Case No: 70943
Event No: 709596
Decision No: 402/14/COL

EFTA SURVEILLANCE AUTHORITY

REASONED OPINION

Delivered in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning Iceland's failing to comply with its obligations under Council Directive 89/662/EEC or Article 18 of the EEA Agreement by subjecting the entry of fresh meat, meat preparations and other meat products in Iceland to an authorisation procedure

1. Introduction

1 In the present reasoned opinion, the EFTA Surveillance Authority ("the Authority") will demonstrate why it considers that the Icelandic legislation currently applicable to the importation of fresh meat, meat preparations and other meat products from other EEA States is in breach of EEA law.

2 In this document, the Authority will rely largely on the legal analysis developed in its letter of formal notice of 30 October 2013[1] as it considers that the arguments presented by Iceland in its reply to the letter of formal notice[2] have not altered its conclusion.

3 First, the Authority will explain why it considers that the authorisation procedure in place in Iceland for the importation of fresh meat constitutes, unlike safeguard measures available under EEA law[3], a permanent measure unilaterally imposed by Iceland, in breach of Directive 89/662/EEC, which is based on trust and mutual recognition of checks carried out in other EEA States.

4 Second, the Authority will develop the reasons why it considers that these rules are not, in the alternative, compatible with Article 18 EEA in so far as they represent obstacles to trade in the form of "*technical barriers*" within the meaning of Article 18 EEA.

5 Finally, the Authority will explain why it considers that the data presented in the two risk assessments presented by Iceland[4] undermines the argument that the measures – such as the requirement to freeze the meat products for a period of 30 days at -18°C – are justified and proportionate to protect the Icelandic livestock. In particular, the Authority will show that it results from the two reports that the principal risk of spreading the pathogens is linked to the marginal activity of "hobby farming" (pigs and poultry) and that most of the pathogens used to justify the measures – and identified as posing a "non-negligible risk" – would survive freezing over a 30 months period. It follows that the Icelandic measures do not appear to be suitable and necessary to eliminate the risk of infection of the Icelandic livestock and protect human health. Consequently, they cannot be justified under Article 13 EEA.

[1] Letter of formal notice of the Authority to Iceland of 30 October 2013.
[2] Reply by Iceland of 27 February 2014 to the Authority's letter of formal notice
[3] See Articles 7 and 8 of Directive 89/662/EEC as well as paragraph 3 of the Introductory Part of Annex I, Chapter I thereto of the EEA Agreement.
[4] Risk assessment prepared by Stephen Cobb of SRC associates entitled: "*Import risk assessment: Unrestricted imports of ruminants, swine and poultry meat and meat products from the European Union*" and evaluation report prepared by MAST in March 2012 entitled: "*Importation of raw beef, pork and broiler meat from the European Union. Evaluation of possible public health risk*".

2. Correspondence

6 By letter of 12 December 2011, the Authority informed the Icelandic Government that it had received a complaint against Iceland concerning the restrictions on the importation of meat into Iceland on 6 December 2011.

7 In the complaint, it is alleged that Iceland, by keeping a ban on the importation of meat into Iceland without reference to available scientific evidence or relevant risk assessment, has failed to comply with its obligations under the EEA Agreement. The complaint identifies Act No. 25/1993 and Regulation No 509/2004 (now Regulation (IS) No. 448/2012 of 23 May 2012) as the main rules governing imports of meat in Iceland.

8 In its letter of 12 December 2011, the Authority invited Iceland to describe in detail the Icelandic rules governing the importation of meat in Iceland originating both from third countries and from EEA States and to provide detailed information in support of the claim that these arrangements are justified under Article 13 EEA.

9 In particular, the Authority requested Iceland to demonstrate (1) that the risk alleged for public health appears sufficiently established on the basis of the latest scientific data available and (2) that no "less trade restrictive measures" were available to Iceland to achieve the same objective.

10 Iceland replied to this request on 12 March 2012 (your reference SLR1111024/2.5). In particular, Iceland set out the reasons why it considers that the rules governing imports of meat in Iceland are justified both under Article 13 EEA (in particular as it allows for protection of health of humans and animals) and the precautionary principle.

11 On 12 June 2012, the Authority requested the Icelandic authorities to provide additional clarification concerning the justifications presented by Iceland (Event no. 637437). The Icelandic Government replied to that letter on 5 September 2012 (your reference ANR12090262).

12 In its second reply, Iceland confirmed that it considers that its rules governing imports of meat in Iceland are justified under Article 13 EEA and that the applicable secondary EEA legislation does not provide sufficient protection against the inherent animal and human health risks attached to imports of meat in Iceland.

13 By letter of 20 February 2013 (Event no. 660557), the Authority presented its preliminary conclusions to Iceland in this case. In this letter, the Authority indicated to Iceland that it considered that Article 10 of Act No. 25/1993 and Articles 3, 4 and 5 of Regulation (IS) No. 448/2012 are in breach of Article 5 of Directive 89/662/EEC and/or Article 18 of the EEA Agreement. Based on the information submitted so far by the Icelandic Government the Authority could not consider the measures justified on the basis of Article 13 EEA.

14 On 27 May 2013, Iceland replied to this letter (your reference no. ANR13010327/2.3.8) and first recalled the purpose and origin of its rules on imports of meat. Stemming from alleged heightened risk of infection of its livestock due to Iceland's geographic isolation over the centuries, the current rules are designed to

protect the Icelandic livestock and population against risks that are not fully and adequately addressed in the EEA legislation. Indeed, the Icelandic livestock is more exposed than most animals in other European countries and an increase in imports of meat from other countries would increase the risk of infection. The current EEA legislation only provides protection against known pathogens and not against pathogens to which livestock in other countries have built up immunity while the Icelandic livestock has not.

15 With regard to the application of secondary EEA legislation, Iceland argued that the legal implications of the incorporation of Directive 89/662/EEC concerning veterinary checks differed depending on whether it applies in Iceland or in countries in the European Union. This stems from the fact that Iceland is not a party to the European Common Agricultural Policy and that agriculture is excluded from the scope of the EEA Agreement. Consequently, Iceland has "*never abandoned its right to apply more stringent requirements for the protection of public health and livestock populations in Iceland*". There is no basis, Iceland argues, for requiring Iceland to ensure the free movement of agricultural products in the same way as within the European Union.

16 Concerning the application of Article 13 EEA, Iceland argued that it must be given a different, wider interpretation in the case of agricultural products than other products in general.

17 Finally, with regard to the justifications, Iceland is of the opinion that its position is supported by the application of the precautionary principle and is proportionate to the aim pursued. The current rules on imports of meat in Iceland constitute the only feasible way to achieve the pursued objective as "*even highly effective control measures would clearly not be sufficient*".

18 After a thorough examination of the information provided for by the Icelandic Government, the Authority issued on 30 October 2013 a letter of formal notice to Iceland (Event No 680889), in which it concluded that the Icelandic legislation currently applicable to the importation of meat from other EEA States was in breach of EEA law in so far as the Icelandic legal and regulatory framework:

- Imposes general and systematic veterinary checks on fresh meat and meat products that go beyond the veterinary checks permitted under Directive 89/662/EEC and are thus not in line with Article 5 of that directive;

  Alternatively,

- Constitutes "technical barriers to trade" that compromise relevant arrangements in Annex I to the EEA Agreement and is thus in breach of Article 18 EEA. The Authority considers that Iceland has not demonstrated that the measures are justified under Article 13 EEA.

19 On 27 February 2014, Iceland replied to this letter of formal notice.

20 In its reply, Iceland first recalled that the Icelandic legislation currently applicable to the importation of meat does not seek to hinder imports but aims at keeping Iceland free of diseases. Iceland also drew the attention of the Authority to the fact that

unlike in the European Union, borders are still relevant in the EEA, as agricultural goods originating in the EEA are submitted to customs control.

21 In response to the Authority's argument that the Icelandic legislation was in breach of Directive 89/662/EEC and that this Directive has fully harmonised veterinary checks in the EEA, making justifications under Article 13 EEA non available, Iceland made the following remarks.

22 First, according to Iceland, Directive 89/662/EEC has not fully harmonised veterinary checks in the EEA and the Icelandic measures serve an objective that lies beyond the Directive's purpose, namely to protect Iceland from pathogens that are common in Europe but unknown in Iceland. Iceland considers that the Directive aims primarily at preventing "double-checks" in importing States.

23 Second, Iceland argued that the Authority's reading of Directive 89/662/EEC was only correct in a European Union context. Due to differences in the scope and objective of the EEA Agreement, Directive 89/662/EEC cannot be read, in the EEA context, as excluding systematic controls at border. According to Iceland, this stems from the fact that there is no over-arching principle of free movement of goods of agricultural products in the EEA and that controls at borders exist in the EEA.

24 With regard to the alternative conclusion reached by the Authority in its letter of formal notice that the Icelandic legislation is in breach of Article 18 EEA, Iceland invited the Authority to clarify its position and give more detail concerning the arrangements in the secondary legislation that it considers compromised by the Icelandic legislation applicable to the importation of meat.

25 Iceland also invited the Authority to clarify what it challenged under Article 13 EEA. Concerning the proportionality principle, Iceland indicated that the Authority should at least 'suggest' the measures it holds to be less restrictive and which Iceland should consider.

26 Finally, Iceland concluded that the measures under review do not constitute a severe restriction to trade since an importer can, without much effort, comply with the measures.

27 On 25 March 2014, Iceland submitted two risk assessments in support of its reply to the Authority's letter of formal notice. The first one, prepared by Stephen Cobb, Director of SRC associates of New Zealand examines the biological risks associated with the unrestricted import of ruminant, swine, and poultry meat from the European Union. The second one, prepared by The Icelandic Food and Veterinary Authority (MAST) addresses the possible public health risk of the importation of raw beef, pork and broiler meat from the European Union.

28 On 27 June 2014, Iceland sent a letter to the Authority (Your reference ANR 13010327/2.3.8) in response to the follow-up letter to the package meeting in Iceland held on 19 May 2014. In this letter, as requested by the Authority, Iceland clarified the actual text of Article 5, points (f) and (g) of Regulation (IS) No 448/2012. With regard to point (f) concerning conformity with the Regulation on food contaminants, Iceland indicated that no specific documentary checks were being carried out[5].

[5] Iceland's letter of 27 June 2014. Your reference: ANR13010327/2.3.8.

However, Iceland indicated that confirmation that the meat was produced according to EU legislation was obtained by referring to the given approval number to the list of approved establishments in the country in question. The Authority understands that such verification is carried out on the basis of the documents presented by the importers when they apply for permission for the importation of each consignment (based on Article 4 of Regulation (IS) No 448/2012). With regard to point (g) concerning conformity with the Regulation on food labelling, Iceland indicates that conformity is ensured by a "one-off" documentary check at the time of application. It involves sending photographs/Pdf documents illustrating the packaging to be examined by the Icelandic Food Safety Authority.

3. Relevant national law

29 Article 10 of *Act No. 25/1993 on Animal Diseases and Preventive Measure against Them*, as amended, provides that:

> *"To prevent animal diseases from reaching the country it is prohibited to import the following types of goods:*
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> *a. raw and lightly salted slaughter products, both processed and non-processed, raw eggs, non-disinfected raw skins and hides, feed for food producing animals (*in Icelandic: alidýraáburður*) and (*rotmassi*) mixed with feed for food producing animals,*
> *b. meat meal, bone flour, blood meal, and fat that is distilled from the production of these materials,*
> *c. hay and straw,*
> *d. any type of used packaging, saddlery, machinery, device, instruments, and other objects that have been in contact with animals, animal products or animal waste,*
> *e. Any type of equipment used for angling.*
>
> *Despite the provision of paragraph 1 the Minister is authorized to allow the import of products mentioned in items a-e, having received recommendations from the Chief Veterinary Officer, if it is considered proven that they will not transmit infectious agents that can cause animal diseases. The Minister can decide by Regulation that paragraph 1 shall not apply to certain categories of those mentioned if the product is disinfected in production or a special disinfection is performed before importation and the product is accompanied with a satisfactory certificate of origin, production and disinfection. The Minister is authorized to prohibit by notice the import of products with carry the risk of transmitting contaminating agents that could cause danger to the health of animals.*
>
> *The execution of this article is also subject to the provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures."*

30 Icelandic *Regulation (IS) No. 448/2012 of 23 May 2012 on measures to prevent the introduction of animal diseases and contaminated products*, which is issued by virtue of an authorisation in Act No. 25/1993 and repealed Regulation 509/2004, provides detailed provisions on the implementation of Article 10 of Act No. 25/1993.

31 According to Article 3 of Regulation (IS) No. 448/2012:

"The importation to Iceland of the following animal products and products that may carry infectious agents which cause diseases in animals and humans is not permitted; cf. however, further details in Chapter III.

a. Raw meat, processed or unprocessed, chilled or frozen, as well as offal and slaughter wastes, which have not been treated by heating, so that the core temperature has reached 72°C for 15 seconds, or other comparable treatment in the assessment of the Icelandic Food and Veterinary Authority (MAST).
(…)
e. Untreated eggs, eggshells and egg products, which have not been treated by heating so that the product has been heated to 65°C for 5 minutes, or received other comparable treatment in the assessment of MAST.
f. Unpasteurised milk and dairy products processed from unpasteurised milk. However, up to 1 kg of cheese processed from unpasteurised milk from approved establishments in the European Economic Area may be imported for personal use; however, the Minister may authorise the import of a larger quantity for the same purpose."

32 Article 4 of Regulation (IS) No. 448/2012 provides that importation of the products listed in Article 3 is nevertheless possible if the Minister of Agriculture, acting on a recommendation of MAST, has authorized the importation.

33 According to Article 4:

"*An importer of raw products shall in all cases apply for a permit to the Minister of Fisheries and Agriculture and submit, for the consideration of MAST, an import declaration, information on the country of origin and production, the type of product and producer, and the required certificates, as provided for in Art. 5*"

34 In practice, when the initial application has been processed, the importer has to apply for permission for the importation of each individual consignment. This is satisfied by submitting all the necessary documentation to the office of import and export at MAST, where an evaluation of conformity with Article 5 of Regulation (IS) No. 448/2012 takes place. If conformity is established, the documents are sent to the Ministry for final approval and the importer may have the consignments released.

35 According to Iceland[6], "*documentary checks are carried out by the office of import and export at the Food and Veterinary Authority (MAST)*".

36 As concerns raw food and dairy products, Article 5 of Regulation (IS) No. 448/2012 provides that:

"Imported foods which are listed under classifications (CN Codes) 0202, 0203, 0204, 0207, 0208, 0210, 1601 and 1602[7], cf. Appendix I to the Customs Act, No.

[6] Reply by Iceland on 12 March 2012 to the Authority's request for information.

[7] Description of the CN Codes: 0202: Meat of bovine animals, frozen, 0203: Meat of swine, fresh, chilled or frozen ; 0204: Meat of sheep or goats, fresh, chilled or frozen ; 0207: Meat and edible offal, of the poultry of heading 0105, fresh, chilled or frozen ; 0208: Other meat and edible meat offal, fresh, chilled or frozen ; 0210: Meat and edible meat offal, salted, in brine, dried or smoked; edible flours and meals of meat or meat offal ; 1601: Sausages and similar products, of meat, meat offal or blood; food preparations based on these products ; 1602: Other prepared or preserved meat, meat offal or blood.

88/2005, which the Minister has authorised for import to Iceland as referred to in Art. 4 and which have not received satisfactory heat treatment must be accompanied by the following certificates:

a. an official certificate of origin and health, in the case of products from producers outside the European Economic Area;
b. an official certificate confirming that the animals from which the products derive were not given growth-promoting substances during rearing, in the case of products from producers outside the European Economic Area;
c. a certificate confirming that the products have been stored at a temperature of at least -18°C for a month prior to customs clearance;
d. an official certificate confirming that the animals from which the products derive were slaughtered in slaughterhouses and the products processed in processing plants authorised in the European Economic Area, in the case of products from producers outside the European Economic Area;
e. an official certificate confirming that the products are free of salmonella bacteria;
f. animal meat products and by-products, dairy products and eggs shall conform to the appropriate provisions of the current Regulation on food contaminants;
g. the product shall be labelled in conformity with current rules on labelling, advertising and promotion of foodstuffs."

37 The Authority thus understands that the measures under review, Article 10 of Act No. 25/1993 and Articles 3, 4 and 5 of Regulation (IS) No. 448/2012, read together do not constitute a total ban on the importation of fresh meat but rather a system of import declaration and further authorisation for these products based on the production of certain certificates by the relevant food business operator. In addition, based on the CN Codes referred to in Regulation (IS) No. 448/2012, the Authority understands that the products concerned are principally "fresh meat", "meat preparations" as well as "meat products". In addition, point *e* of Article 5 of Regulation (IS) No. 448/2012 refers to other products of animal origin, such as animal by-products, dairy products and eggs. All these products, except animal by-products, are defined and covered by Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin[8].

[8] Annex I of Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin (Point 17.6.1 of Chapter I of Annex I to the EEA Agreement) defines "Fresh meat" as "*meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere*" ; "Meat preparations" as "*fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat"* and "Meat products" as "*processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat".*

4. Relevant EEA law

4.1. EEA Agreement

38 Article 8 (3) of the EEA Agreement, which stipulates that free movement of goods between the Contracting Parties shall be established in conformity with the provisions of this Agreement, states that:

"Unless otherwise specified, the provisions of this Agreement shall apply only to:

(a) Products falling within Chapters 25 to 97 of the Harmonized Commodity Description and Coding System, excluding the products listed in Protocol 2;

(b) Products specified in Protocol 3, subject to the specific arrangements set out in that Protocol.

39 It follows that agricultural products and foodstuffs (Harmonized Commodity Description and Coding System – HS – chapters 1 to 24) are, in principle, outside the scope of the main provision of the EEA Agreement concerning free movement of goods unless listed in Protocol 3.

40 Article 11 EEA provides that:

"Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Contracting Parties."

41 According to Article 13 EEA:

"The provisions of Articles 11 and 12 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties."

42 Article 18 EEA states that:

"Without prejudice to the specific arrangements governing trade in agricultural products, the Contracting Parties shall ensure that the arrangements provided for in Articles 17 and 23 (a) and (b), as they apply to products other than those covered by Article 8(3), are not compromised by other technical barriers to trade. Article 13 shall apply."

43 Article 17 refers to Annex I concerning specific provisions and arrangements concerning veterinary and phytosanitary matters. Article 23 (a) refers to Annex II in relation to technical regulations, standards, testing and certification.

4.2. Secondary legislation

44 Secondary rules concerning checks on products of animal origin in cross-border trade within the EEA are governed by *Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view*

to the completion of the internal market[9]. This Directive aims to regulate veterinary checks in intra-EEA trade of products of animal origin and its main objective is to eliminate veterinary checks at the EEA's internal borders while reinforcing those carried out at the point of origin. In addition, the Directive defines and harmonises the type of controls that can be performed within the EEA on products of animal origin.

45 Under Article 1 of that directive, veterinary checks to be carried out on products of animal origin covered by that directive, which are intended for trade between Member States, are (subject to the provisions of Article 6 on products from third countries) no longer to be carried out at frontiers within the Community, but are to take place in accordance with the provisions of Directive 89/662/EEC.

46 Article 2 of Directive 89/662/EEC specifies that the term 'veterinary check' within the meaning of the directive "*means any physical check and/or administrative formality which applies to the products covered by the directive and which is intended for the safeguarding, direct or otherwise, of public or animal health*".

47 Chapter I of that directive, entitled 'Checks at origin' consists of Articles 3 and 4 which regulate veterinary checks in the Member State of dispatch.

48 Article 3 of Directive 89/662/EEC provides that:

"*1. Member States shall ensure that the only products intended for trade are those referred to in Article 1 which have been obtained, checked, marked and labelled in accordance with Community rules for the destination in question and which are accompanied to the final consignee mentioned therein by a health certificate, animal-health certificate or by any other document provided for by Community veterinary rules*".

49 Article 4 of Directive 89/662/EEC provides that:

"*Member States of dispatch shall take the necessary measures to ensure that operators comply with veterinary requirements at all stages of the production, storage, marketing and transport of the products referred to in Article 1. In particular, they shall ensure that*:

- *Member States of dispatch shall take the necessary measures to ensure that operators comply with veterinary requirements at all stages of the production, storage, marketing and transport of the products referred to in Article 1. In particular, they shall ensure that*
- *The products covered by Annex B are not dispatched to the territory of another Member State, if they cannot be marketed on their own territory for reasons justified by Article 36 of the Treaty*"

50 Chapter II of Directive 89/662/EEC, entitled '*Checks on arrival at the destination'*, consists of Articles 5 to 8.

51 As an exception to the main objective of the directive, which is to reduce checking formalities at the place of destination, Article 5 provides that:

[9] Point 1.1.1 of Chapter I of Annex I to the EEA Agreement.

"*Member States of destination shall implement the following measures:*

(a) The competent authority may, at the places of destination of goods, check by means of non-discriminatory veterinary spot-checks that the requirements of Article 3 have been complied with; it may take samples at the same time.

Furthermore, where the competent authority of the Member State of transit or of the Member State of destination has information leading it to suspect an infringement, checks may also be carried out during the transport of goods in its territory, including checks on compliance as regards the means of transport;"

52 For further description of the EEA legal framework, reference is made to section 4.2 of the letter of formal notice.

5. The Authority's assessment

5.1. Introduction

53 At the outset, the Authority observes that in its reply to the letter of formal notice Iceland stated that there are no provisions in the EEA Agreement that would preclude Iceland from imposing a total ban on the import of the products at issue[10]. Such a ban is not at stake in the present case, rather as set out in paragraph 37 above, the Authority views the Icelandic measures as constituting a prior authorisation system.

54 The Authority does not dispute the fact that the products concerned fall outside of the scope of the EEA Agreement further to Article 8(3) EEA. However, these products remain subject to the provisions of Chapters 2 and 4 of Part II the EEA Agreement concerning free movement of goods, as well as to relevant secondary legislation and in particular Directive 89/662/EEC. This directive, which aims *inter alia* to ensure the free movement of agricultural products[11], has been implemented in Iceland as part of the so-called "hygiene package" which harmonised the conditions under which agricultural products are produced and placed on the market and circulated in the EEA. It should also be emphasised that these rules have been taken into the EEA Agreement without any adaptation of relevance to this case[12]. As regards a potential total ban, it follows from the above, that such a ban would not come within the scope of Article 11 EEA, however, this potential measure is without any legal significance for the present case.

[10] Iceland's reply of 27 February 2014 at paragraph 1.1.2.
[11] See, to that effect, Case 37/83 *Rewe-Zentrale* v *Landwirtschaftskammer Rheinland* [1984] ECR 1229, paragraph 19.
[12] Directive 89/662/EEC was incorporated into the EEA Agreement with an adaptation. According to this adaptation, Article 9 of Directive 89/662/EEC does not apply and any reference to this provision must be read as a reference to paragraph 3 of the Introductory Part of Annex I, Chapter I thereto concerning safeguard measures. This has not relevance to the case at hand as the Icelandic measures are not temporary safeguard measures.

5.2. Concerning the breach of Directive 89/662/EEC

5.2.1. Directive 89/662/EEC has fully harmonised veterinary checks

55 In its reply to the letter of formal notice, Iceland indicated that it did not agree with the conclusion by the Authority that Directive 89/662/EEC has fully harmonised veterinary checks carried out at the place of destination in EEA countries. According to Iceland, "*there is no authority to the claim that the Directive at issue here entails exhaustive harmonisation*"[13].

56 According to the Authority, however, it is clear both from the wording of Directive 89/662/EEC and from the interpretation that has been made on several occasions and consistently by the Court of Justice of the European Union (CJEU)[14] of its Article 5, that Directive 89/662/EEC has exhaustively harmonised veterinary checks that can take place in the State of destination of the products covered by the Directive.

57 First, Article 5 of Directive 89/662/EEC describes exhaustively the measures that can be taken by the State of destination and lays down strict limits to their discretion in implementing those provisions. The Directive does not contain any provision that would leave Member States to impose stricter rules, save "protective measures" which are temporary by nature and strictly circumscribed in the Directive[15]. Its main purpose is not, as Iceland suggests, to simply avoid duplication of veterinary checks but rather to ensure that veterinary checks are carried out in the State of origin and not at the place of destination as they are based on a harmonised system of health controls which also includes Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls and Regulation (EC) No. 882/2004 on official controls[16].

58 Second, the Authority would like to draw the attention of Iceland to the consistent interpretation of Directive 89/662/EEC, and in particular its Article 5, in the case law of the CJEU referred to in its letter of formal notice. In these cases the CJEU has expressed that a detailed and harmonised system of health inspections of fresh meat, based on harmonised rules at EEA level, replaces all other inspection systems existing within the country of destination, whatever the place where such inspections may be carried out[17].

59 In addition, in its reply, Iceland suggests that the conclusion reached by the CJEU in case C-*102/96 Commission v. Germany* that veterinary checks have been harmonised

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[13] Iceland's reply of 27 February 2014 at paragraph 2.1.12.

[14] See, in particular, Case C-186/88 *Commission v. Germany* [1988] ECR 3997, Case C-102/96 *Commission v. Germany* [1998] ECR *06871*, Case C-445/06 *Danske Slagterier* [2009] ECR I-02119 and Case C-111/03 *Commission v. Kingdom of Sweden* [2005] ECR I-8789.

[15] Article 7, in conjunction with Article 9 of Directive 89/662/EEC, provides for the application of protective measures that the importing State may take if a serious hazard to animals or humans is identified during a check. These protective measures are, in any event, strictly circumscribed and involve an immediate notification of the competent authorities of other Member States as well as the European Commission and the Authority.

[16] Acts referred to respectively at points 12 and 11.1.1 of Chapter I of Annex I to the EEA Agreement.

[17] See, in particular, Case C-111/03 *Commission v. Kingdom of Sweden* cited above at paragraph 51 and joined cases C-277/91, C-318/91 and C-319/91 *Ligur Carni Srl and Genova Carni Srl v Unità Sanitaria Locale n. XV di Genova and Ponente SpA v Unità Sanitaria Locale n. XIX di La Spezia and CO.GE.SE.MA Coop a r l* [1993] ECR I-06621 at paragraph 26.

lacks authority on the grounds that this conclusion was reached on a combination of provisions (namely Directives 64/433/EEC, 91/497/EEC and 89/662/EEC).

60 The Authority considers, however, that the CJEU has unambiguously expressed its view that veterinary checks have been harmonised. The full harmonisation of veterinary checks by Directive 89/662/EEC stems necessarily from a combination of provisions since Article 5 of this Directive refers to checking compliance with requirements laid down in "Community rules". In practice, these "Community rules" are now to be understood as referring to the so-called "hygiene package" as well as relevant animal health and welfare rules applicable in the EEA[18]. For products of animal origin, this refers mainly to the harmonised requirements laid down in Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin, which are checked according to Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls and Regulation (EC) No. 882/2004 on official controls.

61 Third, in its reply, Iceland also states that: "*The Swedish ruling does not lend support to the claim that the importing State is not entitled to check what has not been checked in the exporting State*".

62 According to the Authority, the Court, in case *C-111/03 Commission v. Kingdom of Sweden*, essentially recalled that Member States at the place of destination, cannot impose systematic veterinary checks and insisted on the fact that: "*The harmonised system of veterinary checks set up by that directive, which is based on full inspection of the goods in the Member State of dispatch, is intended to replace, in principle, inspection in the Member State of destination*".

63 In the context of salmonella control, specific procedures and legal remedies exist and have been harmonised under the EEA legislation and, in particular, Article 8 of Regulation (EC) No. 853/2004 and Regulation (EC) No 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents. EEA States may impose additional controls provided they meet certain requirements (See section 5.2.3. *infra*).

5.2.2. Directive 89/662/EEC in the EEA context

64 In its reply, Iceland also suggests that Directive 89/662/EEC cannot be read, in the EEA context, as excluding systematic controls at borders. According to Iceland, since there remain controls at borders in the EEA (namely customs controls), "*there is no imperative need to interpret the Directive as excluding any controls at borders*"[19].

65 The Authority, however, considers that the existence of customs control on agricultural goods by EFTA States cannot justify the existence of additional veterinary checks.

[18] See Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC

[19] Iceland's reply of 27 February 2014 at paragraph 2.2.5.

66 The Authority considers also, in line with the standard developed by the EFTA Court in the case-law referred to by Iceland[20], that the existence of customs control does not constitute compelling grounds for divergent interpretations of Directive 89/662/EEC since customs control and veterinary checks follow different purposes and operate in different spheres of the EEA Agreement.

67 It should also be emphasised that the "*non-discriminatory spot checks at the places of destination (by the competent authority)*" referred to in Article 5 of Directive 89/662/EEC do not refer to checks carried out necessarily at the border but also to controls that competent authorities in the country of destination can carry at the point of sale or delivery to the final consumer (at retail level for example). It follows that for products originating in the EEA, veterinary checks within the meaning of Directive 89/662/EE are not by nature – and should not be – connected to customs controls.

68 It is worth noting that Iceland admits that "*veterinary controls are made in the context of customs controls" which are "by their very nature (…) systematic*"[21]. This statement only confirms that the Icelandic measures under review treat products originating in the EEA like third country products that are being imported and thus contradict the very spirit of Directive 89/662/EEC, which is to abolish veterinary checks at internal frontiers.

69 The fundamental difference between veterinary checks for products coming from the EEA and customs controls emanates clearly from the CJEU's findings in case C-111/03 *Commission v. Kingdom of Sweden*, where it stated that the rules in question, and in particular the duty of prior notification (and, *a fortiori*, prior authorisation) "*do not comply with the strict conditions laid down in Article 5(3)(c) of Directive 89/662 which clearly show the duty to report the arrival of products from another Member State must not be systematic, but is to depend on a specific request to that effect by the competent authority, made solely where that measure is essential correctly to carry out the checks referred to in Article 5(1)*"[22].

5.2.3. The Icelandic measure is in breach of Directive 89/662/EEC

70 In section 5.1 of its letter of formal notice of 30 October 2013, the Authority explained why it considered that the restriction on imports of meat in the Icelandic legislation and the formalities it imposes on imports are not in line with Article 5 of Directive 89/662/EEC. It also recalled that according to consistent case law of the CJEU, in harmonised fields of European legislation, recourse to justifications under Article 36 of the Treaty on the Functioning of the European Union (TFEU) is not available[23].

71 In the following paragraphs, the Authority intends to further explain why, in its opinion, both the procedural as well as certain substantive requirements of the Icelandic legislation are in breach of Article 5 of Directive 89/662/EEC.

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[20] Joint Cases E-9/07 and 10/07 *L'Oreal Norge AS* EFTA Court Report [2008] p. 261 at paragraph 27; Case E-2/06 *EFTA Surveillance Authority* v *Norway* EFTA Court Report [2007] p. 163, at paragraph 59.
[21] Iceland's reply of 27 February 2014 at paragraph 2.2.7.
[22] Case C-111/03 *Commission v. Kingdom of Sweden* cited above at paragraph 59.
[23] See Case C-52/92 *Commission v Portuguese Republic* [1993] ECR I-02961 at paragraph 17 ; Case C-445/06 *Danske Slagterier* cited above at paragraph 25 ; Case C-1/96 *Compassion in World Farming Limited* [1998] ECR I-1251 at paragraph 47.

72 The Icelandic legal framework governing imports of meat in Iceland described above imposes the completion of certain formalities on the importer. In particular, Article 4 of Regulation (IS) No. 448/2012 requires all operators to submit – systematically and for each consignment – an application to import raw or unsterilized products. In addition, Article 5 of Regulation (IS) No. 448/2012 imposes on producers in the European Economic Area whose products are intended for the Icelandic market an obligation to present the following four certificates: A certificate confirming that the products have been stored at a temperature of at least -18°C for a month prior to customs clearance, an official certificate confirming that the products are free of salmonella bacteria, a certificate confirming that animal meat products and by-products, dairy products and eggs shall conform to the appropriate provisions of the current Icelandic Regulation on food contaminants and a certificate confirming that the product is labelled in conformity with current rules on labelling, advertising and promotion of foodstuffs.

73 As explained above and in Section 5.1.1 of the letter of formal notice, these administrative formalities constitute 'veterinary checks' within the meaning of Article 2 of Directive 89/662/EEC and are not allowed under Article 5 of Directive 89/662/EEC as they constitute obligations that go beyond the controls permitted at the place of destination.

74 The CJEU has ruled that similar additional veterinary checks placed on imports of products of animal origin are not compatible with harmonized rules on veterinary checks[24].

75 In Case C-186/88 *Commission v. Germany*, the Court stated that: "*in the light of the harmonised system of health inspections set up by Community legislation and based on full inspection of the goods in the exporting State, which replaces inspection in the State of destination, considerations based on the need to protect health cannot justify additional specific constraints placed on carriers when they cross a frontier*".[25] The Court therefore found that, "*by systematically requiring carriers to make a prior declaration of such goods in order to ensure a systematic veterinary inspection, the Federal Republic of Germany has failed to fulfill its obligations under Article 30 of the EEC Treaty, under Directive 71/118 and under Directive 83/643*"[26]. According to Article 2 of Directive 83/643/EEC physical inspections within the meaning of Article 1(1) of the directive were to be carried out solely by means of non systematic spot checks.

76 In Case C-111/03 *Commission v. Kingdom of Sweden* the Court of Justice clearly held that a prior notification system is not in line with the requirements of Directive 89/662/EEC[27]. In this judgment, the Court of Justice first recalled the broad definition of the concept of 'veterinary checks' which covers any physical check and/or administrative formality which applies to the products in question and which is intended for the protection of public or animal health.

[24] See Case C-186/88 *Commission v. Germany* cited above, Case C-102/96 *Commission v. Germany* cited above, Case C-445/06 *Danske Slagterier* cited above and Case C-111/03 *Commission v. Kingdom of Sweden* cited above.
[25] Case C-186/88 *Commission v. Germany* cited above at paragraph 16.
[26] Case C-186/88 *Commission v. Germany* cited above at paragraph 16.
[27] Case C-111/03 *Commission v. Kingdom of Sweden* cited above at paragraph 59.

77 The Court went on to consider that the Swedish rule in dispute was incompatible with the requirements of Directive 89/662/EEC. According to the Court, "*the duty of prior notification introduced by [the Swedish] rules is of a general nature and cannot prevent its leading to checks which go beyond a simple spot-check permitted by Article 5*"[28].

78 In addition, the Court added that: "*considerations related to the need to protect public health cannot justify additional specific constraints imposed unilaterally by a Member State when the frontier is crossed, such as the duty of prior notification imposed on importers of products of animal origin from other Member States by the Swedish rules in dispute*"[29].

79 These two judgments confirm that '*additional specific constraints'*, such as a systematic obligation to make a prior declaration of imports of certain products of animal origin, going beyond the framework of the harmonised system of health and/or veterinary inspections applicable in EEA trade in the products in question cannot be imposed on importers of products of animal origin.

80 The Court's reasoning in these cases shows that a prior notification system is not in line with the requirements of Directive 89/662/EEC. The system in place in Iceland is not a prior notification system but a prior authorization system. Of those two types of procedures the Court of Justice has found that prior authorisation schemes are more restrictive than that of prior notification schemes.[30] Thus, *a fortiori*, a systematic authorisation system, such as the one in place in Iceland based on Article 10 of Act No. 25/1993 and Regulation (IS) No. 448/2012, is in breach of the requirements of Directive 89/662/EEC and in particular its Article 5.

81 Article 5 of Directive 89/662/EEC has exhaustively harmonised veterinary checks that may take place in the State of destination of the products covered by the Directive[31]. It follows from settled case law that in harmonised fields of European legislation, recourse to justifications under Article 36 of the European Treaty (Article 13 EEA) is not available.[32]

82 Additionally, the Authority considers that the Icelandic prior authorisation scheme imposes the fulfilment of certain substantive requirements by the importers that are not allowed under Article 5 of Directive 89/662/EEC as they go beyond ensuring that the products have been obtained, checked, marked and labelled in accordance with EEA rules. This would also be true if the fulfillment of these requirements were not subjected to systematic checks at the border but rather to random spot checks.

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[28] Case C-111/03 *Commission v. Kingdom of Sweden* cited above at paragraph 58.
[29] *Ibid.*at paragraph 51.
[30] See *e.g.* C-358/93 and C416/93 *Bordessa* [1995] ECR I-361, paragraph 27; Joined Cases C-163/94, C-165/94 and C-250/94 *Sans de Lera* [1995] ECR I-4821, paragraphs 26-27; Joined Cases C-515/99, C-519/99 to C-524/99 and C-526/99 to C-540/99 *Reisch*, [2002] cited above, paragraphs 37-38.
[31] It should be noted that further to Article 5 of Directive 89/662/EEC, where the competent authority of the Member State of destination has information leading it to suspect an infringement, it can carry out checks during the transport of goods in its territory, including checks on compliance as regards the means of transport.
[32] See for example Case 52/92, *Commission v. Portuguese Republic*, [1993] ECR 2961, para 17; Case 251/78 *Denkavit Futtermittel v Minister für Ernährung, Landwirtschaft und Forsten* [1979] ECR3369, paragraph 14, Case C-1/96 *Compassion in World Farming Limited* [1998] ECR I-1251 at paragraph 47.

83 According to Article 5 of Directive 89/662/EEC veterinary checks by Members States at the place of destination (in the form of non-discriminatory spot checks) can only be aimed at verifying that the requirements of Article 3 of Directive 89/662/EEC have been complied with. Article 3 of Directive 89/662/EEC provides that in carrying out checks at origin, "*Member States shall ensure that the only products intended for trade are those referred to in Article 1 which have been obtained, checked, marked and labelled in accordance with Community rules*". It follows that EEA States cannot impose checks that do not find their basis in EEA law.

84 In practice, following the entry into force of the hygiene package, veterinary checks on fresh meat and meat products can only be aimed at verifying that these products comply with the requirements laid down in Regulations (EC) No. 852/2004 and 853/2004 laying down specific hygiene rules for food of animal origin and are checked according to Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls and Regulation (EC) No. 882/2004 on official controls.

85 In particular, the obligation on importers to demonstrate that products have been frozen for 30 days at -18°C does not find its basis in the EEA legislation on food hygiene and constitutes checks on products that go beyond what is required under EEA rules. There is indeed no legal basis in the EEA legislation and, in particular in Regulation (EC) No. 853/2004 which has harmonised the rules under which products of animal origin are placed on the market, that would allow an EFTA State to require that all fresh meat and meat products imported be frozen.

86 Lastly, and as referred to in point 5.2.1 supra, the obligation for the importer to show that the products are free of salmonella (point *e* of Article 5 of Regulation No. 448/2012), in the absence of additional guarantees established pursuant to Article 8 of Regulation (EC) No. 853/2004, is not allowed under Article 5 of Directive 89/662/EEC.

87 The use of additional guarantees on salmonella control must be based on a specific control plan established by the EEA State and, further to a procedure laid down in Article 8 of Regulation (EC) No. 853/2004 and Regulation (EC) No 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents.

88 Although Iceland has submitted to the Authority on 9 January 2014 a National Control Programme for Salmonella in poultry and poultry products, it has not been granted additional guarantees. Consequently, the obligation for the importer to show that the products are free of salmonella bacteria (point *e* of Article 5 of Regulation (IS) No. 448/2012) goes beyond the requirements contained in the EEA legislation in breach of Article 5 of Directive 89/662/EEC.

89 In conclusion, the Authority considers that the authorisation system for the importation of fresh meat and meat products such as laid down in Article 10 of Act No. 25/1993 and Articles 3, 4 and 5 of Regulation (IS) No. 448/2012 is in breach of Article 5 of Directive 89/662/EEC is not compatible with Article 5 of Directive 89/662/EEC. In addition, this authorisation system imposes the fulfilment of substantive requirements by importers, such as the obligation to freeze all products for 30 days at -18°C or the obligation for the importer to show that the products are

free of salmonella, which are not allowed under EEA rules. These requirements are also not in line with Article 5 of Directive 89/662/EEC.

5.3. Concerning the breach of Article 18 EEA

90 In section 5.2 of its letter of formal notice of 30 October 2013, the Authority considered in the alternative, that, in the event that Directive 89/662/EEC cannot be considered to exhaustively harmonise veterinary checks and/or no breach of Article 5 of Directive 89/662/EEC would be established, the authorisation system for the importation of fresh meat and meat products such as laid down in Article 10 of Act No. 25/1993 and Articles 3, 4 and 5 of Regulation (IS) No. 448/2012, was in breach of Article 18 of the EEA Agreement.

91 In particular, the Authority explained why it considers that this system constitutes an obstacle to trade in the form of "technical barriers" within the meaning of Article 18 EEA.

92 In section 5.2.3. of its letter of formal notice, the Authority identified three specific arrangements in the secondary legislation that it considered to be compromised by the Icelandic legislation applicable to the importation of meat.

5.3.1. Additional requirement concerning salmonella

93 First, in its letter of formal notice, the Authority had concluded that the obligation for the importer to show that the products are free of salmonella constituted a "technical barrier to trade" within the meaning of Article 18 EEA as it submits the placing of meat products that may be compliant with the harmonised rules on salmonella (in particular Regulation (EC) No. 2160/2003) to an additional requirement. Such a requirement can only be imposed under EEA law if it has been established pursuant to Article 8 of Regulation (EC) No. 853/2004.

94 The Authority notes that in paragraph 1.2.3 of its reply, Iceland indicates that the salmonella certificate which is requested from importers is based on the certificate that applies in relation to Sweden and Finland under Commission Regulation (EC) No. 1688/2005. The Authority recalls that this certificate ("additional guarantees") used in Sweden, Finland, Denmark and Norway is based on a control programme established pursuant to Article 8 of Regulation (EC) No. 853/2004. Despite having submitted to the Authority a National Control Programme for Salmonella in poultry and poultry products on 9 January 2014, Iceland has not been granted the right to impose "additional guarantees" on the imports of poultry and poultry products from other EEA States (see point 5.2.1 supra).

95 The Authority must conclude that this obligation to produce a salmonella certificate constitutes an additional requirement of the same kind as foreseen and implemented in the EEA legislation, which is prohibited by Article 18 EEA[33].

[33] See Case E-4/04 *Pedicel*, EFTA Court Reports [2005] at paragraph 27.

5.3.2. Additional requirement concerning food contaminants

96 Second, in its reply, Iceland also considered that the obligation for the importer to show that meat products conform to the appropriate provisions of the current Regulation on food contaminants does not compromise the arrangements in the relevant EEA legislation. According to Iceland, the Authority has failed to demonstrate why this obligation does not comply with the relevant EEA legislation.

97 First, the Authority wishes to recall that the EEA legislation on contaminants in food (Council Regulation (EEC) No. 315/93 and Commission Regulation (EC) No. 1881/2006), sets out maximum levels for certain contaminants in food on the basis of scientific advice provided by the European Food Safety Authority (EFSA). A product that complies with the levels set out in these Acts is presumed to be safe and compliant. Where maximum levels have not been established under EEA law, relevant legislation applicable in each EEA States may continue to apply, provided that it informs the European Commission or the Authority as the case may be. Competent authorities in EEA States are responsible for sampling food products, to ensure that they comply with the legislation. The control and response procedures are based on a process of random checks undertaken by EEA States.

98 In addition, the Authority notes that the legislation on food contaminants (Council Regulation (EEC) No. 315/93 and Commission Regulation (EC) No. 1881/2006) does not contain any provision that gives EEA States a legal basis to impose on importers the completion of a specific procedure that has no basis in the relevant legislation to demonstrate that food products conform to the current EEA legislation on food contaminants. In the absence of such legal basis in the secondary legislation, EEA States are precluded from imposing on importers any obligation going beyond what is required in the legislation.

99 In its letter of 27 June 2014, Iceland indicated that there were no specific documentary checks to check conformity with the Regulation on food contaminants carried out. However, Iceland also explained that there was a procedure to confirm that the meat is produced according to EU legislation by referring the given approval number to the list of approved establishments in the country in question. The Authority understands that such verification is carried out on the basis of the documents presented by the importers when they apply for permission for the importation of each consignment on the basis of Article 4 of Regulation (IS) No 448/2012.

100 It follows that this verification is part of the authorisation procedure. As such, it constitutes an obligation that goes essentially beyond the requirements of the EEA legislation on contaminants in food.

101 Consequently, the Authority must conclude that this obligation constitutes a technical barrier to trade prohibited by Article 18 EEA.

5.3.3. Additional requirement concerning labelling

102 Finally, concerning the obligation for the importer to demonstrate that the product shall be labelled in conformity with current rules on labelling, advertising and promotion of foodstuffs, Iceland invited the Authority to explain how it considers that this obligation compromises the arrangements in Directive 2000/13/EC.

103 In its letter of 27 June 2014, Iceland indicated that conformity is ensured by a "one-off" documentary check at the time of application which involves sending photographs/Pdf documents illustrating the packaging to be examined by the Icelandic Food Safety Authority (MAST). In case of bulk import of raw meat for further processing or for use in catering facilities and restaurants documentary check of labelling is not required. Physical checks are carried out at retail level.

104 The Authority thus understands that there is a systematic obligation for the importer to present certain documents (photographs) at the time of application (albeit only the first time) for inspection by MAST.

105 Similarly to the verification of compliance with the legislation on food contaminants, this one-off documentary check is part of the authorisation procedure goes beyond the specific requirements in the EEA legislation concerning labelling as laid out in Directive 2000/13/EC.

106 Finally, it should be noted that Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[34] does not contain any provision that gives EEA States a legal basis to impose an obligation for the importer systematically demonstrate that food products conform the product is labelled in conformity with current rules on labelling.

107 Consequently, the Authority must conclude that this obligation also constitutes a technical barrier to trade prohibited by Article 18 EEA.

5.3.4. The freezing requirement constitutes a technical barrier to trade

108 In addition to the three specific additional requirements mentioned above, the Authority considers that the requirement to store the products at a temperature of at least -18°C for a month (point *c* of Article 5 of Regulation (IS) No. 448/2012) is in breach of Article 18 EEA.

109 It is the view of the Authority that this requirement constitutes a technical barrier to trade and imposes on importers a requirement "*of the same kind*" as the arrangements laid out in Acts in Annex I to the EEA Agreement.

110 The purpose of this specific obligation is to prevent the introduction of animal diseases in Iceland by reducing the survival rate of pathogens in products of animal origin imported in Iceland.

111 While the efficacy of this obligation is questionable (see discussion below concerning the risk assessment prepared by Stephen Cobb of SRC associates), it constitutes an unjustified additional obligation that compromises arrangements that exist in EEA law, in particular those in Annex I (Veterinary and Phytosanitary Matters) to the EEA Agreement.

[34] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs is applicable in the European Union until 13 December 2014, after which Regulation (EU) 1169/2011 (not yet incorporated into the EEA Agreement) on the provision of food information to consumers will apply.

112 Annex I contains numerous Acts dealing with animal health protection, prevention of animal diseases, which are of crucial importance for the control of infectious diseases and serve the same purpose as the obligation to freeze all meat products. They constitute a coherent and harmonised approach to animal health protection so that individual Member States do not adopt restrictive national measures.

113 By imposing an obligation to store all meat products at a temperature of at least -18°C for a month, Iceland departs from this harmonised approach and compromises the objectives of this body of rules.

114 In conclusion, the Authority considers that these four requirements represent, for operators who want to import raw meat in Iceland, obstacles to trade in the form of "*technical barriers*" within the meaning of Article 18 EEA. As will be set out below, the Authority considers that these additional requirements are not justified under Article 13 EEA.

5.4. Concerning the justification under Article 13 EEA

115 On 25 March 2014, Iceland submitted two scientific reports in support of its claim that the measures are justified on the grounds of protection of public and animal health in Iceland. The first one is a risk assessment prepared by Stephen Cobb of SRC associates entitled: "*Import risk assessment: Unrestricted imports of ruminants, swine and poultry meat and meat products from the European Union*". The second one is an evaluation report prepared by MAST in March 2012 entitled: "*Importation of raw beef, pork and broiler meat from the European Union. Evaluation of possible public health risk*".

116 Both documents conclude that it cannot be excluded that importation of raw beef, pork and broiler meat from the European Union could have a negative impact on public and animal health in Iceland.

117 The Authority has reviewed these two reports and has concluded that the information contained in these documents does not lead to the conclusion that the measures are justified on the grounds of protection of public and animal health in Iceland based on Article 13 EEA.

5.4.1. Risk assessment concerning animal health

118 The first document entitled "*Import risk assessment: Unrestricted imports of ruminants,* swine *and poultry meat and meat products from the European Union*" prepared by Stephen Cobb of SRC associates examines the biological risks associated with the unrestricted import of ruminant, swine, and poultry meat from the European Union.

119 At the outset, the authors of the report point to the fact that this document only provides a risk assessment. Detailed discussion of risk management measures to provide the appropriate level of protection against these identified risks is outside the scope of this assessment. In addition, the authors refer to a number of European Union Council Directives that govern measures to be taken within the European Union in the face of a disease outbreak to minimise the risk and reduce the likelihood of introducing the pathogens in Iceland.

120 Since examination of the effectiveness of these measures is not within the scope of this risk assessment, it is the view of the Authority that it is for the national competent authorities to do this exercise and carry out the risk management exercise on the basis of this risk assessment.

121 This risk assessment begins with the construction of a preliminary hazard list that includes the 69 World Organisation for Animal Health (OIE)-Listed diseases that are associated with ruminants, swine, and poultry together with 60 other diseases that are considered to be of concern to Iceland, namely those diseases listed under Iceland's domestic legislation (Act No. 25/1993).

122 Following a risk assessment for each potential hazard, the authors of the report identify nine pathogens that could pose certain risks if unrestricted imports of ruminant, swine, and poultry meat from the European Union were permitted. These pathogens are the following:

123 Viruses:
- African swine fever virus (imports of pig meat)
- Classical swine fever virus (imports of pig meat)
- Highly pathogenic avian influenza virus (imports of poultry meat)
- Newcastle disease virus (imports of poultry meat)
- Porcine reproductive and respiratory syndrome virus (imports of pig meat)
- Swine vesicular disease virus (imports of pig meat)

124 Bacteria:
- Brucella spp. (imports of ruminant or pig meat)

125 Parasites:
- Taenia ovis (imports of sheep or goat meat)
- Trichinella /several species (imports of pig meat)

5.4.2. Evaluation report concerning public health

126 The second report prepared by MAST in March 2012 and entitled "*Importation of raw beef, pork and broiler meat from the European Union. Evaluation of possible public health risk*" concerns the risk associated with the importation of meat from the European Union to the public health in Iceland. It focuses, in particular, on the following zoonotic agents: Salmonella, campylobacter, Verotoxigenic-Escherichia coli (VTEC), Yersinia as well as the antimicrobial resistance to zoonotic agents.

127 It should be noted at the outset that this report does not constitute a risk analysis but rather an investigation of the difference in the frequency of certain zoonotic agents in the European Union as opposed to Iceland. This report contains an assessment of the risk. However, like the report concerning animal health, it does not contain any risk management analysis.

128 Concerning salmonella, the report points to the fact that salmonella in Icelandic cattle is very rare. The prevalence of salmonella in pork and poultry is also very low due to strict official controls. Consequently, an increase in imports of meat from the European Union, where the prevalence levels of salmonella are higher is likely to increase the exposure of consumers in Iceland to salmonella.

129 Similarly, the report points to a low prevalence of campylobacter in Icelandic broiler meat due to strict surveillance and response to detection of campylobacter. On the other hand, prevalence levels in the European Union are higher and an increase in imports of broiler meat from the European Union would increase the exposure of consumers in Iceland to campylobacter.

130 Concerning VTEC and Yesinia, the report concludes that it cannot be excluded that importation of beef and pork from the European Union would lead to increased risk for public health.

131 Finally, the report raises the issue of antimicrobial resistance to zoonotic agents. Comparing the antimicrobial resistance of salmonella and campylobacter in Iceland and within the European Union, the report concludes that the importation of raw meat into Iceland will increase human exposure to antimicrobial resistant and multi-resistant zoonotic agents such as salmonella and campylobacter.

132 The Authority notes that neither this second report contains a discussion of risk management measures to provide the appropriate level of protection against the identified risks.

5.4.3. The measures cannot be justified under Article 13 EEA

133 As indicated in section 5.3. of the letter of formal notice, while the Authority recognises that EEA States can, within the limits imposed by the EEA Agreement, decide on the level of protection they intend to provide for the legitimate interest pursued[35], the CJEU has consistently recalled that: "*in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade* [36]"

134 As will be set out below, based on a review of the information presented, the Authority concludes that the Icelandic measures are not proportionate to the aim pursued and cannot therefore be justified under Article 13 EEA. In addition, the Authority does not consider that the application of the precautionary principle is warranted in the present case.

5.4.3.1. The measures do not comply with the principle of proportionality

135 As indicated in section 5.3.3. of the letter of formal notice, EEA States imposing a national ban on a product or subjecting the placing on the market to an authorisation system have to show that the measures are necessary and, where appropriate, that those rules are in conformity with the principle of proportionality. This means that the restriction must be limited to what is necessary to attain the legitimate aim of protecting public health. This includes providing the relevant evidence, such as technical, scientific, statistical and nutritional data, and all other relevant information[37]. In addition, EEA States must demonstrate that the stated aim cannot

[35] See Case E-3/06 *Ladbrokes* EFTA Court Report [2007] p. 86 at paragraph 42.
[36] Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375, paragraph 46.
[37] Case C-270/02 *Commission v Italy* [2004] ECR I-1559.

be achieved by any other means that has a less restrictive effect on trade between the Member States[38].

136 At the outset, it should be emphasized that the two risk assessments do not support the view that unrestricted importation of meat and meat products causes a risk to the Icelandic livestock or to public health that ought to be controlled with a systematic authorisation procedure. In line with settled case-law according to which decision-makers may not base their decisions on a "zero risk"[39], the Authority believes that the Icelandic measures are not proportionate to the objective pursued.

137 With regard to animal health, the report prepared by Stephen Cobb indicates that for all nine pathogens identified as presenting a potential risk, the risk level is set at a "non-negligible" level.

138 According to the information in this report, only two possible vectors of contamination of live animals by infected meat have been identified: backyard feeding of pigs or poultry and migratory birds (as regards avian influenza). Setting aside infection via migratory birds, which is not the target of the measures under review, the main risk of spreading the pathogens is linked to the keeping of "hobby" pigs or backyard poultry, which, according to the authors of the risk assessment, is a growing trend in Iceland. Transmission of pathogens would be caused by "swill feeding" or waste feeding of backyard poultry flocks.

139 The authors recognise that the risk to the commercial herds (be it pigs, sheep or bovine) or flocks (poultry) is negligible.[40] For poultry, all commercial operation is done indoor with a high level of biosecurity and for pigs, feeding rules should prevent any risk of accidental feeding of infected meat. In this context, the Authority can only conclude that the risk is further limited by proper enforcement of the feed ban for commercial herds and application of animal health rules in Iceland.

140 In addition, the report prepared by Stephen Cobb does not identify any direct risk to the bovine, ovine and caprine population in Iceland. For livestock to become infected they would have to be exposed to contaminated meat. Since herbivorous animals do not naturally eat meat, the likelihood of exposure by this pathway is so low that it is considered to be negligible.

141 Finally, the Authority notes that this report indicates that most of the pathogens identified as posing a non-negligible risk would survive freezing over a 30 day period (African swine fever, Classical swine fever, Newcastle disease, Porcine reproductive and respiratory syndrome virus, Brucella). For example, the authors of the risk assessment indicate that the African swine fever virus in pork and pork products may persist for up to 104 days in frozen meat or chilled meat; for up to 140 days in Iberian hams including shoulder hams. Classical swine fever virus can

[38] Case C- 104/75 *De Peijper* [1976] ECR 613 at paragraph 17.
[39] See Case T-257/07 *French Republic v. Commission* [2011] ECR II- 05827 at paragraph 79, Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraphs 139 and 141 and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraphs 152 and 154.
[40] The Report highlights on numerous occasions that commercial poultry farms in Iceland are unlikely to feed waste food and there are no commercial free-range poultry flocks in Iceland. Concerning pig farming, the report also indicates that it is unlikely that commercial pig farms in Iceland would use kitchen waste as a source of feed.

remain infectious for nearly 3 months in refrigerated meat and for more than 4 years in frozen meat. In frozen meat Brucellae may survive up to 2 years.

142 It follows that the data presented in the report prepared by Stephen Cobb by Iceland undermines the argument that the measures are proportionate to protect the Icelandic livestock and in particular the requirement to freeze the meat products for a period of 30 days at -18°C as it does not appear to be suitable and necessary to eliminate the risk of infection of Icelandic livestock.

143 With regard to human health and the report prepared by MAST in March 2012, the Authority considers that the risk identified in this report (possible negative impact on public health in Iceland) is not of a nature to justify the strict measures governing imports of meat in place in Iceland as laid out in Iceland in Act No. 25/1993 and Regulation (IS) No. 448/2012.

144 The Authority recognises that the prevalence levels of salmonella and campylobacter are low in Iceland and that the Icelandic legislation implements stricter requirements than those laid down in the EEA legislation to monitor these zoonotic agents[41]. However, the Authority considers that the restrictions placed on the imports of fresh meat in Iceland are not proportionate to the risk addressed.

145 Concerning salmonella, as indicated in section 5.3.1. above, protective measures are available to Iceland in the form of additional guarantees. With regard to campylobacter, the Authority considers that the obligation to freeze all meat products is a disproportionate measure with regard to the risk and the objective pursued. Under current EEA legislation, the protection of consumers in the EEA against campylobacter is carried out through a collaborative approach which consists of both risk assessment and risk management measures involving EEA States, the European Commission, the European Parliament, EFSA and the European Centre for Disease Prevention and Control (ECDC). In contrast, the Icelandic measures have been unilaterally decided by Iceland and are highly restrictive as they force importers to freeze all products covered by Article 5 of Regulation (IS) No. 448/2012.

146 Based on this information, the Authority considers that the measures in place in Iceland, in the form of a systematic authorisation procedure, are not proportionate to the aim pursued.

5.4.3.2. Absence of risk management by Iceland

147 As indicated above, both risk assessments presented by Iceland do not address the adequacy of the Icelandic measures in light of the risk defined. In particular, the document prepared by Stephen Cobb of SRC associates states that there are a number of European Union Council Directives that govern measures to be taken within the European Union in the face of a disease outbreak.

148 The report, however, points out the fact that the examination of existing measures that already exist and minimise the risk and reduce the likelihood of introducing the pathogens in Iceland is outside of the scope of the risk assessment.

[41] See EFTA Surveillance Authority Report following its mission to Iceland from 10 to 14 September 2012 regarding the application of EEA legislation related to control of salmonella and other specified food-borne zoonotic agents.

149 For most of the nine pathogens identified in the risk assessment, there are EEA rules in place designed to limit the risk of contamination and dissemination.

150 By way of example, to control the risk of spreading of African swine fever virus for example, Council Directive 2002/60/EC[42] lays down the minimum control measures where African swine fever is suspected or confirmed. Any suspected or confirmed case of the disease must be notified to the competent authority. The Member State concerned informs the Commission and the other Member States of cases of African swine fever, outbreaks of the disease and the results of epidemiological inquiries. Measures adopted are targeted and proportionate to what is necessary to contain the risk and avoid disturbing trade.

151 With regard to classical swine fever, Council Directive 2001/89/EC[43] provides for preventive and control measures. In case of outbreaks in the European Union, one needs to resort to the slaughtering of all pigs in the infected farms and the destruction of cadavers. A protection zone (3 km radius) and surveillance zone (10 km radius) are established around each outbreak, with restrictions on pig movements. An epidemiological investigation with the tracing of the source of infection and the possible spread is carried out. If appropriate, emergency vaccination can also be used. Additional ad hoc protection measures may be adopted by the Commission.

152 Council Directive 2005/94/EC on Community measures for the control of avian influenza[44] are designed to prevent and control avian influenza are coordinated at EU level. There are preventive measures against avian influenza which must be implemented by all the Member States and surveillance for the disease has been increased. Prescribed measures must be enacted by national authorities if there is a suspected or confirmed case of highly pathogenic avian influenza in either wild birds or domestic flocks in their territories. EU import bans have also been placed on potentially risky poultry products and susceptible imports from third countries with HPAI outbreaks. When there is an outbreak in a domestic poultry holding, all birds must be culled and measures are taken to prevent the further spread of the infection to other holdings. Zones with movement restriction (protection and surveillance zones) are established. In these zones, movement of live poultry and certain poultry products are restricted. Poultry has to be kept indoors and must be closely monitored.

153 These control measures at the European Union level minimise the risk and are likely to have a significant impact on the risk for products originating in the European Union of introducing a number of the diseases identified in the risk assessment.

154 As the author of the risk assessment indicates in the introduction of the document, "*an assessment of whether these measures alone are sufficient to meet Iceland's appropriate level of protection is beyond the scope of this report and is rightly a decision for the Competent Authority in Iceland*".[45]

[42] Point 9b of Chapter I of Annex I to the EEA Agreement.
[43] Point 3 of Chapter I of Annex I to the EEA Agreement.
[44] Point 5a of Chapter I of Annex I to the EEA Agreement.
[45] "*Import risk assessment: Unrestricted imports of ruminants, swine and poultry meat and meat products from the European Union*" prepared by Stephen Cobb of SRC associates in the executive summary.

155 The Authority considers, in light of the case law of the CJEU[46], that the decision by the Icelandic authorities to decide which measures are appropriate and necessary to prevent the risk from materializing must be based on a scientific risk assessment in relation to risk management.

156 Iceland has not indicated in its reply whether it has carried out this risk management and if it considers, in light of the two risk assessments prepared by Stephen Cobb of SRC associates and MAST that the measures are appropriate to meet Iceland's appropriate level of animal health protection.

5.4.3.3. The conditions for the application of the precautionary principle are not met

157 Finally, concerning the application of the precautionary principle, as explained in section 5.3.2. of its letter of formal notice, the Authority considers that Iceland may not rely on the precautionary principle as measures relying on the precautionary principle should be of a provisional nature, pending the availability of more reliable scientific data[47]. A review of the information at hand does not indicate that the Icelandic rules on imports of meat are provisional in nature and that maintenance of the measures depends on the development of scientific knowledge.

158 In conclusion, for all the reasons above, the Authority considers that the Icelandic measures are not justified under Article 13 EEA.

[46] See Case T-70/99 *Alpharma* v *Council* cited above at paragraph 163.
[47] See Case C-504/04 *Agraproduktion Staebelow GmbH* [2006] ECR I-00679 at paragraph 40

FOR THESE REASONS,

THE EFTA SURVEILLANCE AUTHORITY,

pursuant to the first paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, and after having given Iceland the opportunity of submitting its observations,

HEREBY DELIVERS THE FOLLOWING REASONED OPINION

That by maintaining in force an authorisation system for, *inter* alia, fresh meat and meat products such as laid down in Article 10 of Act No. 25/1993 and Articles 3, 4 and 5 of Regulation (IS) No. 448/2012, Iceland has failed to comply with its obligations under the Act referred to at point 1.1.1 of Chapter I of Annex I to the EEA Agreement, *Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market*, in particular Article 5 thereof.

Alternatively, the Authority considers that this authorisation system is in breach Article 18 of the EEA Agreement.

Pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the EFTA Surveillance Authority requires Iceland to take the measures necessary to comply with this reasoned opinion within *two months* following notification thereof.

Done at Brussels, 8 October 2014

For the EFTA Surveillance Authority

Signed version!

Helga Jónsdóttir
College Member

Xavier Lewis
Director