basis for identifying products for inclusion in the 'high-risk' list. In addition, it was suggested that evidence from Trade Associations and investigative newspaper and magazine articles on imported feed and food may be used. The importance of identifying clearly specific products/hazards and origins such as to avoid creating inappropriate barriers to trade was stressed.</p> <p>It was highlighted that the mechanism to add to or remove products from the 'high-risk' list should be transparent, flexible and dynamic such that prompt action may be taken where there is evidence of risk or potential risk to public health, and allow products to be removed from the list where it can be demonstrated that such risk no longer exists.</p> <p>The criteria suggested by respondents for assessing whether products should be added to or removed from the list included; information relating to product history, the volume of imports</p>	<p>The views expressed have been noted and are being taken into account in the on-going EU level discussions. The UK is pressing for:</p> <ul style="list-style-type: none"> <li>• criteria for adding/removing products from the 'high-risk' list to be agreed and set out in the Working Document;</li> <li>• the legal mechanism for adding/removing products to be clarified and included in the Working Document;</li> <li>• the description of products included in the 'high-risk' list to be as specific as possible to ensure clarity for the enforcement authorities and industry;</li> <li>• quarterly reporting by Member States to the Commission on the results of controls carried out for 'high-risk' products to help ensure that the list of products remains flexible and dynamic.</li> </ul>

## Draft - July 2008

Consultation question	Summary of responses	FSA evaluation/proposed way forward
	and size of consignments.	
<p><b><u>Relationship with safeguard measures established under Article 53 of Regulation 178/2002<sup>10</sup></u></b></p> <p>The possibility of linking the two systems (the Working Document for Article 15(5) products, and safeguard measures) by referencing the Article 53 safeguard measures in Annex I of the Working Document had been discussed at EU level. This would mean that the general framework of the Working Document - prior notification, designated points for checks and a system of fees - would also apply to non-POAO subject to Article 53 safeguard measures. The safeguard measures themselves would continue to impose any special import conditions.</p> <ul style="list-style-type: none"> <li>• <i>Do you have any views on this approach?</i></li> <li>• <i>Do you think that the common framework for official controls that will be provided by this Working Document is appropriate for, and should apply to, all those products that are currently or will in the future be subject to emergency measures made under Article 53 of Regulation 178/2002 other than those which suspend or prohibit imports?</i></li> </ul>	<p>Those respondents that expressed a view believed that all products subject to safeguard measures made under Article 53 of Regulation 178/2002 must be included in the list of 'high-risk' products established by the Working Document.</p>	<p>The views expressed on this issue have been noted and are being taken into account in the on-going EU level discussions.</p> <p>The Commission has now clarified that it is proposing a cascade approach whereby Article 15(5) (i.e. the Working Document) will be used where there is a known or emerging risk and Article 53 of Regulation 178/2002 will continue to be used as now when there is a serious risk.</p> <p>The UK has argued that products that represent a serious risk should not be subject to any less stringent control measures than those of known or emerging risk. In view of this, it is essential that the common framework for official controls that will be provided by the Working Document - prior notification using the CED, controls at designated points only, mandatory fees for all controls - be applied also to those products that are currently or will in the future be subject to Article 53 measures.</p> <p>The Commission has agreed with this and indicated that existing and future Article 53 measures will be brought into line with those set out in the Working Document.</p>

<sup>10</sup> Regulation EC 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. Official Journal L31, 1.2.2002, 1-24.

## Draft - July 2008

Consultation question	Summary of responses	FSA evaluation/proposed way forward
<p><b><u>Standard documentation for prior notification</u></b></p> <p>It is proposed that prior notification of the arrival of consignments of 'high-risk' non-POAO will be facilitated by means of a Common Entry Document (CED) via TRACES (Trade Control and Export System).</p> <ul style="list-style-type: none"> <li>• <i>Do you agree that the CED will facilitate prior notification?</i></li> <li>• <i>Do you have any comments on the information requirements set out in the CED and the associated guidance notes?</i></li> <li>• <i>As regards timing, we believe that prior notification should be given before consignments physically arrive in the Community. Do you agree?</i></li> <li>• <i>What are your views on using TRACES for non-POAO generally and for prior notifications in particular?</i></li> </ul>	<p>The majority of respondents that commented agreed that the CED will facilitate prior notification. One industry stakeholder, however, was concerned that completion of the CED will be time-consuming where a large number of individual products are imported in a single container.</p> <p>There was general agreement that prior notification should be given before consignments <i>physically</i> arrive in the Community.</p> <p>A number of detailed suggestions were made for improving the CED and associated guidance notes.</p> <p>The use of TRACES was supported by APHA and SSA.</p> <p>One respondent suggested that provision should be made for products accompanied by health certificates and/or certificates of analysis from competent laboratories or authorities in the third country to be fast tracked through the designated port of entry.</p>	<p>The views expressed have been noted and are being taken into account in the on-going EU level discussions.</p> <p>The UK is continuing to support use of the CED to facilitate prior notification and for the notification to be provided before the <i>physical</i> arrival of consignments into the Community.</p> <p>The UK has provided written comments to the Commission reflecting the suggested amendments to the CED.</p> <p>As regards TRACES, we support its use in the longer term but we have some concerns about making its use mandatory until it has been demonstrated that this system is working effectively in the area of POAO. In view of this, the UK is continuing to press for a flexible approach at this stage.</p> <p>The possibility of reduced controls or fast-tracking in cases where pre-export checks have been carried out by the authorities in a third country is provided for under Regulation 882/2004 (Article 23) and the FSA will consider stakeholders views when the relevant implementing measures are developed in this area.</p>

## Draft - July 2008

Consultation question	Summary of responses	FSA evaluation/proposed way forward
<p><b><u>Designated points of entry</u></b></p> <p>The Working Document proposes that documentary checks must be carried out at a designated 'point of introduction' (DPI) but permits Member States to designate 'points of entry' (DPE), which may be inland, where identity and, as appropriate physical, checks may be carried out before release into free circulation. It will be for Member States to designate these points. For 'points of entry', these may only be designated if they meet the requirements for facilities etc. set out in Annex III of the Working Document.</p> <ul style="list-style-type: none"> <li>• <i>Do you support this flexible approach?</i></li> <li>• <i>Should anything else be included to the appropriate facilities?</i></li> <li>• <i>The proposal envisages that consignments may be split following documentary checks at the DPI and before other checks at the DPE - do you agree?</i></li> <li>• <i>Would it be helpful to define 'consignment' in the Document and, if so, how should it be defined?</i></li> </ul>	<p>All respondents that commented agreed that a flexible approach to the designation of points of introduction and entry should be adopted.</p> <p>APHA emphasised that where the DPI and DPE are designated separately, both must be within the same Member State.</p> <p>Responses from enforcement stakeholders highlighted the need to specify the infrastructure requirements and inspection facilities required at DPIs/DPEs and the need to be explicit in the legislation that the facilities should be provided and maintained by the port operator.</p> <p>As regards specific facilities, SSA suggested that appropriate office space (and associated equipment) and storage capacity should be included in the requirements.</p> <p>All respondents that commented agreed that consignments should not be split following documentary checks as this may result in loss of control of 'high-risk' products, the creation of additional paperwork and increase the difficulty of carrying out representative analytical sampling and products recall.</p> <p>Respondents that commented agreed that a definition of 'consignment' is needed.</p>	<p>These views are noted and are being taken into account in the on-going EU level discussions.</p> <p>The UK has continued to support the flexible approach provided by a DPI/DPE system and has been pressing for clarification in the Working Document as to the roles and responsibilities of each.</p> <p>As regards provision of appropriate facilities at designated points, the FSA agrees with the views expressed by our enforcement partners. Different arrangements apply in other Member States but we are considering how some flexibility may be introduced into the Working Document to reflect the various systems.</p> <p>As regards splitting of consignments, the UK is continuing to press for this to be permitted only after the necessary official controls have been completed and the consignment has been cleared for release for free circulation.</p> <p>The UK continued to press for the inclusion of a definition of 'consignment' in the Working Document and this been agreed with the Commission and other Member States.</p>

## Draft - July 2008

Consultation question	Summary of responses	FSA evaluation/proposed way forward
<p><b><u>Fees</u></b></p> <p>The proposal includes mandatory fees for official controls of 'high-risk' non-POAO. A minimum fee is to be set but the relevant competent authority may recover up to full costs. Again, this is in line with the system of fees for POAO imports.</p> <ul style="list-style-type: none"> <li>• <i>Do you have any comments on this approach?</i></li> <li>• <i>Where minimum fees are being set, it is essential that any figures agreed take account of costs in all the Member States so we would be grateful if stakeholders, particularly enforcement stakeholders, could provide up-to-date information on typical costs for relevant official controls.</i></li> </ul>	<p>Views on the application of mandatory fees varied.</p> <p>SSA expressed concern that mandatory fees would place an additional cost burden on industry, highlighting that any fees should be restricted to the actual cost incurred arising from the controls undertaken and that these should be charged at commercial rates and be transparent.</p> <p>GC did not feel that minimum fees were necessary where the competent authority may recover its full costs.</p> <p>The adoption of a minimum fee was supported by enforcement stakeholders. APHA suggested that a single tier minimum fee charging system in line with the POAO regime is used. LPHA agreed that a basic flat rate minimum charge should apply per tonnage and cover cost for identity and routine examination and that competent authorities should be able to impose a second significantly higher charge if the product required time consuming examinations and sampling.</p>	<p>The views expressed were noted.</p> <p>The UK is continuing to support the introduction of mandatory fees on the basis that this will give consistency with the POAO regime for third country imports.</p>

## Draft - July 2008

### Section B - Summary of comments made on the partial Regulatory Impact Assessment (RIA)

Consultation question	Summary of responses	FSA evaluation/proposed way forward
<p><b><u>Social and environmental impacts</u></b></p> <p>Stakeholders were invited to comment on the Agency's assessment that the proposed measures will not have any impact on racial equality or on social or environmental sustainability issues.</p>	<p>No respondents commented on this issue.</p>	-
<p><b><u>Administrative burdens</u></b></p> <p>Stakeholders were requested to provide evidence of any additional administrative costs that may be incurred (over and above those that would be incurred commercially) that may result from using the CED for prior notification.</p>	<p>No respondents commented on this issue.</p>	-
<p><b><u>Costs for the competent authorities</u></b></p> <p>Stakeholders were invited to comment on the Agency's assessment: the proposed measures do not represent an increase in the control activities currently carried out though there may be some new administrative costs for the competent authorities in terms of receiving prior notification from business operators and processing the CED, but these are expected to be minimal.</p>	<p>APHA highlighted that the use of TRACES in association with the data entry requirements for the Common Veterinary Entry Document for animal products requires additional administrative and envisaged similar burdens for data entry with respect to CEDs.</p> <p>GC highlighted the possibility that test results for 'high-risk' products will be more frequently challenged, leading to an increase in the frequency with which formal samples are submitted for referee analysis. It estimated that the additional cost burden to the GC may be £60,000 per year.</p>	<p>These views are noted and will be taken into consideration as the RIA is developed further.</p>

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<p><b><u>Costs for businesses</u></b></p> <p>Stakeholders were asked to comment on the estimate included in the partial RIA and provide any information that may help to update these.</p>	<p>Respondents highlighted the difficulty in appraising costs without knowledge of the range of the `high-risk' products subject to the control system established in the Working Document. However, of those that commented, the majority noted that fees and prior notification would impose additional costs to those currently though no cost information was provided.</p>	<p>These views are noted and will be taken into consideration as the RIA is developed further.</p>
<p><b><u>Options</u></b></p> <p>Two were considered:</p> <ul style="list-style-type: none"> <li>• Option 1 - Do nothing. This would retain the status quo in the UK in terms of the import control arrangements for non-POAO.</li> <li>• Option 2 - Implement the detailed rules set out in the Working Document.</li> </ul>	<p>The respondents that commented supported option 2.</p>	<p>These views are noted.</p> <p>The FSA will continue to work with stakeholders to ensure that the rules set out in the Working Document are effective without imposing unnecessary burdens on the enforcement authorities carrying out controls or on the businesses that are subject to them.</p>

**Appendix 3**

**EN**

**2007/02697**

## Appendix 3



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.01.2008  
Rev.13

Draft

**COMMISSION REGULATION (EC) No .../..**

**on an increased level of official controls at the designated point of first arrival or at the designated point of import into the Community of feed and food of non animal origin due to known or emerging risk as foreseen in Art. 15.5 of Regulation 882/2004**

**(Text with EEA relevance)**

Draft

**COMMISSION REGULATION (EC) No .../..**

**on an increased level of official controls at the designated point of first arrival or at the designated point of import into the Community of feed and food of non animal origin due to known or emerging risk as foreseen in Art. 15.5 of Regulation 882/2004**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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<sup>1</sup>, and in particular Article 15 (5) thereof,

Whereas:

- (1) 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 establishes at Community level a harmonised framework of general rules for the organisation of official controls.
- (2) For some feed- and foodstuffs of non animal origin from certain third countries an increased level of official controls on basis of known or emerging risk is appropriate.
- (3) Article 17 (1) of Regulation (EC) No 882/2004 requires feed and food business operators responsible for consignments to give prior notification of the arrival and nature of feed and food. A specific form of the prior notification should be laid down for imports of feed and food covered by this Regulation in order to ensure a uniform approach.
- (4) In the interests of public and animal health, Member States should keep the Commission informed of all positive findings in the official controls carried out in respect of consignments of feeding- and foodstuffs covered by this Regulation. Such information should be given via the Rapid Alert System for Food and Feed established by Regulation (EC) No 178/2002 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.

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<sup>1</sup> OJ L 165, 30.4.2005, p. 1. Corrigendum published in the OJ L 191, 28.5.2004.

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- (5) The operation of this Regulation should be kept under review on the basis of the guarantees provided by the competent authorities of the concerned third countries and of the results of the official controls carried out by Member States in order to assess whether the special conditions provide a sufficient level of protection of public health within the Community and whether they are still needed
- (6) 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* *Scope*

1. This Regulation shall apply to official controls of feed and food of non-animal origin specified in Annex I imported into the Community on the basis of a known or emerging risk as foreseen in Article 15(5) of Regulation (EC) No 882/2004 of the European Parliament and of the Council.
2. It is without prejudice to the special conditions on the import of feed and food laid down in the safeguard measures according to Article 53 (1) (b) (ii) of Regulation (EC) No 178/2002.

### *Article 2* *Definitions*

1. Controls referred to in Article 1 will be carried out at the Designated Point of First Arrival (DPFA) and/or at the Designated Point for Identity and Physical checks (DPIP).
2. For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 and in Article 2 of Regulation (EC) No 882/2004 shall apply.
3. The following definitions shall also apply:
  - (a) ‘Designated point of first arrival (DPFA)’ means the point where feed and food of non-animal origin specified in Annex I being imported into the Community shall first be presented for official control.
  - (b) ‘Designated point for identity and physical checks (DPIP)’ means the point where the competent authority finalises the check and completes the Common Entry Document (CED).
  - (c) ‘Common Entry Document (CED)’ means the official document used by the feed or food business operator or his representative for the prior notification of

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the arrival of feed and food specified in Annex I at the DPFA, and by the competent authority at the DPFA and the DPIP for confirming completion of official controls.

- (d) 'Consignment' means a quantity of products of the same class or description, covered by the same certificate or other document(s) conveyed by the same means of transport and coming from the same third country or part of such country.

### *Article 3*

#### *Use of the Common Entry Document*

Elements foreseen in the CED shall be produced, completed, transmitted and stored through TRACES system or any other electronic data transmission system. Member States shall use solely the TRACES system starting from 1 January 2011.

### *Article 4*

#### *Prior notification*

1. Before the physical arrival of consignments of feed and food specified in Annex I, the feed or food business operator responsible for the consignment or his representative shall provide the competent authority at the DPFA with prior notification, using the CED at Annex II of this Regulation.
2. The feed or food business operator responsible for the consignment or his representative shall complete Part I of the CED and transmit the original of the Document to the competent authority at the DPFA.
3. The CED shall be drawn up at least in the official language or languages of the Member State where the DPFA is located and those of the DPIP if this one is located in a different Member State. However, a Member State may consent to the use of an official Community language other than its own.

### *Article 5*

The Competent Authorities of Member States shall provide to the Commission a list for DPFA's, and DPIP's at the moment of entry into force of this Regulation. The Commission Services shall publish the list in the website of Health and Consumer Protection Directorate General providing for a link from his homepage to the national lists.

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### *Article 6*

#### *Precaution against prediction*

Member States shall organize physical checks in such a way that it is not possible for an importer to predict whether any particular consignment will be subjected to a physical check.

### *Article 7*

#### *Official controls at the Designated Point of First Arrival (DPFA)*

1. Where the DPFA is also a DPIP, the procedures set out in Article 8 shall apply, including documentary checks
2. Where the DPFA is not also a DPIP, the procedure set out in paragraphs 3 to 11 of this Article shall apply.
3. The competent authority shall carry out documentary checks of all consignments of feed and food of non-animal origin specified in Annex I.
4. After completion of documentary checks, the competent authority shall complete Part II of the CED, and the responsible official shall stamp and sign the original of the CED.
5. Where the results of the documentary checks are satisfactory, the procedure set out in paragraphs 6 to 9 shall apply.
6. The competent authority, after receiving information from the feed or food business operator responsible for the consignment or his representative, shall identify a DPIP at which identity and physical checks shall be carried out, and shall provide prior notification to the competent authority at the DPIP of the arrival of the consignment.
7. The original of the CED shall accompany the consignment on its onward transport to the DPIP, and the competent authority at the DPFA shall make and retain a copy.
8. Consignments shall not be split until all the necessary official controls have been completed at a DPIP with satisfactory results and the CED issued
9. Where the results of documentary checks are not satisfactory, consignments may not enter the Community for onward transport to a DPIP. The responsible official of the competent authority shall, where appropriate, complete Part III of the CED, and action shall be taken in accordance with Articles 19 to 21 of Regulation (EC) No 882/2004.
10. The competent authorities shall immediately notify the Commission through the Rapid Alert System for Feed and Food, as foreseen in Article 50 of Regulation (EC) 178/2002, any information relating to the existence of a serious direct or indirect risk to human or animal health detected during the official controls carried out at the DPFA.

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### Article 8

#### *Official controls at the Designated Point for Identity and Physical Checks (DPIP)*

1. Identity and physical checks on feed and food of non-animal origin specified in Annex I must be carried out in DPIPs authorised for this purpose.
2. Where the DPIP is also a DPFA, the competent authority at the DPIP shall carry out documentary checks of all consignments of feed and food of non-animal origin specified in Annex I.
3. The competent authority at the DPIP shall carry out identity and physical checks, as appropriate, of feed and food specified in Annex I at the frequency laid down therein.
4. The competent authority shall place the consignment concerned under official detention until all official controls have been completed and, where appropriate, the results of physical checks have been obtained. The official controls, including any laboratory analysis, shall be undertaken without undue delay.
5. The feed or food business operator responsible for the consignment or his representative shall make available sufficient human resources and logistics, storage facilities, and facilities to unload the consignment, thus enabling the necessary official controls to take place.
6. In the case of special transport and/or specific packaging forms, the feed and food business operator responsible for the consignment or his representative shall make available to the competent authority the appropriate sampling equipment insofar as the sampling cannot be representatively performed with standard sampling equipment.
7. After completion of documentary, identity and physical checks, as appropriate, the competent authority shall complete Part II of the CED and the responsible official shall stamp and sign the original of the CED.
8. The competent authority shall transmit a copy of the CED to the feed or food business operator responsible for the consignment or his representative, and shall make and retain a copy of the CED.
9. After customs clearance, the original of the CED shall accompany the consignment to the first establishment of destination. Where consignments are split, authenticated copies shall accompany each part of the consignment.
10. In the case of non-compliance, the responsible official of the competent authority shall complete Part III of the CED, and action shall be taken in accordance with Articles 19 to 21 of Regulation (EC) No 882/2004.
11. The competent authorities shall immediately notify the Commission through the Rapid Alert System for Feed and Food, as foreseen in Article 50 of Regulation (EC) 178/2002, any information relating to the existence of a serious direct or indirect risk to human or animal health detected during the official controls carried out at the DPI.

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### *Article 9 Release for free circulation*

Customs authorities shall not allow release for free circulation of consignments of products unless-without prejudice to the customs regulations- proof has been supplied that the relevant feed and food checks have been carried out with satisfactory results. For this purpose, a CED duly endorsed by the competent authority of the DPIIP must be presented together with the customs declaration

### *Article 10*

#### *Fees*

1. Member States shall ensure the collection of fees or charges to cover the costs occasioned by official controls of feed and food listed in Annex I.
2. Fees shall be paid by the feed- and food business operator responsible for the consignment or its representative.
3. The calculation of the costs shall use the criteria laid down in Annex VI of Regulation No 882/2004. The fees shall not be lower than the minimum rate specified in Annex IV of this Regulation and not higher than the costs borne by the responsible competent authority.

### *Article 11 Reporting to the Commission and review*

1. Member States shall submit to the Commission a report of all analytical results of official controls on consignments of feed and food as referred to in this Regulation on a three-month basis.
2. The list of feed and food as referred in Annex I shall be reviewed on the basis of the reports provided for in point 1 and on the basis of the results of the sampling and analysis carried out by Member States in order to assess whether the conditions set out in this Regulation provide a sufficient level of protection of public health within the Community and whether they are still necessary

### *Article 12*

#### *Criteria in order to listing products with known or emerging risk*

In order to introduce feed or food in the list referred to in Annex I, at least the following criteria should be taken into account:

- Notifications received from the Rapid Alert System for Food and Feed (RASFF)
- Reports received from the Food and Veterinary Office (FVO)

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- Quantity of products introduced into the European Community
- Reports received from third countries
- Communication between Member States, European Commission and European Food Safety Authority (EFSA)
- Scientific assessment, where appropriate
- Any other relevant information

The Commission may recommend the introduction of feed or food in the list referred to in Annex I, in accordance with the procedures referred to in Article 62(1) of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

### *Article 13*

#### *Criteria in order to delisting products with known or emerging risk*

In order to delisting feed or food introduced in the list referred to in Annex I, at least the following criteria should be taken into account:

- Absence or significant decrease of notifications from the Rapid Alert System for Food and Feed (RASFF)
- Reports received from the Food and Veterinary Office (FVO)
- Reports from third countries
- Scientific assessment, where appropriate
- Any other relevant information

The Commission may recommend the delisting of feed or food in the list referred to in Annex I, in accordance with the procedures referred to in Article 62(1) of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

### *Article 14*

#### *Applicability*

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

Member States shall adopt and publish the necessary measures to comply with this Regulation. They shall forthwith inform the Commission thereof.

### **Appendix 3**

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

Done at Brussels, [...]

*For the Commission*  
*Markos KYPRIANOU*  
*Member of the Commission*

**ANNEX I**

**FEED AND FOOD OF NON-ANIMAL ORIGIN WITH KNOWN OR EMERGING  
RISK**

**ANNEX II**

Common Entry Document (CED)

### ANNEX III

#### MINIMAL REQUIREMENTS TO BE ENSURED AT THE DPFA AND AT THE DPIP

##### **Part I - Minimum requirements for approval to operate as a DPFA**

1. A sufficient number of suitably qualified and experienced staff to perform the documentary checks on consignments of the food and feed referred to in Annex I.
2. The availability of office facilities for the competent authority to undertake the necessary documentary checks which are accessible at all times required by the competent authority.

##### **Part II - Minimum requirements for approval to operate as a DPIP**

1. A sufficient number of suitably qualified and experienced staff to perform the official controls on consignments of the food and feed specified in Annex I.
2. The availability of office facilities for the competent authority to use which accessible at all times required by the competent authority.
3. The availability of detailed instructions regarding sampling and the sending of the samples to laboratories, and access to adequate official control laboratory capacity.
4. The availability of toilets, and hand washing facilities for the use of the all personnel working in the DPIP.
5. An area for unloading which shall be enclosed or covered by a roof (except in the case of consignments of loose bulk animal feed not fit for human consumption or bulk liquids, oils and fats, which are transported in tank containers or enclosed in ships or boats).
6. The availability of unloading equipment.
7. An inspection area or room. For products transported under temperature control, the inspection areas shall be capable of being operated as a temperature controlled environment. The inspection areas or rooms must have:
  - (a) a table with smooth washable surfaces that are easy to clean and disinfect;
  - (b) hot and cold water supply drawn from potable water sources;
  - (c) clean walls and ceiling with smooth washable surfaces, which together with the floors, should be easy to clean and disinfect;
  - (d) adequate drainage;
  - (e) adequate natural or artificial lighting;
  - (f) equipment or access to equipment for weighing parts of consignments that are subject to controls;
  - (g) equipment needed to open, examine and take samples from the type of consignments presented for examination at the DPIP;

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- (h) facilities for the temporary storage of samples under temperature control, pending their dispatch to the laboratory;
  - (i) cleansing and disinfection equipment; and,
  - (j) as appropriate, equipment to maintain the temperature at the appropriate level in controlled environment rooms.
8. Procedures to ensure maintenance of hygienic conditions and prevention of contamination, including cross contamination, during the handling and official controls carried out at the DPIIP.
9. Appropriate storage rooms, container stacks or storage areas.

## Appendix 3

### ANNEX IV MINIMUM RATES FOR FEES

Kind of control	Net weight of consignment		
	< 1 t	1 – 30 t	> 30 t
Documentary			
Identity/physical check (Sampling and analysis)			

# Appendix 4

## EUROPEAN COMMUNITY

## Common Entry Document, CED

Part I: Details of consignment presented	I.1. Consignor Name Address  Country + ISO code		I.2. CED reference number DPFA DPFA Unit N°	
	I.3. Consignee Name Address Postal code Country + ISO code		I.4. Person responsible for the load Name Address	
	I.7. Importer Name  Address Postal code Country + ISO code		I.5. Country of origin + ISO code   I.6. Country from where consigned ISO code	
	I.9. Arrival at DPFA (estimated date) Date		I.8. Place of destination Name  Address Postal code Country + ISO code	
	I.11. Means of transport: Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Identification: Documentary references:		I.10. Documents Number Date of issue	
	I.12. Description of commodity		I.13. Commodity code (HS code)	
	I.16. Temperature Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		I.14. Gross weight/Net weight	
	I.18. Commodity certified as: Human consumption <input type="checkbox"/> Further process <input type="checkbox"/> Feedingstuff <input type="checkbox"/> Other <input type="checkbox"/>		I.15. Number of packages	
	I.19. Seal number and container numbers		I.17. Type of packages	
	I.20. For transhipment to DPI DPI Unit N°		/	
	I.22. For import			
	I.24. Means of transport after DPFA Railway wagon <input type="checkbox"/> Registered No. Aeroplane <input type="checkbox"/> Flight No. Ship <input type="checkbox"/> Name Road vehicle <input type="checkbox"/> Plate No.		/	
	I.25. Declaration I, the undersigned person responsible for the load detailed above, certify that to the best of my knowledge and belief the statements made in Part I of this document are true and complete and I agree  to comply with the legal requirements of Regulation (EC) N° 882/2004, including payment for official controls, and consequent official measures in case of non compliance with the feed and food law.			
			Place and date of declaration Name of signatory Signature	

# Appendix 4

## EUROPEAN COMMUNITY

## Common Entry Document, CED

Part II: decision on consignment	II.1. CED Reference Number:	II.2. Customs Document Reference:
	II.3. Documentary Check: Satisfactory <input type="checkbox"/> Not satisfactory <input type="checkbox"/>	/
	II.5. ACCEPTABLE for transshipment DPI <input type="text"/> DPI Unit N° <input type="text"/>	
	II.6. NOT ACCEPTABLE <input type="checkbox"/> 1. Re-dispatching <input type="checkbox"/> 2. Destruction <input type="checkbox"/> 3. Transformation <input type="checkbox"/>	
	II.8. Full identification of DPFA and official stamp. DPFA <input type="text"/> Stamp <input type="text"/> DPFA Unit N° <input type="text"/>	II.7. Details of Controlled Destinations (II.6) Approval no (where relevant): <input type="text"/> Address: <input type="text"/> Postal code: <input type="text"/>
	II.10.	II.9. Official Inspector I the undersigned official inspector of the DPFA, certify that the checks on the consignment have been carried out in accordance with EU requirements.
	II.12. Physical Check: Derogation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Not satisfactory <input type="checkbox"/>	II.11. Identity Check: Derogation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Not satisfactory <input type="checkbox"/>
	II.14. ACCEPTABLE for definitive import <input type="checkbox"/> Human consumption <input type="checkbox"/> Further process <input type="checkbox"/> Feedingstuff <input type="checkbox"/> Other <input type="checkbox"/>	II.13. Laboratory Tests: No <input type="checkbox"/> Yes <input type="checkbox"/> Tested for: Results: Satisfactory <input type="checkbox"/> Not satisfactory <input type="checkbox"/>
	II.16. NOT ACCEPTABLE <input type="checkbox"/> 1. Re-dispatching <input type="checkbox"/> 2. Destruction <input type="checkbox"/> 3. Transformation <input type="checkbox"/>	II.15.
	II.18. Details of Controlled Destinations (II.16) Approval no (where relevant): <input type="text"/> Address: <input type="text"/> Postal code: <input type="text"/>	II.17. Reason for Refusal 1. Absence/Invalid certificate <input type="checkbox"/> 2. ID: Mis-match with documents <input type="checkbox"/> 3. Physical hygiene failure <input type="checkbox"/> 4. Chemical contamination <input type="checkbox"/> 5. Micro biological contamination <input type="checkbox"/> 6. Other <input type="checkbox"/>
II.20. Full identification of DPI and official stamp. DPI <input type="text"/> Stamp <input type="text"/> DPI Unit N° <input type="text"/>	II.19. Consignment resealed New seal no: <input type="text"/> II.21. Official Inspector I the undersigned official inspector of the DPI, certify that the checks on the consignment have been carried out in accordance with EU requirements. Name (in Capital): <input type="text"/> Date: <input type="text"/> Signature: <input type="text"/>	
Part III: Control	III.1. Details on re-dispatching: Means of transport n°: Railway wagon <input type="checkbox"/> Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Road vehicle <input type="checkbox"/> Country of destination: <input type="text"/> + ISO code Date: <input type="text"/>	
	III.2. Follow up Arrival of the consignment Yes <input type="checkbox"/> No <input type="checkbox"/> Local Competent Authority Unit <input type="text"/> Correspondence of the consignment Yes <input type="checkbox"/> No <input type="checkbox"/>	
	III.3. Official Inspector Name (in Capital): <input type="text"/> Address: <input type="text"/> Unit N° <input type="text"/> Date: <input type="text"/> Stamp <input type="text"/> Signature: <input type="text"/>	

## Appendix 4

### Notes for guidance for the CED

General: Complete the document in capitals.

**Part I.** **This section is for completion by the declarant (feed and food business operator) or person responsible for the load. Notes are shown against the relevant box number.**

“ISO code” refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.

- Box I.1. Consignor: name and full address of the natural or legal person (feed and food business operator) dispatching the consignment. Information on telephone and fax numbers or email address is recommended.
- Box I.2. Designated point of first arrival (DPFA) as defined in Decision/XXX/EC. The CED reference number is the unique reference number given by TRACES (after 2011). The DPFA can also be a DPI, if all the required controls are performed and the requirements given in annex III are complied with.
- Box I.3. Consignee: name and full address of the natural or legal person (feed and food business operator) to whom the consignment is destined. Information on telephone and fax numbers or email address is recommended.
- Box I.4. Person responsible for the load (also agent, declarant or feed and food business operator): this is the person who is in charge of the consignment when presented to the DPFA who makes the necessary declarations to the competent authorities on behalf of the importer: name and full address. Information on telephone and fax numbers or email address is recommended.
- Box I.5. Country of origin: this refers to the country where the commodity is originating from, grown, harvested or produced.
- Box I.6. Country from where consigned: this refers to the country where the consignment was placed aboard the means of final transport for the journey to the EU.
- Box I.7. Importer: name and full address. Information on telephone and fax numbers or email address is recommended.
- Box I.8. Place of destination: delivery address in the EU. Information on telephone and fax numbers or email address is recommended.
- Box I.9. Arrival at DPFA: give the estimated date that consignments are expected to arrive at the DPFA.
- Box I.10. Documents: indicate the date of issue and the number of official documents accompanying the consignment.
- Box I.11. Give full details of the means of arrival transport: for aircraft the flight number, for vessels the ship name, for road vehicles the registration number plate with trailer number if appropriate, for railways the train identity and wagon number.  
Documentary references: number of airway bill, bill of lading or commercial number for railway or truck.
- Box I.12. Description of commodity: describe the commodity or use the titles as they appear in the Harmonized System of the World Customs Organization.
- Box I.13. Heading or HS code of the Harmonized System of the World Customs Organization.
- Box I.14. Gross weight: overall weight in Kg. This is defined as the aggregate mass of the products with immediate containers and all their packaging, but excluding transport containers and other transport equipment.  
Net weight: weight of actual product excluding packaging in Kg. This is defined as the mass of the products themselves without immediate containers or any packaging.
- Box I.15. Number of packages: quantity of the commodity.
- Box I.16. Temperature: tick the appropriate mode of transport/storage temperature.
- Box I.17. Type of packaging: identify the type of packaging of products.
- Box I.18. Commodity certified as: tick the category for which the consignment is being presented; ‘Human consumption’, ‘Further process’ i.e. human consumption after physical treatment or salting, ‘Feedingstuff’, and ‘Other’.
- Box I.19. Give all seal and container identification numbers where relevant.
- Box I.20. Transshipment: must be used where a consignment is not to be released for free circulation at the DPFA defined in box I.2 but is to travel onward for importation into the EU at the designated point of import (DPI) into the Community.
- Box I.21. Not applicable.

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- Box I.22. For import: this also applies to those consignments that after receiving clearance as acceptable for free circulation, may be stored under customs control, and receive customs clearance at a later stage, either at the customs office on which the DPI is geographically dependent, or at another location.
- Box I.23. Not applicable.
- Box I.24. Tick the appropriate means of transport.
- Box I.25. Place and date of declaration: this commits the signatory also to accept back consignments in transit that are refused entry by a third country.

### **Part II. This section is for the completion by the competent authority or designated official agent.**

- Box II.1. This refers to the unique reference number given by the DPFA issuing the certificate and is as in Box I.2.
- Box II.2. For use by Customs services to add relevant information (e.g. for the number of the customs document) where consignments remain under customs control for a given period. This information is normally added after signature by the official responsible.
- Box II.3. Documentary check: To be completed for all consignments.
- Box II.4. Tick appropriate box: customs warehouse, free zone/free warehouse, ship supplier or ship.
- Box II.5. Complete where relevant for acceptability for transshipment.
- Box II.6. Indicate clearly when import is refused, the subsequent process to be carried out. The address of any transformation establishment should be entered in Box II.7.
- Box II.7. Give approval number and address (or ship name and port) for all destinations where further control of the consignment is required i.e. for Box II.6, 'Re-dispatching', 'Destruction' or 'Transformation'.
- Box II.8. Put here the Official Stamp of the DPFA (competent authority).
- Box II.9. Signature of the official responsible of the DPFA (competent authority).
- Box II.10. Not applicable.
- Box II.11. Tick 'Derogation' if an identity check has not been performed.
- Box II.12. Physical checks:  
Reduced checks: tick the box only when a consignment is considered checked satisfactorily with documentary check only.
- Box II.13. Complete with the category of substance or pathogen for which an investigation procedure is undertaken.
- Box II.14. This box is to be used for all consignments approved for free circulation within the single market. (It should also be used for consignments that meet EU requirements but for financial reasons are not being customs cleared immediately at the DPFA or DPI, but are being stored under customs control in a customs warehouse or will be customs cleared later and/or at a geographically separate destination.)
- Box II.15. Not applicable.
- Box II.16. Indicate clearly when import is refused, the subsequent process to be carried out. The address of any transformation establishment should be entered in Box II.18.
- Box II.17. Reasons for refusal: for use as appropriate to add relevant information. Tick the appropriate box.
- Box II.18. Give approval number and address (or ship name and port) for all destinations where further control of the consignment is required i.e. for Box II.16, 'Re-dispatching', 'Destruction' or 'Transformation'.
- Box II.19. Use this box when the original seal recorded on a consignment is destroyed on opening the container. A consolidated list of all seals that have been used for this purpose should be kept.
- Box II.20. Put here the Official Stamp of the DPI (competent authority).
- Box II.21. Signature of the official responsible of the DPI (competent authority).

### **Part III This section is for the completion by the competent authority or designated official agent for control**

- Box III.1. Details on re-dispatching: the official agent at designated point must indicate the used means of transport, its identification and the country and date of re-dispatching as soon as they are known.
- Box III.2. Follow-up: indicate the local competent authority unit responsible for the supervision in case of destruction or transformation of the consignment.

## Appendix 4

Box III.3. Signature of the Local Competent Authority in case of destruction or transformation and signature of the official responsible of the DPI/DPFA in case of re-dispatching.