

## COMMISSION IMPLEMENTING REGULATION (EU) No 1097/2012

of 23 November 2012

**amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive as regards dispatch of animal by-products and derived products between Member States**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002<sup>(1)</sup>, and in particular Article 21(5)(a) and Articles 23(3) and 48(2) thereof,

Whereas:

- (1) Regulation (EC) No 1069/2009 lays down public and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products. It also provides rules for placing on the market of animal by-products and derived products.
- (2) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive<sup>(2)</sup>, lays down implementing rules for Regulation (EC) No 1069/2009, including rules on the registration of operators, the content of commercial documents which accompany consignments of animal by-products and derived products in trade between Member States and the layout of the notification form which must be provided for certain animal by-products and derived products pursuant to Article 48(1) of Regulation (EC) No 1069/2009.
- (3) Pursuant to Regulation (EC) No 1069/2009, operators are to ensure that animal by-products and derived products are traceable at all stages of the chain of collecting, manufacturing, use and disposal, so as to

avoid unnecessary disruptions of the internal market in the case of events which are linked to actual or potential risks to public or animal health.

- (4) Operators must ensure that activities covered by the scope of animal by-products legislation are registered or approved. However, handling of small quantities of Categories 2 and 3 materials may present negligible risk if they originate from areas where no transmissible disease to humans or animals has been notified. Member States should therefore be authorised to allow particular activities without registration as provided for in Article 23 of Regulation (EC) No 1069/2009. Such a derogation must be limited only to activities concerning the direct supply of the products within the region to the final user, on the local market or to local retail establishments.
- (5) Each consignment of animal by-products or derived products to be traded between Member States is to be accompanied by a commercial document. However, it is necessary to amend and extend current requirements on the commercial document to ensure that it includes all necessary information on the safe handling, treatment and intended use or disposal of the concerned material.
- (6) On the commercial document operators must specify certain information on the consignment, in particular the category of animal by-products or derived products, nature of commodity and type of treatment. According to Article 3 of Regulation (EU) No 142/2011 there is no need to issue a commercial document for derived products which have been declared as the end point in the manufacturing chain. Also a reference to processing standards in Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>(3)</sup> may be removed. Annex VIII to Regulation (EU) No 142/2011 should therefore be amended.
- (7) Several animal by-products and derived products referred to in Article 48(1) of Regulation (EC) No 1069/2009 must be authorised in advance by the competent authority of the Member State of destination upon application by the operator. Annex XVI to Regulation (EU) No 142/2011 sets out a standard format for the authorisation of the dispatch of animal by-products and derived products to another Member State. That format

<sup>(1)</sup> OJ L 300, 14.11.2009, p. 1.

<sup>(2)</sup> OJ L 54, 26.2.2011, p. 1.

<sup>(3)</sup> OJ L 139, 30.4.2004, p. 55.

should be amended to include information on the end date of validity of authorisations, the volume or mass of the consignment, the name and address of the consignor, the origin of the animal by-products and the place of destination of the consignment. Annex XVI to Regulation (EU) No 142/2011 should therefore be amended.

- (8) Regulation (EU) No 142/2011 should therefore be amended accordingly.
- (9) 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*

Regulation (EU) No 142/2011 is amended as follows:

- (1) in Article 20, point (c) of paragraph 4 is replaced by the following:
- '(c) operators transporting dry untreated wool and hair, provided they are securely enclosed in packaging, and

directly dispatched to a plant producing derived products for uses outside the feed chain or to a plant carrying out intermediate operations, under conditions which prevent the spreading of pathogenic agents;

- (d) operators using small quantities of Categories 2 and 3 materials referred to in Articles 9 and 10 of Regulation (EC) No 1069/2009 or of products derived therefrom, for the purpose of direct supply of the products within the region to the final user, on the local market or to local retail establishments, if the competent authority does not consider such activity to present a risk of spreading any serious transmissible disease to humans or animals; this point shall not apply where those materials are used as feed for farmed animals other than fur animals.;

- (2) Annexes VIII and XVI are amended in accordance with the text in the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 23 November 2012.

*For the Commission*  
*The President*  
José Manuel BARROSO

## ANNEX

The Annexes to Regulation (EU) No 142/2011 are amended as follows:

- (1) in Annex VIII, Chapter III, the model commercial document is replaced by the following:

**'Commercial document**

For the transport of animal by-products and derived products not intended for human consumption in accordance with Regulation (EC) No 1069/2009 within the European Union

**EUROPEAN UNION****Commercial document**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name Address Postcode		I.2. Document reference No		I.2.a. Local reference No			
			I.3. Central competent authority					
			I.4. Local competent authority					
	I.5. Consignee Name Address Postcode Tel.		I.6.					
			I.7.					
	I.8. Country of origin	ISO code	I.9. Region of origin	Code	I.10. Country of destination	ISO code	I.11. Region of destination	Code
	I.12. Place of origin Establishment <input type="checkbox"/>  Name Address Postcode		Approval number		I.13. Place of destination Establishment <input type="checkbox"/>  Name Address Postcode		Other <input type="checkbox"/>  Approval number	
	I.14. Place of loading		I.15. Date of departure					
	I.16. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification		I.17. Transporter Name Address Postcode Approval number Member State					
	I.18. Description of commodity				I.19. Commodity code (CN code)		I.20. Quantity	
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/> Controlled temperature <input type="checkbox"/>				I.22. Number of packages			
	I.23. Seal/Container No				I.24. Type of packaging			
	I.25. Commodities certified for: Animal feedingstuff <input type="checkbox"/> Technical use <input type="checkbox"/>							
I.26.				I.27. Transit through Member States <input type="checkbox"/> Member State Member State Member State ISO Code ISO Code ISO Code				
I.28. Export <input type="checkbox"/> Third country Exit point		ISO Code Code		I.29.				
I.30.								
I.31. Identification of the commodities								
Species (scientific name)		Nature of commodity	Category	Treatment type	Approval number of establishments Manufacturing plant		Batch number	

COUNTRY		Animal by-products/derived products not intended for human consumption	
II.	Health information	II.a. Certificate reference number	II.b.
II.1.	Declaration by the consignor		
	I, the undersigned, declare that:		
II.1.1.	the information in Part I is factually correct;		
II.1.2.	all precautions have been taken to avoid contamination of the animal by-products or derived products with pathogenic agents and cross-contamination between various categories.		
	<b>Notes:</b>		
	<b>Part I:</b>		
	— Box reference I.9 and I.11: if appropriate.		
	— Box reference I.12, I.13 and I.17: approval number or registration number. In the case of processed manure indicate in Box I.13 the approval or registration number of plant or holding of destination.		
	— Box reference I.14: complete if different from 'I.1. Consignor'.		
	— Box reference I.25: technical use: any use other than for animal consumption.		
	— Box reference I.31:		
	<b>Animal species:</b>	For Category 3 material and products derived therefrom destined for use as feed material. Select from the following: Aves, Ruminants, Non-Ruminants, <i>Mammalia</i> , <i>Pesca</i> , <i>Mollusca</i> , <i>Crustacea</i> , Invertebrates.	
	<b>Nature of commodity:</b>	Enter a commodity chosen from the following list: 'apiculture by-products', 'blood products', 'blood', 'bloodmeal', 'digestion residues', 'digestive tract content', 'dog-chews', 'fishmeal', 'flavouring innards', 'gelatine', 'greaves', 'hides and skins', 'hydrolysed proteins', 'organic fertilisers', 'pet food', 'processed animal protein', 'processed pet food', 'raw pet food', 'rendered fats', 'compost', 'processed manure', 'fish oil', 'milk products', 'centrifuge or separator sludge from milk processing', 'dicalciumphosphate', 'tricalciumphosphate', 'collagen', 'egg products', 'serum of equidae', 'game trophies', 'wool', 'hair', 'pig bristles', 'feathers', 'animal by-products for processing', 'derived products'.	
	<b>Category:</b>	Specify Category 1, 2 or 3 materials. In case of Category 3 material, indicate the point of Article 10 of Regulation (EC) No 1069/2009 that refers to the animal by-product concerned (e.g. Article 10(a), Article 10(b), etc.). In the case of Category 3 material for use in raw petfood indicate '3a', '3b(i)' or '3b(ii)' depending on whether the animal by-products are referred to in Article 10(a) or in Article 10(b)(i) or (ii) of Regulation (EC) No 1069/2009. In the case of hides and skins and products derived therefrom, indicate '3b(iii)' or '3(n)' depending on whether the animal by-products or derived products are referred to in Article 10(b)(iii) or in Article 10(n) of Regulation (EC) No 1069/2009. Where the consignment is made of more than one category, indicate the quantity and if applicable the number of containers per category of materials.	
	<b>Treatment type:</b>	For treated hides and skins indicate the treatment: '(a)' for dried; '(b)' for dry-salted or wet-salted for at least 14 days prior to dispatch; '(c)' for salted for seven days in sea salt with the addition of 2 % sodium carbonate. For Categories 1 and 2 materials describe the method of processing or transformation. Indicate the relevant processing method (choose a method from 1 to 5 referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011). For Category 3 materials and derived products from Category 3 material destined for use in feed: if appropriate describe the nature and the methods of the treatment. Indicate the relevant processing method (choose a method from 1 to 7 referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011).	
	<b>Batch number:</b>	Enter batch number or ear tag number, if applicable.	
	<b>Part II:</b>	— <i>The signature must be in a different colour to that of the printing.</i>	
	Signature		
	Done at .....	on .....	
	(place)	(date)	
	(signature of the responsible person/consignor (name, in capital letters)'		

(2) in Annex XVI, Chapter III, Section 10 is replaced by the following:

*Section 10*

**Standard format for applications for certain authorisations in intra-Union trade**

Operators shall apply to the competent authority of the Member State of destination for the authorisation of the dispatch of animal by-products and derived products referred to in Article 48(1) of Regulation (EC) No 1069/2009 in accordance with the following format:

**APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OF ANIMAL  
BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE**

**(ARTICLE 48 OF REGULATION (EC) No 1069/2009)**

<b>Name and address of place of origin</b>	<b>Approval or registration number, issued by (competent authority)</b>
<b>Name and address of consignor</b>	<b>Approval or registration number, issued by (competent authority)</b>
<b>Name and address of applicant</b>	<b>Approval or registration number, issued by (competent authority)</b>
<b>Name and address of place of destination</b>	<b>Approval or registration number, issued by (competent authority)</b>
<p><b>Animal by-products/derived products <sup>(1)</sup></b></p> <p><input type="checkbox"/> Category 1 material consisting of: ..... (nature of the material)</p> <p><input type="checkbox"/> Category 2 material consisting of: ..... (nature of the material)</p> <p><input type="checkbox"/> Meat-and-bone meal derived from Category 1 material</p> <p><input type="checkbox"/> Animal fat derived from Category 1 material</p> <p><input type="checkbox"/> Meat-and-bone meal derived from Category 2 material</p> <p><input type="checkbox"/> Animal fat derived from Category 2 material</p>	<p><b>Intended use <sup>(1)</sup></b></p> <p><input type="checkbox"/> Disposal</p> <p><input type="checkbox"/> Processing</p> <p><input type="checkbox"/> Combustion</p> <p><input type="checkbox"/> Application to land</p> <p><input type="checkbox"/> Transformation into biogas</p> <p><input type="checkbox"/> Composting</p> <p><input type="checkbox"/> Petfood <sup>(2)</sup></p> <p><input type="checkbox"/> Production of biodiesel</p> <p><input type="checkbox"/> For feeding to <sup>(3)</sup>: .....</p> <p><input type="checkbox"/> For the manufacture of the following derived products <sup>(4)</sup>: .....</p>
<p>Indicate the quantity of animal by-products/derived products (volume or mass) <sup>(4)</sup> <sup>(5)</sup></p> <p>.....</p>	

(APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE (ARTICLE 48 OF REGULATION (EC) No 1069/2009))

In case of meat-and-bone meal and animal fat:

Species of origin:

The materials have been processed according to the following method (6): .....

I, the undersigned, declare that the above information is factually correct.

(Signature: name, date, contact details: telephone, fax (if applicable), e-mail)

Decision by the competent authority of the Member State of destination (7):

The dispatch of the consignment is:

- refused.
accepted.
accepted subject to the application of pressure sterilisation (method 1) to the materials.
accepted subject to the following conditions for the dispatch (4):

This authorisation is valid until: ..... (8)

(Date, stamp and signature of the competent authority)

Notes:

Complete the document in BLOCK capitals.

- (1) Tick as appropriate.
(2) In the case of petfood produced with Category 1 material comprising animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC.
(3) Specify in accordance with Article 18 of Regulation (EC) No 1069/2009.
(4) Fill in, if appropriate.
(5) Specify.
(6) Specify one of the processing methods referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011.
(7) For the competent authority: tick as appropriate.
(8) Insert date of expiration of authorisation.