



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

General Affairs
Legal affairs

Brussels,

EU PILOT 7150/14/SNCO

Request for observations of the authorities of the United Kingdom

Subject: Alleged breaches of Union legislation in relation to the collection and disposal of animal by-products originating from aquaculture establishments in Scotland

I. Summary of the complaint

The Commission services have received a complaint against the United Kingdom alleging breaches of Union legislation in relation to the collection and disposal of animal by-products originating from aquaculture establishments in Scotland. The main allegations can be summarised as follows:

1. The United Kingdom would fail to comply with Regulation (EC) No 1069/2009¹ (Animal by-products Regulation) by making use of the derogation for remote areas under the Regulation in a way that almost the entire aquaculture industry in Scotland takes place within remote areas.

2. The United Kingdom would fail to monitor and verify that the relevant requirements of Regulation (EC) NO 1069/2009 are fulfilled by operators of aquaculture establishments in Scotland, in particular as regards the disposal of animal by-products in specific instances, i.e. so-called event mortality incidents. With this regard, the complainant refers to an event where, between August 2011 and June 2012, more than 80 000 salmon would have perished as a result of an outbreak of the amoebic gill disease (AGD) and sea lice and their unsuccessful treatment with Hydrogen Peroxide in a fish farm located at Ardmaddy, Argyll, Scotland. The amount of dead fish would have been reported by the operator as approximately 203 tonnes during December 2011 alone. The complainant has contacted the Scottish Environment Protection Agency (SEPA), Argyll and Bute Council and Marine Scotland on the issue, and received information from all of these authorities. Allegedly, none of these authorities has monitored or is even aware of the way in which this dead fish has been disposed of, although SEPA would have recorded the mortalities

¹ 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 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

and the Fish Health Inspectorate of Marine Scotland would have carried out inspections at the relevant establishment.

The complainant has submitted documents to support the allegations, including copies of the correspondence with the above mentioned authorities.

II. Relevant Union legislation

Regulation (EC) No 1069/2009

Regulation (EC) No 1069/2009 lays down health rules as regards animal by-products and derived products not intended for human consumption. Its 50th and 51st recitals read as follows:

"(50) Burial and burning of animal by-products, in particular of dead animals may be justified in specific situations, in particular in remote areas, or in disease control situations requiring the emergency disposal of the animals killed as a measure to control an outbreak of a serious transmissible disease. In particular, disposal on site should be allowed under special circumstances, since the available rendering or incinerator capacity within a region or a Member State could otherwise be a limiting factor in the control of a disease.

(51) [...] The overall size of remote areas in a Member State should be limited, on the basis of the experience gained with the application of Regulation (EC) No 999/2001 so as to ensure that the general obligation to have in place a proper disposal system which complies with the rules laid down in this Regulation is fulfilled."

A "remote area" is defined in Article 3(23) of the Regulation as meaning *"an area where the animal population is so small, and where disposal establishments or plants are so far away that the arrangements necessary for the collection and transport of animal by-products would be unacceptably onerous compared to local disposal"*.

Article 4 of the Regulation lays down the following obligations to the Member States:

"3. Member States shall monitor and verify that the relevant requirements of this Regulation are fulfilled by operators along the entire chain of animal by-products and derived products as referred to in paragraph 2. For that purpose, they shall maintain a system of official controls in accordance with relevant Community legislation.

4. Member States shall ensure that an adequate system is in place on their territory ensuring that animal by-products are:

(a) collected, identified and transported without undue delay; and

(b) treated, used or disposed of in accordance with this Regulation."

Articles 8 to 10 of the Regulation lay down the lists of specific categories into which animal by-products are categorised in order to reflect the risk of public and animal health arising from those animal by-products, as laid down by Article 7(1) of the Regulation.

According to Article 9 of the Regulation, the following animal by-products are classified as Category 2 material:

"(f) animals and parts of animals, other than those referred to in Article 8 or Article 10,

(i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;

[...]"

"(h) animal by-products other than Category 1 material or Category 3 material."

Category 2 material must be disposed of or used in accordance with Article 13 of the Regulation. The methods authorised by that Article include disposal as waste by incineration or co-incineration in an incineration or co-incineration plant approved in accordance with Article 24(1)(b) or (c) of the Regulation, processing in a processing plant approved in accordance with 24(1)(a) of the Regulation and, in the case of material originating from aquatic animals, ensilage, composting or transformation into biogas in a plant approved for such purposes under Article 24(1)(a) or (g) of the Regulation. Disposal by burial or burning is generally prohibited, save in exceptional circumstances and in territories classified as remote areas.

Article 19 of the Regulation lays down the following provisions on remote areas:

"1. The competent authority may, by way of derogation from Articles 12, 13, 14 and 21, authorise the disposal:

[...]"

"(b) by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health of Category 1 material referred to in Article 8(a)(v) and (b)(ii), Category 2 and Category 3 materials in remote areas; [...]"

"2. The animal population of a particular species in the remote areas referred to in paragraph 1(b) shall not exceed a maximum percentage of the animal population of this species in the Member State concerned.

3. Member States shall make available to the Commission information on:

(a) the areas that they categorise as remote areas for the purpose of applying paragraph 1(b) and the reasons for that categorisation, and updated information concerning any change to such categorisation;"

Article 45 of Regulation (EC) No 1069/2009 concerns official controls and lays down the following:

"1. Without prejudice to Article 5, the competent authority shall at regular intervals carry out official controls and supervision of the handling of animal by-products and derived products falling within the scope of this Regulation."

Regulation (EU) No 142/2011

Regulation (EU) No 142/2011² lays down measures implementing Regulation (EC) No 1069/2009. According to Article 15 of Regulation (EU) No 142/2011, the following special rules on disposal set out in Chapter III of Annex VI of that Regulation shall apply

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 (OJ L 54, 26.2.2011, p. 1).

if the competent authority authorises the disposal of animal by-products by way of the derogation provided for in Article 19(1)(b) of Regulation (EC) No 1069/2009 for remote areas:

"(a) the special disposal rules for animal by-products set out in Section 1;

(b) the rules for the burning and burial of animal by-products in remote areas set out in Section 2;"

Article 32 of the said Regulation lays down the following on official controls:

"1. The competent authority shall take the necessary measures to control the entire chain of collection, transport, use and disposal of animal by-products and derived products, as referred to in Article 4(2) of Regulation (EC) No 1069/2009.

*Those measures shall be carried out in accordance with the principles for official controls laid down in Article 3 of Regulation (EC) No 882/2004.
[...]"*

"3. The competent authority shall carry out the following official controls, as referred to in Article 45(1) of Regulation (EC) No 1069/2009, in accordance with the requirements set out in Annex XVI hereto:

[...]"

"(b) official controls of other activities which involve the handling of animal by-products, and derived products as set out in Sections 1 to 9 of Chapter III."

Section 1 of Chapter III of Annex VI to the Regulation lays down special disposal rules for animal by-products. These rules must be complied with, inter alia, where the competent authority has authorised the disposal of animal by-products in remote areas under the derogation provided for by Article 19(1)(b) of Regulation (EC) No 1069/2009.

Section 2 of Chapter III of Annex VI to the Regulation is titled *"burning and burial of animal by-products in remote areas"* and reads as follows:

"The maximum percentage as referred to in Article 19(2) of Regulation (EC) No 1069/2009 shall not exceed the following:

(a) 10 % of the bovine population of the Member State concerned;

(b) 25 % of the ovine and caprine population of the Member State concerned;

(c) 10 % of the porcine population of the Member State concerned; and

(d) a percentage of the population of other species which is determined by the competent authority, on the basis of an assessment of the possible risks for public and animal health which arise from the disposal of animals of those species by burning or burial on site."

Section 3 of Chapter III of Annex XVI to the Regulation is titled *"official controls in remote areas"* and worded as follows:

"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."

Regulation (EC) No 882/2004

Official controls to ensure the verification of compliance with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011 must be carried out in accordance with Regulation (EC) No 882/2004³.

Article 3 of the Regulation lays down general obligations on the Member States with regard to the organisation of official controls, including the obligation to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of the Regulation.

Article 4 of the Regulation lays down, inter alia, the following operational criteria for competent authorities:

"2. The competent authorities shall ensure:

[...]"

"(e) that they have the legal powers to carry out official controls and to take the measures provided for in this Regulation;

(f) that they have contingency plans in place, and are prepared to operate such plans in the event of an emergency;

[...]"

"3. When a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.

[...]"

"5. When, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units."

Article 13(1) of the Regulation lays down the requirement for the Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment. Article 13(2) of the Regulation lists the following elements which these contingency plans must specify:

"(a) the administrative authorities to be engaged;

(b) their powers and responsibilities;

and

(c) channels and procedures for sharing information between the relevant parties."

III. Questions to the authorities of the United Kingdom

³ 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 (OJ L 165, 30.4.2004, p. 1). See the 3rd recital of the Regulation where rules governing animal by-products are specifically mentioned as part of feed and food law.

The Commission Services would invite the authorities of the United Kingdom to provide their observations on the following questions:

1. As regards the current designation of remote areas under Article 19(1)(b) of Regulation (EC) No 1069/2009 in Scotland, the Commission services are aware of The Animal By-Products (Enforcement) (Scotland) Regulations 2013⁴, Article 8 of which lists the areas which are categorised as remote areas for the purposes of Article 19(1)(b) of Regulation (EC) No 1069/2009. Could the authorities of the United Kingdom confirm that this is the provision which is currently in force in order to designate the remote areas in Scotland? If not, could the authorities of the United Kingdom provide copies of the legislative provisions or administrative decisions in force which designate such areas?
2. Could the authorities of the United Kingdom provide the Commission services with data on the size of the different populations of livestock species in territories designated as remote areas in Scotland in comparison with the entire populations of those species in the United Kingdom, including such data on the populations of the fish species which are subject to aquaculture activities in the United Kingdom?
3. Could the authorities of the United Kingdom provide the Commission services with data on the amounts of animal by-products, in particular dead animals, generated and disposed of in territories designated as remote areas in Scotland?
4. As regards fish in aquaculture, could the authorities of the United Kingdom provide the Commission services with the average mortality rate observed in aquaculture in periods without so called event mortalities due to disease outbreaks and the amounts of animal by-products, in particular dead fish, generated and disposed of in territories designated as remote areas in Scotland?
5. Have the authorities of the United Kingdom determined, within the meaning of point (d) of Section 2 of Chapter III of Annex VI to Regulation (EU) No 142/2011, a maximum percentage in remote areas of the populations of the fish species which are subject to aquaculture activities in the United Kingdom?
6. Could the authorities of the United Kingdom provide the Commission services with data on the disposal facilities available for the disposal of animal by-products originating from territories designated as remote areas in Scotland, including dead fish originating from aquaculture establishments?
7. Could the authorities of the United Kingdom explain how they justify the designation of remote areas in Scotland as currently in force on the basis of the EU legislation explained above, having particular regard to the general obligation of the Member State under Article 4(4) of Regulation (EC) No 1069/2009 to have in place a proper disposal system which complies with the rules laid down in the Regulation, the obligations laid down in Articles 12 to 14 of that Regulation as regards the disposal of different categories of animal by-products, and the definition of a "remote area" as laid down in Article 3(23) of the Regulation? In answering this question, particular account should be taken of the disposal of animal by-products originating from aquaculture establishments.
8. Do the authorities of the United Kingdom consider amending their legislation in relation to the designation of remote areas in Scotland taking account of the foregoing considerations and questions? If so, could they provide the Commission services with a time frame for such amendments?

⁴ Scottish Statutory Instruments 2013 No. 307.

9. Could the authorities of the United Kingdom explain how they monitor and verify that the relevant requirements of Regulation (EC) No 1069/2009 and Regulation (EU) no 142/2011 are fulfilled by operators as regards animal by-products originating from aquaculture establishments in Scotland? Could they in particular explain:

a) how they ensure that the disposal of such animal by-products in territories designated as remote areas takes place under official supervision by means which prevent the transmission of risks to public and animal health, as required by Article 19(1)(b) of Regulation (EC) No 1069/2009;

b) how they ensure that the special disposal rules laid down in Section 1 of Chapter III of Annex VI to Regulation (EU) No 142/2011 are complied with as regards the disposal of such animal by-products in territories designated as remote areas;

c) how they ensure that the competent authorities monitor regularly the areas categorised as remote areas to ensure that those areas and the disposal operations are properly controlled as regards such animal by-products, as required by Section 3 of Chapter III of Annex XVI of Regulation (EU) No 142/2011?

10. Could the authorities of the United Kingdom explain what particular arrangements, if any, are in place to monitor and verify that animal by-products originating from aquaculture activities, which take place in territories designated as remote areas in Scotland, are disposed of in accordance with the relevant requirements of Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011, in the case of increased fish mortality relating to specific incidents such as disease outbreaks, i.e. so-called event mortality incidents?

11. Could the authorities of the United Kingdom explain what arrangements are in place to ensure, as required by Article 4(3) and (5) of Regulation (EC) No 882/2004, the efficient and effective coordination between all the competent authorities and units involved in the official controls performed to ensure the verification of compliance with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011 as regards the disposal of animal by-products originating from aquaculture activities which take place in territories designated as remote areas in Scotland? Are there any contingency plans in place which would specify, in particular, channels and procedures of sharing information between the relevant parties in the case of event mortality incidents as referred to in question No 10?

12. Do the authorities of the United Kingdom consider amending or modifying their legislation or administrative guidance or practices in relation to the system of monitoring and verifying compliance with Regulation (EC) NO 1069/2009 and (EU) No 142/2011 taking account of the foregoing considerations and questions? If so, could they provide the Commission services with a time frame for such amendments or modifications?

We would be grateful to receive your comments and explanations on the above-mentioned questions.