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 (Text with EEA relevance)

ANNEX XVI

OFFICIAL CONTROLS

CHAPTER I

OFFICIAL CONTROLS IN PROCESSING PLANTS

Section 1

Supervision of the production

1. The competent authority shall supervise processing plants to ensure compliance with the requirements of Regulation (EC) No 1069/2009 and with this Regulation.

It shall, in particular:

(a) check:

(i) the general conditions of hygiene of the premises, equipment and staff;

(ii) the efficacy of the own checks carried out by the operator of the processing plant, in accordance with Article 28 of Regulation (EC) No 1069/2009; such checks must include an examination of the results of those checks and if necessary, the taking of samples;

(iii) the effective implementation of the permanent written procedure based on the HACCP principles in accordance with Article 29(1) of Regulation (EC) No 1069/2009; such checks must include an examination of the results of this implementation and if necessary, the taking of samples;

(iv) the standards of the products after processing; the analyses and tests must be carried out in accordance with scientifically recognised methods, in particular, those laid down in Union legislation or, where no such methods are laid down in Union legislation, in accordance with recognised international standards or, in their absence, national standards; and

(v) the storage conditions;

(b) take any samples required for laboratory tests; and

(c) make any other checks it considers necessary to ensure compliance with Regulation (EC) No 1069/2009 and with this Regulation.

2. To allow it to carry out its responsibilities under point 1, the competent authority must have free access at all times to all parts of the processing plant and to records, commercial documents and health certificates.

Section 2

Validation procedures

1. Prior to issuing an approval for a processing plant, as provided for in Article 44(1) of Regulation (EC) No 1069/2009, the competent authority must check that a validation

of the processing plant has been carried out by the operator in accordance with the following procedures and indicators:

(a) a description of the process by a process flow diagram;

(b) an identification of critical control points (CCPs) including the material process rate for continuous systems;

(c) the compliance with the specific process requirements laid down by this Regulation; and

(d) the achievement of the following requirements:

(i) particle size for batch-pressure and continuous processes, defined by the mincer hole or the anvil gap size;

(ii) temperature, pressure, processing time and, in the case of continuous processing systems, the material processing rate, as specified in points 2 and 3.

2. In the case of a batch pressure system:

(a) the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;

(b) the pressure stage must be monitored with a permanent pressure gauge; pressure must be plotted against real time;

(c) the processing time must be shown by time/temperature and time/pressure diagrams.

At least once a year the thermocouple and the pressure gauge must be calibrated.

3. In the case of a continuous pressure system:

(a) the temperature and the pressure must be monitored with thermocouples, or an infrared temperature gun, and pressure gauges must be used at defined positions throughout the process system in such a way that temperature and pressure comply with the required conditions inside the whole continuous system or in a section of it; the temperature and pressure must be plotted against real time;

(b) measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required conditions, must be provided to the competent authorities, using insoluble markers, such as manganese dioxide, or a method which offers equivalent guarantees.

Accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:

(i) feed screw revolutions per minute (rev./min.);

(ii) the electric power (amps at given voltage);

(iii) the evaporation/condensation rate; or

(iv) the number of pump strokes per unit time.

All measuring and monitoring equipment must be calibrated at least once a year.

4. The competent authority must repeat the checks on the validation procedures when it considers it necessary, and in any case each time any significant alterations are made to the process, such as modifications of the machinery or changes of raw materials.

CHAPTER II

LISTS OF REGISTERED AND APPROVED ESTABLISHMENTS, PLANTS AND OPERATORS

1. Access to lists of registered and approved establishments, plants and operators

In order to assist Member States in making up-to-date lists of registered and approved establishments, plants and operators available to other Member States and to the public, the Commission shall provide a website which shall contain links to the national websites provided by each Member State, as referred to in point 2(a).

2. Format for national websites

(a) Each Member State shall provide the Commission with a linking address to a single national website containing the master list of all registered and approved establishments, plants and operators on its territory (‘master list’).

(b) Each master list shall consist of one sheet and shall be completed in one or more official languages of the Union.

3. The layout, including the relevant information and codes, of master lists shall follow the technical specifications which are published by the Commission on its website.

CHAPTER III

SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS

Section 1

Official controls regarding marking of derived products

The competent authority shall carry out a performance check of the monitoring and recording system referred to in point 2 of Chapter V of Annex VIII to this Regulation to ascertain compliance with this Regulation and may, where necessary, request the testing of additional samples in accordance with the method referred to in the second paragraph of the same point.

Section 2

Official controls in low-capacity incineration plants

The competent authority shall inspect a low-capacity incineration plant for incineration of specified risk materials before approval, and at least once a year to monitor compliance with Regulation (EC) No 1069/2009 and with this Regulation.

Section 3

Official controls in remote areas

In the case of disposal of animal by-products in remote areas in accordance with Article 19(1)(b) of Regulation (EC) No 1069/2009, the competent authority shall monitor regularly the areas categorised as remote areas to ensure that those areas and the disposal operations are properly controlled.

Section 4

Official controls in registered farms for the feeding of fur animals

1. The competent authority shall take the necessary measures to control:

(a) the appropriate composition, processing and use of the feed containing meat-and-bone meal or other products which have been processed in accordance with the processing methods set out in Chapter III of Annex IV and which are derived from the bodies or parts of bodies of animals of the same species;

(b) that the animals are fed with the feed referred to in point (a), including:

(i) strict supervision of the health status of those animals; and

(ii) appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.

2. The samples referred to in point 1(b)(ii) shall include samples taken from animals showing neurological symptoms and from older breeding animals.

Section 5

Official controls regarding collection centres

1. The competent authority shall:

(a) include collection centres into the list drawn up in accordance with Article 47(1) of Regulation (EC) No 1069/2009;

(b) assign an official number to each collection centre; and

(c) update the list of collection centres and make it available together with the list drawn up in accordance with Article 47(1) of Regulation (EC) No 1069/2009.

2. The competent authority shall carry out official controls at collection centres in order to verify compliance with this Regulation.

[F1 Section 6

Official controls regarding the feeding of wild animals and certain zoo animals with Category 1 material

The competent authority shall monitor the health status of the farmed animals in the region where feeding is carried out as referred to in Sections 2, 3 and 4 of Chapter II of Annex VI

and shall carry out appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.

Those samples shall include samples taken from suspected animals and from older breeding animals.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EU) No 294/2013 of 14 March 2013 amending and correcting 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 (Text with EEA relevance).

Section 7

Official controls regarding the application of certain organic fertilisers and soil improvers

The competent authority shall carry out controls along the entire chain of production and use of organic fertilisers and soil improvers subject to the restrictions referred to in Chapter II of Annex II.

Those controls shall include checks on the mixing with a component referred to in point 2 of Section 1 of Chapter II of Annex XI, and checks on the stocks of such products kept on farm and the records kept in accordance with Regulation (EC) No 1069/2009 and with this Regulation.

Section 8

Official controls regarding approved photographic factories

The competent authority shall carry out documentary checks in approved photographic factories referred to in Table 3 of point 1 of Section 11 of Chapter II of Annex XIV on the channelling chain from the border inspection posts of first entry to the approved photographic factories for the purpose of reconciliation of the quantities of products imported, used and disposed of.

Section 9

Official controls regarding certain imported rendered fats

The competent authority shall carry out documentary checks in registered establishments or plants receiving rendered fats which have been imported in accordance with Section 9 of Chapter II of Annex XIV on the channelling chain from the border inspection posts of first entry to the registered establishment or plant for the purpose of reconciliation of the quantities of products imported, used and disposed of.

[F2 Section 10

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

Operators shall inform the competent authority of the Member State of origin and 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, and fish oil or fishmeal of Category 3 materials intended for detoxification in accordance with the following format in TRACES:**]**

Reference number:	**PAGE 1/2**
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)	
Name and address of applicant	**Approval or registration number** (2)
Name and address of place(s) of origin	**Approval or registration number(s)** (2)
Name and address of consignor (1)	**Approval or registration number** (2)
Name and address of place(s) of destination(s) (3)	**Approval or registration number(s)** (3)
Animal by-products/derived products (4) ☐ Category 1 material consisting of: _____ (nature of the material) ☐ Category 2 material consisting of: _____ (nature of the material) ☐ Meat-and-bone meal derived from Category 1 material ☐ Rendered fats derived from Category 1 material ☐ Meat-and-bone meal derived from Category 2 material ☐ Rendered fats derived from Category 2 material ☐ Fish oil or fishmeal with excessive level(s) of dioxins and/or PCBs in accordance with Annex I to Directive 2002/32/EC destined for detoxification in an approved establishment	**Intended use** (4) ☐ Disposal as a waste ☐ Processing ☐ Combustion ☐ Incineration or co-incineration in ABP approved establishments or plants ☐ Application to land ☐ Transformation into biogas ☐ Composting ☐ Establishment for intermediate activities ☐ Petfood (5) ☐ Production of biodiesel or other biofuels ☐ For feeding to (6): _____ ☐ For the manufacture of the following derived products (7) (2): _____ ☐ Destined for detoxification in an approved establishment (2)
Indicate the quantity of animal by-products/derived products (volume or mass) (2) (8): _____	

Reference number: **PAGE 2/2**

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 rendered fats:	**Species of origin (information should correspond to the indication of species in DOCOM/CD ([12])):**
The materials have been processed according to the following method ([9]): ..... The materials have been marked with GTH.	

In the case of fish oil intended for detoxification, processing method:

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 ([10]):

The dispatch of the consignment is:

☐ refused.

☐ accepted.

☐ accepted subject to the application of pressure sterilisation (method 1) to the materials and GTH marking.

☐ accepted subject to the following conditions for the dispatch ([2]):

_____

_____

_____

_____

This authorisation is valid until _____ ([11])

_____

(Date, stamp and signature of the competent authority)

Notes:
Complete the document in BLOCK capitals.
([1]) Fill in, if consignor is different from applicant.
([2]) Fill in, if appropriate.
([3]) In case of consignments in bulk multiple places of destination, the applicant is responsible for providing the LVU with all the details of the various places of destination The size of the box may be extended to include all required data. The number of multiple places of destination is subject to decision of the competent authority, responsible for the place(s) of destination.
([4]) Tick as appropriate.
([5]) In the case of petfood produced with Category 1 material, imported from third countries, referred to in Article 8(c) of Regulation (EC) No 1069/2009.
([6]) Specify in accordance with Article 18 of Regulation (EC) No 1069/2009.
([7]) Specify intended uses, such as for the manufacture of fur, organic fertilisers/soil improvers, taxidermy, etc.
([8]) Specify. In case of dead equidae indicate the number of the transponder (microchip), if available, or the unique life number as defined in Article 2(o) of Commission Regulation (EU) 2015/262 as indicated in the identification document.
([9]) Specify one of the processing methods referred to in Chapter III or Chapter IV of Annex IV to Regulation (EU) No 142/2011.
([10]) For the competent authority: tick as appropriate.
([11]) Insert date of expiration of authorisation.
([12]) DOCOM: commercial document in TRACES form/CD: commercial document.

Textual Amendments

F2 Substituted by Commission Implementing Regulation (EU) 2019/1084 of 25 June 2019 amending Regulation (EU) No 142/2011 as regards the harmonisation of the list of approved or registered establishments, plants and operators and the traceability of certain animal by-products and derived products (Text with EEA relevance).

[F3 Section 11

Official controls regarding hydrolysis with subsequent disposal

The competent authority shall carry out controls at sites where hydrolysis with subsequent disposal is carried out in accordance with point B of Section 2 of Chapter V of Annex IX.

Such controls shall, for the purpose of reconciliation of the quantities of hydrolysed materials dispatched and disposed of, include documentary checks:

(a) of the amount of materials which are hydrolysed at the site;

(b) in the establishments or plants where the hydrolysed materials are disposed of.

Controls shall be carried out regularly on the basis of a risk assessment.

During the period of the first 12 months of operation, a control visit to a site, where a container for the hydrolysis is located, shall be carried out every time hydrolysed material is collected from the container.

Following the period of the first 12 months of operation, a control visit to such sites shall be carried out every time the container is emptied and checked for the absence of corrosion and leaking in accordance with point B(3)(j) of Section 2 of Chapter V of Annex IX.**]**

Textual Amendments

F3 Substituted by Commission Regulation (EU) 2015/9 of 6 January 2015 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 (Text with EEA relevance).

[F4 Section 12

Official controls regarding plants approved for the combustion of animal by-products

The competent authority shall carry out documentary checks in accordance with the procedures referred to in Article 6(7) and (8) in approved plants referred to in Chapter V of Annex III.**]**

Textual Amendments

F4 Substituted by Commission Regulation (EU) 2017/1262 of 12 July 2017 amending Regulation (EU) No 142/2011 as regards the use of manure of farmed animals as a fuel in combustion plants (Text with EEA relevance).

Status:
Point in time view as at 08/03/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX XVI.