Brussels, 30 October 2013
Case No: 70943
Event No: 680889

Icelandic Mission to the EU
Rond-Point Schuman 11
1040 Brussels

Dear Sir or Madam,

Subject: Letter of formal notice to Iceland for failing to comply with its obligations under Council Directive 89/662/EEC and Article 18 of the EEA Agreement by restricting the entry of fresh meat, meat preparations and other meat products in Iceland and subjecting such entry to an authorisation procedure

1 Introduction

By letter of 12 December 2011 (Event no. 618214), the EFTA Surveillance Authority ("the Authority") informed the Icelandic Government that it had received a complaint against Iceland concerning the restrictions on the importation of meat into Iceland. 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 No. 448/2012 of 23 May 2012) as the main rules governing imports of meat in Iceland.

In light of the discussions and exchanges of correspondence with the Icelandic Government, and as set out below in detail, the Authority has reached the following conclusion:

The Icelandic legislation currently applicable to the importation of meat from other EEA States is 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.

2 Correspondence

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.

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.

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.

The case was then discussed at the package meeting in Reykjavik on 7 June 2012.

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).

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 applicable secondary EEA legislation does not provide sufficient protection against the inherent animal and human health risks attached to imports of meat in Iceland.

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 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.

On 27 May 2013, Iceland replied to this letter (your reference no. ANR13010327/2.3.8).

In its letter, Iceland first recalls 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.

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.

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

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*".

The case was discussed during the package meeting that took place on 6 June 2013. During the meeting, Professor Karl G. Kristinsson of Landspítali University Hospital made a presentation on "Imported raw foods and the associated risk of infection for humans" and Dr. Vilhjálmur Svansson, of the Institute for Experimental Pathology at Keldur made a presentation on the health status of Icelandic livestock and whether it is threatened by the import of raw meat.

3 Relevant national law

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:

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."

Icelandic Regulation 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.

According to Article 3 of Regulation 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."

Article 4 of Regulation 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.

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*"

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 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.

According to Iceland[1], "*documentary checks are carried out by the office of import and export at the Food and Veterinary Authority (MAST)*".

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

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

"Imported foods which are listed under classifications (CN Codes) 0202, 0203, 0204, 0207, 0208, 0210, 1601 and 1602[2]*, cf. Appendix I to the Customs Act, No. 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."

The Authority thus understands that the measures under review, Article 10 of Act No. 25/1993 and Articles 3, 4 and 5 of Regulation No. 448/2012, read together do not constitute a total ban on the importation of fresh meat but rather a system of import 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 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 No. 448/2012 refers to other products of animal origin, such as animal by-products, dairy products and eggs. All these products are defined and covered by Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin[3].

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[2] 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

3 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

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.*

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.

Article 11 EEA provides that:

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

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."*

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."*

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

At the outset, it should be noted that the incorporation of the hygiene package into the EEA Agreement, by way of five Joint Committee Decisions adopted on 26 October 2007[4], included, *inter alia*, the following derogations/adaptations for Iceland.

First, all EEA Acts concerning live animals, other than fish and aquaculture animals, and animal products such as ova, embryo and semen fall outside the scope of the EEA Agreement for Iceland. Consequently, the relevant Acts of the hygiene package concerning live animal do not apply to Iceland[5].

Second, Iceland maintained a specific status concerning fishmeal and meat and bone meal, and Regulation (EC) No. 999/2001 *laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies* (TSE) was incorporated into the EEA Agreement with the following adaptations: "*Iceland may continue feeding fishmeal to ruminants*" and "*Iceland continues to prohibit the import of meat and bone meal and products containing meat and bone meal from the Community, the EFTA States and third countries"*[6]. Neither of these two derogations is relevant for the case at hand.

Finally, with regard to meat products, as well as milk and milk products and eggs, Iceland was granted an 18 month transitional period to implement the relevant provisions of Chapter I to Annex I to the EEA Agreement. Following this transitional period that ended on 1 November 2011, Iceland was obliged to incorporate the relevant food law and veterinary acquis.

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[7] aims to regulate veterinary checks in intra-Community trade of products of animal origin. Its main objective is to eliminate veterinary checks at the EEA's internal borders while reinforcing those carried out at the point of origin. It defines and harmonises the type of controls that can be performed within the EEA on products of animal origin.

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.

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"*.

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.

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[4] Joint Committee Decisions No. 133/2007, 134/2007, 135/2007, 136/2007 and 137/2007.
[5] According to point 2 of the introductory chapter of Annex I to the EEA Agreement "*The provisions contained in this Chapter shall apply to Iceland, except for the provisions concerning live animals, other than fish and aquaculture animals, and animal products such as ova, embryo and semen*".
[6] Joint Committee Decision No. 133/2007.
[7] Point 1.1.1 of Chapter I of Annex I to the EEA Agreement.

Under the first of those two provisions, the Member State of dispatch is to ensure that the only products intended for intra-Community trade are those 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 by the certificates required by the Community veterinary rules. In practice, further to the entry into force of the "hygiene package"[8] this means that products of animal origin can only be placed on the market if they comply with the requirements laid down in Regulation (EC) No. 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.

In accordance with Article 4 of Directive 89/662/EEC, the Member State of dispatch is to take the necessary measures to ensure that the veterinary requirements are complied with at all stages of the production, storage, transport and marketing of the goods covered and penalise any infringement of the Community rules in that context. In particular, that State is to ensure, first, that the products obtained in accordance with the veterinary harmonisation directives, listed in Annex A to Directive 89/662/EEC, are checked in the same way, from a veterinary point of view, whether they are intended for intra-Community trade or for the national market and, second, that those products which are not subject to Community harmonisation, but which are listed in Annex B to that same directive, are not dispatched to the territory of another Member State, if they cannot be marketed on its own territory for reasons justified by Article 30 of the EC Treaty (now, Article 36 TFEU).

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

As an exception to the main objective of the directive, which is to reduce checking formalities at the place of destination, Article 5 defines - restrictively - the types of checks that can be carried out by the competent authority at the place of destination and states in particular that:

'*1. Member States of destination shall implement the following measures:*

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;'

It is interesting to note that Article 3(6) of Regulation (EC) No. 882/2004, the overarching regulation on official controls[9] is based on the same principle: "*The competent authority of*

[8] After the entry into force the "hygiene package", Council Directive 89/662/EEC was amended by 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 (OJ L157, 30.4.2004).

[9] Point 11.1.1 of Chapter I of Annex I to the EEA Agreement.

the Member State of destination may check compliance of feed and food with feed and food law by means of non-discriminatory checks".

Articles 7 and 8 of Directive 89/662/EEC lay down the measures to be taken and the procedure to be followed if, during a check carried out at the place of destination of a consignment, the competent authority establishes the existence of an epizootic disease, any new serious and contagious disease or other cause likely to constitute a serious hazard to animals or to human health. The detailed rules for implementing those two articles are to be adopted in accordance with the procedure laid down in Article 18 of the directive.

Article 9 of Directive 89/662/EEC provides that, in cases of an outbreak in its territory of any zoonoses, disease or other cause likely to constitute a serious hazard to animals or human health, Member States may adopt safeguard measures.

It should be noted that 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, which provides that:

"Safeguard and protective measures

(a) If the Community or an EFTA State intends to adopt safeguard measures against the other Contracting Parties, if shall inform the other Parties without delay.

The proposed measures shall be notified without delay to each Contracting Party and to both the EC Commission and the EFTA Surveillance Authority.

Without prejudice to the possibility of putting the measures into force immediately, consultations among the EC Commission and the Parties concerned, at the request of any of them, shall take place as soon as possible in order to find appropriate solutions.

In case of disagreement, any of the Parties concerned may refer the matter to the EEA Joint Committee. If an agreement cannot be reached in this Committee, a Contracting Party may adopt appropriate measures. Such measures shall be restricted to what is strictly necessary to remedy the situation. Priority shall be given to such measures as will least disturb the functioning of the Agreement." This paragraph applies to Iceland for live animals as well.

Finally, it should be mentioned that pursuant to Article 8 of Regulation (EC) No. 853/2004, special guarantees in respect of certain foodstuffs of animal origin may be extended, in whole or in part, to any Member States, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Finland and Sweden in respect of the food of animal origin concerned.

Member States may apply[10], based on their respective salmonella control programme, to the European Commission (to the Authority for EFTA States) for special additional guarantees for the importation of certain products[11].

[10] See, for example, Commission Implementing Regulation (EU) No. 427/2012 on the extension of special guarantees concerning salmonella laid down in Regulation (EC) No. 853/2004 of the European Parliament and of the Council to eggs intended for Denmark.

[11] In a statement attached to Joint Committee Decision No. 137/2007 Iceland declared its intentions to establish a control programme equivalent to that approved for Sweden, Finland and Norway in respect of

5 The Authority's assessment

5.1 Directive 89/662/EEC

EEA rules concerning importation of products of animal origin and veterinary checks have been harmonised in the EEA and Iceland was under an obligation to comply with Directive 89/662/EEC as of 1 November 2011[12]. According to Directive 89/662/EEC, veterinary checks are to take place at the place of dispatch and the competent authority at the place of destination may carry checks only by means of non-discriminatory spot-checks. In addition, Article 5 of Directive 89/662/EEC provides that the veterinary checks at the place of destination are limited to verifying the fulfilment of the requirements in the EEA legislation (i.e. general and specific requirements laid down in *Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin*).

5.1.1 The Icelandic legal framework regarding imports of meat is in breach of Directive 89/662/EEC

A review of the Icelandic legal framework has led the Authority to conclude 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.

Article 10 of Act No. 25/1993 as well as Regulation No. 448/2012, impose additional requirements for the importation of fresh meat and meat products into Iceland to those laid out in the EEA legislation and that these additional obligations are incompatible with the requirements of Directive 89/662/EEC. Iceland imposes, in a systematic manner, administrative formalities for the importation of fresh meat originating from EEA States. In particular, Article 4 of Regulation 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 No. 448/2012 imposes an obligation to present certain certificates.

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 essentially beyond the controls permitted at the place of destination.

On several occasions, the Court of Justice of the European Union (CJEU) has ruled that similar additional health checks placed on imports of products of animal origin are not compatible with harmonized rules on veterinary checks[13].

In particular, the system of compulsory prior notification and health checks for imports of certain food products of animal origin from other Member States in place in Sweden was

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food of animal origin and to have it approved in accordance with Regulation (EC) No. 2160/2003 by the time the transitional period expires (i.e. 01/11/2011). However, Iceland has never established such programmes. In its reply of 5 September 2012 to a request for information by the Authority, Iceland indicated that it had no intention to apply for special salmonella guarantees.

[12] On 11 November 2011, the Icelandic Government notified the national measures considered by Iceland to ensure full implementation of Directive 89/662/EEC. Implementation was made by way of Regulation (IS) No. 1043/2011 on import controls on animal products from countries within the EEA. The legal basis for Regulation (IS) No. 1043/2011 is, among others, Act No. 25/1993 on Animal Diseases and Preventive Measures Against them.

[13] Case C-186/88 *Commission v. Germany* [1988] ECR 3997 and Case C-111/03 *Commission v. Kingdom of Sweden* [2005] ECR I-8789.

considered incompatible with Article 5 of Council Directive 89/662/EEC Directive 89/662/EEC [14].

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.

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"*[15].

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*"[16].

With regard to the argument presented by Sweden that the measures were in part justified by the need to limit the presence of salmonella, the Court stated that: "*the explanations provided by the Swedish Government as regards the reason for the existence of the national provision challenged by the Commission, namely to guarantee the effectiveness of health checks to prevent food products infected with salmonella from entering Sweden, contradict the spirit of Directive 89/662 which is to promote the free movement of agricultural products by placing the emphasis on the checks which have been carried out in the Member State of origin.*[17]"

The Authority considers that the conclusions of the Court of Justice in this case are applicable to the Icelandic measures as they constitute, like the Swedish measures, additional 'veterinary checks' within the meaning of Article 2 of Directive 89/662/EEC.

The Court of Justice clearly held that a prior notification system is not in line with the requirements of Directive 89/662/EEC. *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 No. 448/2012, is in breach of the requirements of Directive 89/662/EEC and in particular its Article 5.

As a further support for that conclusion, the Authority refers to another judgment from the Court of Justice concerning a procedure in Germany which entailed an obligation on the part of the importer to declare all imports of raw poultry meat in order to be inspected, the Court held that: "*In the light of the harmonized 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*"[18].

[14] Case C-111/03 *Commission v. Kingdom of Sweden* cited above.
[15] Case C-111/03 *Commission v. Kingdom of Sweden* cited above at paragraph 58.
[16] *Ibid.*at paragraph 51.
[17] *Ibid.*at paragraph 62.
[18] Case C-186/88 *Commission v. Germany* cited above at paragraph 16.

The Court stated 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"*[19] (According to Article 2 of Directive 83/643 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).

Finally, it should be noted that the Icelandic measures under review contradict the spirit of Directive 89/662/EEC which is based on trust and the mutual recognition of checks carried out in EEA States. In contrast, the Icelandic measures do not fully recognise the efficiency of veterinary checks carried out in other EEA States. Protective measures that Member States can adopt within the framework of the EEA legislation, cannot be unilateral but the result of a consultation with other Member States[20].

5.1.2 Response to Iceland's arguments

While Iceland does not contest the fact that veterinary checks have been harmonised in the EU by way of Directive 89/662/EEC (See point IV of its letter of 27 May 2013), it argues that "*the legal implications of the Directive differ in nature according to whether their sphere of application is in the EU or Iceland*". According to Iceland, this conclusion is derived from the fact that it does not participate in the Common Agricultural Policy (CAP) of the European Union and does not benefit from the various CAP's market supports mechanisms. The non participation of Iceland in the CAP, according to Iceland, means that Iceland shall not be required to ensure the free movement of agricultural goods in the same way as within the EU. In addition, Iceland considers that "*by agreeing to and incorporating Directive 89/662/EEC, Iceland only did this to ensure that the same minimum standards would apply to veterinary checks*" (See point IV of its letter of 27 May 2013).

The Authority disagrees with this interpretation and fails to see how the legal implications of Directive 89/662/EEC might differ in nature depending on whether it is applied as matter of EU or EEA law.

First, Directive 89/662/EEC has been incorporated in Annex I to the EEA Agreement without any limitations on the scope of its application. In a case concerning the applicability of the labelling Directive 2000/13 to products that might fall outside of the product scope of the Agreement, as defined in Article 8(3) EEA, the EFTA Court concluded as follows:

"Directive 2000/13 has been incorporated into Annex II to the EEA Agreement. Since it has been made part of the Agreement without specifying any limitations on the scope of its application except the general exception concerning Liechtenstein, the Directive must be considered to apply to all foodstuffs. For the purposes of the applicability of Directive 2000/13 in the present proceedings, it is therefore of no relevance under which Chapter of the Harmonized Description and Coding System the nine beverages at issue in the

[19] *Ibid.* at paragraph 17.

[20] Point 3 of the Introductory Chapter of Annex I to the EEA Agreement on protective measures and safeguards provides that: "*If the Community or an EFTA State intends to adopt safeguard measures against the other Contracting Parties, if shall inform the other Parties without delay. The proposed measures shall be notified without delay to each Contracting Party and to both the EC Commission and the EFTA Surveillance Authority*".

national proceedings might fall."[21] It follows that Directive 89/662/EEC applies to the products as described in Regulation No. 448/2012, even though these products might be outside the product scope of the EEA Agreement on the basis of Article 8(3) EEA.

Second, it should be noted that Directive 89/662/EEC is not part of the CAP but is an integral part of the EEA food safety legislation which is fully applicable in Iceland since 1 November 2011[22]. The CAP and the European food safety legislation have different purposes. On the one hand, the CAP aims at improving agricultural productivity, ensure reliable supply and the sustainable development of the agricultural industry (fair standard of living for farmers). On the other hand, the European food safety legislation aims to assure a high level of food safety, animal health through wide ranging farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. Directive 89/662/EEC concerns, in particular, intra-EEA movement of products of animal origin. As is apparent from the wording of the title of Directive 89/662/EEC and of the first recital in its preamble, that directive was adopted with a view to the completion of the internal market and to harmonise the way veterinary checks are carried out in the EEA for products that are covered by secondary legislation in the EEA Agreement (in particular Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin, Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls and Regulation (EC) No. 882/2004 on official controls). All these Acts have been incorporated in the EEA Agreement and are fully applicable in Iceland since 1 November 2011.

It is thus the view of the Authority that the applicability of Directive 89/662/EEC to the Icelandic measures is not contingent upon participation in the CAP but is rather directly connected to the application of the legislation on the hygiene of foodstuffs (the so-called "hygiene package") in the EEA States. Article 5 of Directive 89/662/EEC provides that the veterinary checks that EEA States may carry out are limited to verifying that products meet the requirements of the hygiene package in the country of origin. The Icelandic measures target the intra-EEA movement of products of animal origin and therefore fall directly within the ambit of Directive 89/662/EEC. The non-participation of Iceland in the CAP is irrelevant.

Third, based on the principle of homogeneous interpretation and application of common legal provisions in the EEA enshrined in Article 6 EEA, the Authority does not agree with Iceland's claim that the legal implications of Directive 89/662/EEC differ in nature according to whether it is being applied in the context of EU law or EEA law.

As the EFTA Court has held on several occasions, "*The main objective of the EEA Agreement is to create a homogeneous EEA (…). The principle of homogeneity therefore leads to a presumption that provisions framed in the same way in the EEA Agreement and EC law are to be construed in the same way. However, differences in scope and purpose may under specific circumstances lead to a difference in interpretation between EEA law and EC law.*[23]"

[21] Case E-2/12 *HOB-vín ehf*, EFTA Court Reports [2012] p. 1092 at paragraph 46.
[22] Directive 89/662/EEC applies to the animal products covered by the Directives listed in Annex A to this Directive. This Annex was amended by Directive 2004/41/EC so as to incorporate the new provisions of the hygiene package.
[23] 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.

While it is not contested that the CAP is outside the material scope of the EEA Agreement, Directive 89/662/EEC, as indicated above, is not part of the CAP but rather is an integral part of the EEA food safety legislation which is fully applicable in Iceland since 1 November 2011. Consequently, the difference between the scope of the EEA Agreement and the Treaty of the European Union concerning agriculture does not constitute compelling grounds for divergent interpretations of Directive 89/662/EEC.

Therefore, the Authority considers that Iceland has not presented any argument that would rebut the presumption that this Directive should be interpreted in the same way in the EEA Agreement as under EU law.

5.1.3 The non availability of justifications under Article 13 EEA in harmonised legislation

According to consistent case law of the CJEU, in harmonised fields of European legislation, recourse to justifications under Article 36 of the European Treaty (Article 13 EEA) is not available.

According to the Court: "*While Article 36 of the Treaty* (Article 13 EEA) *allows the maintenance of restrictions on the free movement of goods, justified on grounds of public morality, public policy or the protection of the health and life of animals, which constitute fundamental requirements recognised by Community law, recourse to Article 36 is nevertheless no longer possible where Community directives provide for harmonisation of the measures necessary to achieve the specific objective which would be furthered by reliance upon this provision (see, in particular, Case C-5/94 The Queen v MAFF ex parte Hedley Lomas [1996] ECR I-2553, paragraph 18). In such a case, the appropriate checks must be carried out and protective measures adopted within the framework outlined by the harmonising directive (see Case C-323/93 Centre d'Insémination de la Crespelle v Coopérative de la Mayenne [1994] ECR I-5077, paragraph 31). In that regard, the Member States must rely on mutual trust to carry out checks on their respective territories*"[24].

As the Court of Justice has held on several occasions, Directive 89/662/EEC has harmonised the field of veterinary checks for the trade of products of animal origin[25]. As stated above, this directive was adopted with a view to the completion of the internal market and the free movement of goods is thus one of its objectives[26]. According to the Court: "*This harmonisation consequently prevents the Member States, in the field exhaustively harmonised, from justifying an obstacle to the free movement of goods on grounds other than those envisaged by Directives 64/433 and 89/662*"[27].

In the above-mentioned case against Sweden concerning the application of Directive 89/662/EEC, the Court also concluded that: "*Since that directive aims to regulate, in detail, veterinary checks to be carried out at the place of dispatch of the goods, in order to restrict as far as possible checks which could be carried out at the place of destination and, a fortiori, to abolish checks at internal frontiers of the Community in order gradually to complete the internal market, that directive must be understood as having*

[24] Case C-1/96 *Compassion in World Farming Limited* [1998] ECR I-1251 at paragraph 47.
[25] Case C-111/03 *Commission v. Kingdom of Sweden*, cited above; Case C-102/96 *Commission v. Germany* [1998] ECR I-6871 and Case C-445/06 *Danske Slagterier* [2009] ECR I-02119.
[26] Case C-445/06 *Danske Slagterier* cited above at paragraph 23.
[27] *Ibid*. at paragraph 25.

circumscribed, in a clear and precise manner, the power of the Member States when implementing health checks likely still to be carried out at the place of destination"[28].

In its opinion, the Advocate General had reached the following conclusion: "*I consider that Directive 89/662 exhaustively harmonised the veterinary inspections which can take place in the Member State of destination of the products of animal origin covered by the directive*"[29].

It follows that in the present case, Article 13 EEA cannot be relied upon by Iceland to justify derogating from the obligations laid out in Directive 89/662/EEC. Any restriction on the imports of meat can only occur where it is found that the goods do not meet the conditions laid down in the hygiene package and strictly within the framework of the relevant acts (see in particular, Article 7 and 9, as adapted for the purposes of the EEA Agreement, of Directive 89/662/EEC).

5.2 Article 18 EEA

In the event the Icelandic rules on imports of fresh meat and meat products pursuant to Article 10 of Act No. 25/1993, and Regulation No. 448/2012 were not found to be in breach of Article 5 of Directive 89/662/EEC, the Authority believes that these rules are not compatible with Article 18 EEA and not justified under Article 13 EEA.

5.2.1 Article 18 EEA

Article 18 EEA is placed in Chapter 2 of Part II of the EEA Agreement (free movement of goods / Agricultural and fishery product) and applies specifically to agricultural products that are not covered by Article 8 (3). This article obliges the Contracting Parties to ensure that the "*arrangements*" provided in the relevant Annexes and protocols referred to in Articles 17 and 23 EEA are not "*compromised*" by other "*technical barriers to trade*".

The notion of "*technical barriers to trade*" in Article 18 EEA must be interpreted in the context of the EEA Agreement and in light of its place in the Agreement (Chapter 2 of Part II). It draws upon concepts that relate to both international trade, as developed within the GATT or WTO, and technical regulations, as defined in Directive 98/34/EC[30] concerning technical standards and regulations.

Article 1 Directive 98/34/EC defines "technical specification" as: "*specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures. The term 'technical specification' also covers production methods and processes used in respect of agricultural products*".

It is worth noting that in *Pedicel*[31], the EFTA Court provided some clarification as regards the scope of Article 18 EEA and the definition of "*technical barriers to trade*". In this

[28] Case C-111/03 *Commission v. Kingdom of Sweden* cited above at paragraph 52.
[29] Opinion of the Advocate General in case C-111/03 *Commission v. Kingdom of Sweden* cited above at paragraph 38.
[30] Point 1 of Chapter XIX of Annex II to the EEA Agreement.
[31] Case E-4/04 *Pedicel*, EFTA Court Reports [2005] at paragraph 1.

case, the EFTA Court indicated that "*technical barriers to trade*" should be understood as having a narrower scope than "*measures having equivalent effect*" to quantitative restrictions in Article 11 EEA[32]. The EFTA Court added that: "*the prohibition of other technical barriers to trade in Article 18 EEA can only be understood to the effect that no further requirements of the same kind as foreseen and implemented in the EC legislation shall be imposed*" [33].

5.2.2 The Icelandic measures as technical barriers to trade

The Authority understands that the measures under review do not constitute an absolute ban on the importation of fresh meat but rather a system of import authorisation for these products based on the production of certain certificates by the relevant food business operator.

Consequently, it is the view of the Authority, that Article 10 of Act No. 25/1993, in conjunction with Articles 3, 4 and 5 of Regulation No. 448/2012, read together[34], constitute a technical barrier to trade (or a "technical specification") as it establishes a specific procedure (akin to conformity assessment procedure) to check whether a specific category of product complies with certain requirements. These requirements are, *inter alia*, that the products do not transmit infectious agents that can cause animal disease.

5.2.3 The Icelandic measures and the "arrangements" in Annex I to the EEA Agreement

EEA law – in particular Annex I (Veterinary and Phytosanitary Matters) or Annex II (in particular Chapter XII on foodstuffs) – contains numerous Acts dealing with animal health protection, prevention of animal diseases, which are of crucial importance for the control of infectious diseases. In addition, rules on veterinary checks and border control are also laid out in these Annexes.

The purpose of these Acts, which lay down specific requirements for private undertakings and obligations for public authorities, is to protect and raise the health status and condition of animals in the Union, in particular food-producing animals, and to lay down specific hygiene rules for food of animal origin.

The underlying purpose of this legislation is also to participate in the creation of an internal market by removing obstacles to trade in these products as is recalled in the recitals of the overarching "Food Law" Regulation (EC) No. 178/20002[35]:

"(4) There are important differences in relation to concepts, principles and procedures between the food laws of the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal

[32] Case E-4/04 *Pedicel* cited above at paragraph 27.
[33] Case E-4/04 *Pedicel* cited above at paragraph 27.
[34] In its report in the Asbestos case (WT/DS135/AB/R), the WTO Appellate Body considered that the measure under review should be, in view of the applicability of the TBT Agreement, examined "as a whole". "*In our view, the proper legal character of the measure at issue cannot be determined unless the measure is examined as a whole. Article 1 of the Decree contains broad, general prohibitions on asbestos and products containing asbestos. However, the scope and generality of those prohibitions can only be understood in light of the exceptions to it which, albeit for a limited period, permit, inter alia, the use of certain products containing asbestos and, principally, products containing chrysotile asbestos fibres"*.
[35] Regulation (EC) No. 178/2002 of the Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

conditions of competition, and may thereby directly affect the functioning of the internal market.
(5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. (…)".

Since 1 November 2011, with the exception of provisions relating to live animals, all these Acts are fully in force in Iceland. Altogether, these Acts - which create obligations on both the EEA States (official controls and veterinary checks) and private operators (which are responsible for the safety of all food products placed on the market) - aim at harmonising existing national requirements in order to prevent human and animal disease while ensuring the free movement of food of products of animal origin.

In the Authority's opinion, Article 10 of Icelandic Act No. 25/1993 and Regulation No. 448/2012 provide for requirements "*of the same kind*" as the arrangements laid out in Acts in Annex I to the EEA Agreement.

The Icelandic legislation contains additional requirements to prevent the introduction or spread of animal diseases resulting from the placing on the market of products of animal origin such as the obligation for operators to submit certain certificates for the consideration by MAST (see Article 4 and 5 of Regulation (IS) No. 448/2012).

Concerning the obligation for the importer to show that the products are free of salmonella bacteria (point *e* of Article 5 of Regulation No. 448/2012), this requirement – which already exist in Sweden, Finland, Norway and Denmark – can only be imposed under EEA law if it has been established pursuant to Article 8 of Regulation (EC) No. 853/2004[36]. In the absence of such "additional guarantees", this obligation is tantamount to a "*technical barrier to trade*" within the meaning of Article 18 EEA as it submits the placing of a product on the market to an additional requirement. If Iceland wants to impose such requirements, it should use the applicable procedure pursuant to Article 8 of Regulation (EC) No. 853/2004[37] and Regulation (EC) No. 2160/2003[38].[39]

Concerning the obligation for the importer to show that meat products and by-products, dairy products and eggs shall conform to the appropriate provisions of the current Regulation on food contaminants (point *f* of Article 5 of Regulation No. 448/2012), the obligations under EEA legislation on contaminants in food are already laid out in Council Regulation (EEC) No. 315/93 of 8 February 1993 (while maximum levels for certain contaminants in food are set in Commission Regulation (EC) No. 1881/2006). Article 5 of Regulation (EEC) No. 315/93 provides that "*Member States may not prohibit, restrict, or impede the placing on the market of foods which comply with this Regulation*". If Iceland wants to depart from the applicable EEA legal framework on food contaminants, or considers that fresh meat and meat products coming from the EEA do not comply with EEA legislation, it has to demonstrate particular reasons for doing so and bring forth adequate justifications (Article 4 of Regulation (EEC) No. 315/93 provides for a safeguard clause and temporary restrictions further to consultation with other contracting parties).

Finally, 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 (point

[36] Act referred to at Point 1.1.12 of Chapter I of Annex I to the EEA Agreement.
[37] Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement.
[38] Act referred to at Point 7.1.8b of Chapter I of Annex I to the EEA Agreement.
[39] See footnote 11.

g of Article 5 of Regulation No. 448/2012), already exists in the EEA in application of Directive 2000/13/EC.[40] Point g of Article 5 of Regulation No. 448/2012 thus constitutes a "requirement of the same kind" than requirement that already exists in harmonised EEA legislation.

Therefore, the Authority considers that these 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, of the same kind than the arrangements that already exist in Annex I and II to the EEA Agreement.

5.3 Justifications under Article 13 EEA

Article 18 EEA states that Article 13 EEA shall apply. Consequently, national measures that come within the scope of Article 18 EEA can be justified on grounds, *inter alia*, of protection of health and life of humans or animals.

In its various communications with the Authority, Iceland has consistently argued that the measures under review are justified under Article 13 EEA. According to Iceland, the measures under review are also justified based on the application of the precautionary principle.

After reviewing the arguments and documentation presented by Iceland in support of these claims, the Authority considers that the conditions for the application of the precautionary principle are not met and that the measures under review are not justified under Article 13 EEA.

5.3.1 Justifications presented by Iceland

In previous correspondence with the Authority, Iceland stated that these arrangements are justified based on the application of the precautionary principle, which, Iceland argues, should be applied when, "*on the basis of the best scientific advice available in the time-frame for decision making, there is good reason to believe that harmful effects may occur to human, animal or plant health (…) and the level of scientific uncertainty about the consequences or likelihood is such that risk cannot be assessed with sufficient confidence to inform decision-making*"[41].

In its letter of 12 March 2012 to the Authority, Iceland had indicated that: "*it cannot be excluded that the importation of raw pork, broiler meat and beef from the European Union could have a negative impact on the public health in Iceland. The importation would probably lead to a higher proportion of meat on the market in Iceland, in which zoonotic agents would be present. In addition it is likely that the meat would contain more virulent strains of bacteria than has previously been detected in Iceland".*

With regard to Article 13 EEA, Iceland argues that in light of the EFTA Court case-law, the measures meet the proportionality test and are thus justified.

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[40] 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.

[41] Reply by Iceland of 12 March 2012 to the Authority's request for information of 12 December 2011.

In addition, the scientific evaluations carried out by Professor Karl G. Kristinsson of Landspítali University Hospital on "*Imported raw foods and the associated risk of infection for humans*" and Dr. Vilhjálmur Svansson, of the Institute for Experimental Pathology at Keldur on the health status of Icelandic livestock and whether it is threatened by import of raw meat bring further information in support of the claim by Iceland that the measures are justified under Article 13 EEA.

The presentations stress in particular on the specific situation of the Iceland livestock with regards susceptibility to infectious agents (pathogens) and risks to the human population. The arguments made in these presentations can be summarised as follows:

- The disease status of Icelandic livestock populations is unusual compared to the situation in other countries;
- Due to centuries of isolation of Icelandic livestock breeds, i.e. cattle (dairy cows), horses, sheep and goats, the animals are susceptible, i.e. are immunologically naive to various transmissible agents common overseas, some of which are even considered as harmless in other countries;
- There are cases of infection in livestock from contaminated meat in the world and in Iceland (food and mouth disease or classical swine fever) in the past;
- There are several possible routes for transmission of pathogens from raw meat to animals. These routes include free range horses, sheep, goats and cattle (food leftover feeding in particular), hobby farming or companion animals (also mainly leftover feeding)
- It is possible that diseases carried by raw meat can lead to severe epidemics and threaten Icelandic breeds, which are unique in respect to biological diversity and adaptation to Icelandic circumstances;
- Thanks to successful operations in order to control food born diseases in Iceland, such as Salmonella and Campylobacter, the importation of raw meat, as well as fresh vegetables, would increase the risk of human infection. Particular attention should be paid to *gram-negative bacilli* (such as *E-coli*) which has become resistant to most or all types of antibiotics.

As far as assessing the risk level is concerned, the Authority notes that the presentations by Iceland (in particular Dr. Vilhjálmur Svansson's presentation) acknowledges the importance of disease surveillance and control in countries from where animal products are imported. These controls should be "*active and reliable*".

In addition, the presentation recognises that "*if all rules and regulations are in place then the risk of new introduction of infectious agents to Icelandic livestock is probably moderate or low*".

Summing up, the Authority considers that the justifications relied on by Iceland, protection of human and animal health are within the scope of Article 13 EEA. The main question is therefore, whether the Icelandic measures are compatible with the precautionary principle and the principle of proportionality.

5.3.2 Application of the precautionary principle

The conditions for the application of the precautionary principle have been clearly defined in the case law of the European Courts. According to the CJEU, "*a correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health (…), and, secondly, a comprehensive assessment of the risk to*

health based on the most reliable scientific data available and the most recent results of international research"[42].

The EFTA Court has given following guidance on the application of this principle:

"[…] measures taken […] must be based on scientific evidence; they must be proportionate; non-discriminatory, transparent and consistent with similar measures already taken" [43].

In particular, concerning the scientific requirement, the Court added that while *"[a] purely hypothetical or academic consideration will not suffice"*, what is required is *"a comprehensive evaluation of the risk to health based on the most recent scientific information"* [44].

"Such restrictive measures must be non-discriminatory and objective, and must be applied within the framework of a policy based on the best available scientific knowledge at any given time. The precautionary principle can never justify the adoption of arbitrary decisions and the pursuit of the objective of "zero risk" only in the most exceptional circumstances". [45]

Based on the documentation provided by Iceland, the Authority believes that the conditions for the application of the precautionary principle are not met in the present case.

While the Authority recognises that Iceland has put forth substantial scientific evidence, it considers that it does not sufficiently establish the existence of scientific uncertainty, which is the premise upon which the precautionary principle can be invoked.

Iceland has provided information concerning the susceptibility of the Icelandic livestock to various pathogens and the existence of a specific risk attached to imports of fresh meat and meat products into Iceland. It stems from the information provided that there is a risk of infection, in particular in cases of viruses, prions and bacteria which are well identified (Food and mouth disease, scrapie, BSE, Salmonella or Campylobacter). However, no scientific evaluation of the potential adverse effects has been presented or any information concerning the existence of any scientific uncertainty to that effect.

The information provided by Iceland does not establish either the insufficiency of the scientific data, its inconclusive nature nor, in general, the impossibility to determine with sufficient certainty the risk in question.

In addition, Iceland's claim that the measures are justified under the precautionary principle rests solely on the hypothetical suggestion that it cannot be excluded that the importation of fresh meat and meat products from the EEA could have a negative impact on the public and animal health in Iceland as it would probably lead to a higher proportion of meat on the market in Iceland, in which zoonotic agents could be present.

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[42] Case C-333/08 *Commission v France* [2010] ECR I-00757, at paragraph 92, Case C-343/09 *Afton Chemical Limited* [2010] ECR I- 07027, at paragraph 60.
43 Case E-3/00 *EFTA Surveillance Authority v Norway* cited above at paragraph 26.
44 *Ibid*. at paragraph 30.
45 *Ibid*. at paragraph 32.

As the European Courts have consistently held, a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified[46].

In the present instance, Iceland indicated that the means of transmission of pathogens from raw meat to animals can only be either accidental (food leftover feeding in particular[47]) or by way of a breach of EEA legislation on feed (such as Regulation (EC) No. 999/2001 concerning the prevention, control and eradication of certain transmissible spongiform encephalopathies). Iceland further recognises that the risk of new introduction of infectious agents to Icelandic livestock is probably moderate or low if all rules and regulations are in place[48] (such as specific hygiene rules for food of animal origin as laid down in Regulation (EC) No. 853/2004).

As a result, the Authority believes that the risk identified by Iceland – but not scientifically verified – is already addressed by EEA legislation and remains contingent upon accidental or illegal handling of foodstuff.

Finally, it is generally agreed that measures relying on the precautionary principle must be of a provisional nature, pending the availability of more reliable scientific data. When new elements change the perception of risk or show that that risk can be contained by less restrictive measures, measures based on the precautionary principle should be re-examined and if necessary modified depending on the results of the scientific research and the follow up of their impact[49].

In the present case, nothing seems to 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.

5.3.3 Proportionality of the measures

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[50].

Moreover, EEA States must demonstrate that the stated aim cannot be achieved by any other means that has a less restrictive effect on trade between the Member States.[51] Consequently, national rules or practices do not fall within the exception specified in Article 13 EEA if human and animal health can be as effectively protected by measures which do not restrict trade as much.

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[46] Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 143, Case C-333/08 *Commission v France* cited above, at paragraph 91, Case C-236/01 *Monsanto Agricoltura Italia and others* [2003] ECR I-08105 at paragraph 106.

[47] See Dr. Vilhjálmur Svansson's presentation on the health status of Icelandic livestock and whether it is threatened by the import of raw meat referred to above.

[48] *Ibid.*

[49] Case C-504/04 *Agraproduktion Staebelow GmbH* [2006] ECR I-00679 at paragraph 40, Case C-601/11 *French Republic v. Commission* Not yet published at paragraph 110, Communication from the Commission of 2 February 2000 on the precautionary principle (COM (2000) 12.02.2000) page 1.

[50] Case C-270/02 *Commission v Italy* [2004] ECR I-1559.

[51] Case C- 104/75 *De Peijper* [1976] ECR 613 at paragraph 17.

Article 13 EEA must be interpreted strictly[52] and it is for EEA States who invoke it to demonstrate in each case, taking into account the results of international scientific research, that their legislation is necessary[53].

Iceland argues that the Icelandic rules on importation of meat constitute the only feasible way to achieve the pursued objective. According to Iceland, "*Any other measures that might achieve the same results would be prohibitively expensive*". Iceland adds that "*even highly effective control measures would clearly be not sufficient*" (See section VII of letter of 27 May 2013 from Iceland to the Authority).

The Authority, however, considers that the Icelandic rules on importation of meat are not proportionate to the aim they are pursuing.

First, the Authority considers that the Icelandic measures are overly broad as they cover all fresh meat and meat products, whether from bovine, ovine or poultry, both processed (sausages, etc.) and non-processed and are based on a generalized presumption of health risk. No specific assessment of the health risk for each category of products has been presented.

In this regard, it should be noted that the CJEU has recalled, in a case that concerned a prior authorisation scheme for processing aids and foodstuffs with processing aids, that, "(the national measure) *is disproportionate in that it systematically prohibits, (…), the marketing of any processing aids or any foodstuffs in the preparation of which processing aids lawfully manufactured and/or marketed in other Member States were used, without making any distinction according to the various processing aids or according to the level of risk which their use might potentially pose for health*"[54].

It follows that the measures are disproportionate as it has not been demonstrated that they are strictly targeted to the products that pose a certain risk, based on specific risk assessment.

Second, with regard to the existence of less trade restrictive measures, the Authority questions the argumentation of Iceland and, in particular, the fact that the measures constitute the only feasible way to achieve the pursued objective.

As Iceland admits (see, in particular Dr. Vilhjálmur Svansson's presentation), the risk of new introduction of infectious agents to Icelandic livestock is contingent upon the existence of active and reliable disease surveillance and control in countries from where animal products are imported as well as enforcement of all rules and regulations that already exist. If all controls are in place, Iceland suggests, "*the risk of new introduction of infectious agents to Icelandic livestock is probably moderate or low*".

Iceland therefore recognises that there are rules and regulations that are designed to achieve the same objective (*inter alia* human and animal health protection) and that proper application of these rules and regulations will reduce the risk.

[52] Case E-4/04 *Pedicel* cited above at paragraph 53.
[53] Case C-333/08 *Commission v France* cited above at paragraph 87.
[54] *Ibid.* at paragraph 100.

The Authority agrees with this argument and considers that the Icelandic rules on importation of meat pursue an objective that is already the subject of a comprehensive set of Acts set in Annex I to the EEA Agreement that have been applicable since 1 November 2011 in Iceland. These Acts have harmonised hygiene rules for food of animal origin, official controls on products of animal origin intended for human consumption or veterinary checks.

The Authority has not received evidence from Iceland to the effect that these Acts, which have less restrictive effect on trade between the EEA States and which contain – for example – safeguard clauses, additional guarantees or other protective measures, cannot satisfactorily achieve the stated aim.

The Authority further notes that infection to livestock and humans may come from other sources than the products banned (for example, travellers, seasonal workers on farms, etc.). These risks are not addressed by these measures.

For these reasons, the Authority believes that Iceland has not demonstrated that the measures under review are the only measures that could achieve the stated objective and that they are consistent with other measures adopted.

6 Conclusion

Accordingly, as its information presently stands, the Authority must conclude 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 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.

In these circumstances, and acting under Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the Authority invites the Icelandic Government to submit its observations on the content of this letter *within two months* following receipt thereof.

After the time limit has expired, the Authority will consider, in the light of any observations received from the Icelandic Government, whether to deliver a reasoned opinion in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

For the EFTA Surveillance Authority

Signed version!

Sverrir Haukur Gunnlaugsson
College Member