E-17/15-22

REPORT FOR THE HEARING

in Case E-17/15

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by Reykjavík District Court (*Héraðsdómur Reykjavíkur*) in the case between

Ferskar kjötvörur ehf.

and

The Icelandic State

concerning the applicability of the provisions of the Agreement on the European Economic Area to the import of raw meat products.

I Introduction

1. In 2014, the Icelandic meat distribution company Ferskar kjötvörur ehf. ("the plaintiff") applied to the Icelandic Minister of Fisheries and Agriculture for permission to import 83 kg of raw beef fillets from the Netherlands via Denmark to Iceland. The permission was granted *inter alia* on the condition that the meat was stored at a temperature of at least -18°C for one month before customs clearance. The plaintiff objected to this, stating that the purpose of the import was to offer fresh meat to Icelandic consumers. The condition was nevertheless maintained. In the meantime, the meat had already been transported to Iceland and was being stored at the customs office. It was subsequently discarded.

2. In the case before Reykjavík District Court, the plaintiff claims payment from the Icelandic State ("the defendant") of EUR 1 909 and ISK 80 606, which correspond to the price of the meat and its transport. In the context of those proceedings, the District Court has decided to refer to the Court several questions concerning the compatibility of the abovementioned condition with the Agreement on the European Economic Area ("the EEA Agreement" or "EEA").

II Legal background

EEA law

3. In Part II of the EEA Agreement ("Free Movement of Goods") Chapter 1 is headed "Basic Principles". The first provision of that chapter, Article 8, reads:

> *1. Free movement of goods between the Contracting Parties shall be established in conformity with the provisions of this Agreement.*
>
> *2. ...*
>
> *3. 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.*

4. Agricultural products and foodstuffs fall outside Chapters 25 to 97 of the Harmonized Commodity Description and Coding System. Furthermore, raw meat is not among the products specified in Protocol 3. The goods at issue in the main proceedings are therefore outside the scope of the EEA Agreement unless otherwise specified.

5. Article 18 EEA reads:

> *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.*

6. Article 17 EEA, which is included in Chapter 2 on "Agricultural and Fishery Products", refers to Annex I concerning specific provisions and arrangements concerning veterinary and phytosanitary matters. Article 23(a) EEA, in Chapter 4 on "Other Rules relating to the Free Movement of Goods", refers to specific provisions and arrangements laid down in Protocol 12 and Annex II in relation to technical regulations, standards, testing and certification. Article 23(b) EEA is not relevant for the present case. Article 13 EEA, which is referred to in the last sentence of Article 18 EEA, reads:

> *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.

7. Chapter I of Annex I to the EEA Agreement contains provisions on veterinary issues. The first paragraph of point 2 of the introductory part reads:

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. When an act is not to apply or is to apply partly to Iceland, it shall be stated in relation to the specific act.

8. In Chapter I of Annex I to the EEA Agreement under heading 1.1, which sets out the basic texts concerning control matters, point 1 refers to Council Directive 89/662/EC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market[1] ("the Directive"), and to subsequent amendments to that directive.

9. The preamble to the Directive includes the following recitals:

[3] Whereas in the veterinary field frontiers are currently being used for carrying out checks aimed at safeguarding public health and animal health;

[4] Whereas the ultimate aim is to ensure that veterinary checks are carried out at the place of dispatch only; whereas the attainment of this objective implies the harmonization of the basic requirements relating to the safeguarding of public health and animal health;

[5] Whereas with a view to the completion of the internal market, pending the attainment of this objective, the emphasis should be placed on the checks to be carried out at the place of dispatch and in organizing those that could be carried out at the place of destination; whereas such a solution would entail the suspension of veterinary checks at the Community's internal frontiers;

10. Article 1 of the Directive reads:

Member States shall ensure that the veterinary checks to be carried out on products of animal origin covered by the acts referred to in Annex A or by Article 14 and which are intended for trade are no longer carried out … at frontiers but are carried out in accordance with this Directive.

11. It is not disputed that the reference to Annex A covers products such as those at issue in the main proceedings.

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[1] OJ 1989 L 395, p. 13.

12. Article 2(1) of the Directive contains the following definition:

> *'Veterinary check' means any physical check and/or administrative formality which applies to the products referred to in Article 1 and which is intended for the protection, direct or otherwise, of public or animal health;*

13. Chapter I of the Directive is concerned with "Checks at origin", and consists of Articles 3 and 4. The first subparagraph of Article 3(1) reads:

> *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.*

14. The first sentence of Article 4(1) reads:

> *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.*

15. Chapter II of the Directive contains rules on "Checks on arrival at the destination". In that regard, Article 5(1)(a) requires EEA States to implement the following measure:

> *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.*

16. Articles 7 and 8 of the Directive lay down the measures to be taken if the competent authority of the EEA State of destination establishes the presence of agents responsible for a disease named in Directive 82/894/EEC, a zoonosis or disease, or any cause likely to constitute a serious hazard to animals or humans. In such a case, protective measures provided for in Article 9 may be applied.

17. In Chapter I of Annex I to the EEA Agreement under heading 7.1, which sets out the basic texts concerning measures relating to many sectors, point 13 refers to Regulation (EC) No 178/2002 of the European 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[2] ("the Regulation"), and to subsequent amendments to that regulation. Point 13 also contains a number of adaptations of the Regulation for the purposes of the EEA Agreement.

18. Article 1(1) and (2) of the Regulation reads:

> *1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.*
>
> *2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.*
>
> *…*

19. Article 5(1) and (2) of the Regulation, under Chapter II on "General food law", reads:

> *1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.*
>
> *2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.*

20. Article 6 of the Regulation reads:

> *1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.*
>
> *2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.*
>
> *3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other*

[2] OJ 2002 L 31, p. 1, and Icelandic EEA Supplement 2011 No 59, p. 123.

factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.

21. Article 7 of the Regulation lays down the following "Precautionary principle":

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

22. Article 14 of the Regulation on "Food safety requirements" reads:

1. Food shall not be placed on the market if it is unsafe.

...

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

...

National law

23. Since 1882, the import of horses, cattle and sheep to Iceland has been prohibited. There are therefore a number of diseases against which the Icelandic animal population has not developed immunity. Based on the finding that not only live animals, but also animal products such as raw meat can transmit pathogens, Iceland has for decades also banned the import of raw meat, allowing exceptions only if the meat has undergone heat treatment or freezing.

24. Article 10 of Act No 25/1993 on Animal Diseases and Preventive Measures against them[3] ("the Act") reads:

> *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*
> *…*
>
> *Despite the provisions of paragraph 1 the Minister [of Fisheries and Agriculture] is authorized to allow the import of products mentioned in items a-e, having received recommendations from the Food and Veterinary Authority, if it is considered proven that they will not transmit infectious agents that can cause animal diseases.[4] 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 which carry the risk of transmitting contamination agents that could cause danger to the health of animals.*
>
> *…*

25. Regulation No 448/2012 on Measures to prevent the Introduction of Animal Diseases and Contaminated Products[5] ("the Icelandic Regulation") sets out detailed provisions on the implementation of Article 10 of the Act. Article 3 of the Icelandic Regulation reads:

> *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 Food and Veterinary Authority.*
>
> *…*

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[3] *Lög nr. 25/1993 um dýrasjúkdóma og varnir gegn þeim*.

[4] The second paragraph of Article 10 was amended by Act No 71/2015 which, *inter alia*, transferred the authority to permit the import of products mentioned in items (a) to (e) from the Minister to the Food and Veterinary Authority.

[5] *Reglugerð nr. 448/2012 um varnir gegn því að dýrasjúkdómar og sýktar afurðir berist til landsins*.

26. Article 4 of the Icelandic Regulation reads:

The Minister of Fisheries and Agriculture is authorized to allow the import of products mentioned in Article 3, cf. Article 10 of [the Act] and subsequent amendments, having received recommendations from the Food and Veterinary Authority, if it is considered proven that they will not transmit infectious agents that can cause diseases in animals and humans, and the conditions imposed for the import have been fulfilled, see however Article 7.

When an application is submitted for the first time to import a raw or unsterilized product as referred in the first paragraph, an importer must provide the Ministry of Fisheries and Agriculture with the necessary information on the product for consideration and approval before the product is dispatched from the country of export.

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 the Food and Veterinary Authority, 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 Article 5.

27. Article 5 of the Icelandic Regulation reads:

Imported foods which are listed under [Combined Nomenclature (CN) Codes] 0202 ... which the Minister has authorised for import to the country as referred to in Article 4 and which have not received satisfactory heat treatment must be accompanied by the following certificates:

a. ...
b. ...
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. ...
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.

28. CN Code 0202, as referred to in Article 5 of the Icelandic Regulation, covers frozen meat of bovine animals. Fresh or chilled meat of bovine animals, on the other hand, is included under CN Code 0201.

Infringement proceedings against Iceland

29. On 30 October 2013, the EFTA Surveillance Authority ("ESA") sent a letter of formal notice to Iceland, concluding that Iceland had failed to fulfil its obligations under the Directive, in particular its Article 5, by maintaining in force the authorisation system for fresh meat and meat products provided for in Article 10 of the Act and Articles 3 to 5 of the Icelandic Regulation. Alternatively, ESA considered the authorisation system to be in breach of Article 18 EEA. That conclusion was maintained in a reasoned opinion submitted on 8 October 2014 in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice ("SCA"). However, it appears from its written observations to the Court that ESA has decided to postpone further handling of the infringement case until the Court has given its Advisory Opinion in the present case.

III Facts and procedure

30. In February 2014, the plaintiff ordered 83 kg of beef fillets from a Dutch company for EUR 1 909. On 26 February 2014, the plaintiff applied to the Icelandic Minister of Fisheries and Agriculture for permission to import the meat to Iceland. The day after, the meat was transported by air from Denmark to Iceland. The freight costs amounted to ISK 80 606. The meat was stored at the customs office in Keflavík awaiting a decision on the application to permit the import.

31. On 6 March 2014, acting on behalf of the Minister of Fisheries and Agriculture, the Minister of Industries and Innovation authorised the import, provided that the conditions in Article 5(c), (e) and (g) of the Icelandic Regulation were met.

32. On 11 March 2014, stating that the purpose of the import was to offer consumers fresh meat that had not been frozen, the plaintiff requested the Food and Veterinary Authority to process a request to allow the import and to permit customs clearance of the fresh meat without requiring it to be frozen in accordance with Article 5(c).

33. On 14 March 2014, the Food and Veterinary Authority replied that it was not able to grant the request. It stated that the conditions imposed were in accordance with the Icelandic Regulation. It also stated that the authority to allow the import lay with the Ministry and that the role of the Food and Veterinary Authority was merely to give its comments.

34. Following this correspondence, the Directorate of Customs stopped clearance of the meat, and it was subsequently discarded at the request of the plaintiff.

35. In April 2014, the plaintiff brought a case before Reykjavík District Court, claiming compensation for the costs of the meat and its transport. The plaintiff claims that the defendant's refusal to grant permission to import fresh meat violates Icelandic law and EEA law, in particular Article 18 EEA, the Directive and the Regulation.

36. By order of 24 February 2015, Reykjavík District Court accepted the request of the plaintiff to refer certain questions to the Court. Following an appeal from the defendant, the Supreme Court of Iceland (*Hæstirettur Íslands*) decided by judgment of 27 April 2015 to rephrase and amend the questions. Accordingly, by letter of 22 May 2015, registered at the Court on 16 June 2015, the District Court referred the following questions to the Court:

1. **Does the field of application of the EEA Agreement, as defined in Article 8 thereof, entail that a Member State of the Agreement has discretion regarding the setting of rules on the importation of raw meat products and is, in this respect, not bound by the provisions of the Agreement and the acts based thereon?**

2. **If the answer to the first question is in the negative, then the question arises whether it is compatible with the provisions of [the Directive] that a Member State of the EEA Agreement should set rules demanding that an importer of raw meat products applies for a special permit before the products are imported, and require the submission, for this purpose, of an import declaration, information on the country of origin and production, the type of product and the producer, and the required certificates, including a certificate confirming that the products have been stored frozen for a certain period prior to customs clearance.**

3. **The national court requests the opinion of the Court whether the provisions of [the Regulation] are relevant in answering the second question.**

4. **Following on from the second and third questions, an answer is requested to the question of whether it constitutes a technical barrier to trade in the sense of Article 18 EEA if an EEA State sets rules under which the importation to that State of raw meat products is not permitted.**

5. **An opinion is requested on whether it affects the answer to the fourth question, if it is permitted, under the rules of the EEA State of destination, to grant exceptions from the general prohibition referred to in that question.**

6. **If the answer to the fourth and/or fifth question is in the affirmative, an answer is then requested to the question of in which cases such a prohibition on the importation of raw meat products taking into account, as appropriate, the circumstances described in the fifth question, could be considered justifiable with reference to Article 13 EEA. Also, an answer is requested to the question of what requirements should be made regarding proof in this connection,**

particularly in the light of the precautionary principle of EEA law.

IV Written procedure before the Court

37. Pursuant to Article 20 of the Statute of the Court and Article 97 of the Rules of Procedure, written observations have been received from:

- the plaintiff, represented by Arnar Þór Stefánsson, Supreme Court Attorney, acting as Counsel;

- the defendant, represented by Kristján Andri Stefánsson, Director General, Ministry of Foreign Affairs, and Einar Karl Hallvarðsson, State Attorney General and Supreme Court Attorney, acting as Agents, and Jóhannes Karl Sveinsson and Gizur Bergsteinsson, Supreme Court Attorneys, acting as Counsel;

- the Government of Norway, represented by Janne Tysnes Kaasin, Senior Adviser, Department of Legal Affairs, Ministry of Foreign Affairs, and Torje Sunde, Advocate, Office of the Attorney General (Civil Affairs), acting as Agents;

- ESA, represented by Carsten Zatschler, Director, Maria Moustakali, Officer, and Írís Ísberg, Temporary Officer, Department of Legal & Executive Affairs, acting as Agents;

- the European Commission ("the Commission"), represented by Daniele Bianchi, member of its Legal Service, and Kathleen Skelli, a national civil servant on secondment to the Legal Service, acting as Agents.

V Summary of the observations submitted to the Court

Question 1

38. By its first question, the referring court asks in essence whether an EEA State is bound by the provisions of the EEA Agreement and secondary legislation when setting rules on the import of raw meat products.

39. There is agreement between those who have submitted written observations that, pursuant to Article 8(3) EEA, the products at issue fall outside the scope of the EEA Agreement unless otherwise specified. However, there are different views on the significance of Articles 17, 18 and 23 EEA and the legal acts referred to in Annexes I and II.

The plaintiff

40. The plaintiff submits that the provisions of Chapters 2 and 4 of Part II to the EEA Agreement are applicable to the products at issue. Those provisions limit the discretion of the EEA States in setting rules on the import of raw meat products.

41. The plaintiff observes that there are specific provisions and arrangements concerning veterinary and phytosanitary matters in Annex I, and concerning technical regulations, standards, testing and certification in Annex II to the EEA Agreement. Article 18 EEA prohibits technical barriers to trade other than those laid down in those arrangements.[6] Accordingly, rules which concern the import of fresh meat and meat products are subject to Article 18 EEA. The plaintiff considers that the rules at issue cannot be justified under Article 13 EEA.

42. Moreover, the plaintiff argues that the disputed rules must be in conformity with the Directive, which was incorporated into the EEA Agreement without any adaptation of relevance for this case. The Regulation is also of relevance in this regard.

The defendant

43. The defendant submits that it follows from Article 8 EEA that an EEA State has discretion in establishing rules on the imports of raw meat, unless otherwise specified by the Agreement. Article 18 EEA and the arrangements referred to there do not alter that conclusion.

44. As regards the Directive, the defendant contends that the legal effects of it are different in the EU and in Iceland. First, Iceland is not part of the EU's agricultural policy, so it is unable to adjust to the EU rules in the manner expected within the EU. Therefore, unrestricted trade in agricultural products cannot be maintained for Iceland. This was the basis for the negotiation of the EEA Agreement and in particular its Article 17. Second, the application and objective of the Directive is completely different in the EU to what it is in the EEA. The Directive aims at the completion of the internal market for agricultural products, but there is no internal EEA market for such products.

45. Consequently, the defendant argues, by introducing the Directive into the EEA context, Iceland merely contributed to ensuring that certain procedures and formalities in terms of health standards would apply to facilitate trade in agricultural products. However, the point has always been maintained that the agricultural system falls in its entirety outside the scope of the EEA Agreement. Iceland can therefore adopt the required safety measures concerning protection of livestock and public health.

The Government of Norway

46. The Government of Norway observes that the EEA States have agreed to a common regulation of some aspects of trade in agricultural and fishery products. This is shown, in particular, in Article 17 EEA with its reference to Annex I on veterinary and phytosanitary matters. Annex I largely reflects the unique expansion of the EEA Agreement that took place from 1999, with the "veterinary agreement" adopted by EEA

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[6] Reference is made to Case E-1/94 *Restamark* [1994-1995] EFTA Ct. Rep. 15, paragraph 42.

Joint Committee Decision No 69/98.[7] This expansion was a result of the gradual acknowledgement of the need to ease especially the border controls of animal products to avoid unnecessary delays in the transport of such goods. The legal acts in Annex I therefore apply both to agricultural products and to fishery products.

47. In the view of the Norwegian Government, Article 18 EEA is intended to ensure that the effects of the harmonised legal acts in Annex I are not counteracted by technical barriers to trade not foreseen in those acts. It is clear from its wording that this provision is not meant to bring agricultural products within the general scope of the EEA Agreement. That is why Article 18 EEA refers specifically to Article 13 EEA to ensure the applicability of that provision.[8]

48. The Norwegian Government argues that the scope and purpose of the EEA Agreement as regards agricultural products is an example of an area where EEA law and EU law is not fully harmonised. Thus, a difference in the interpretation of the two agreements cannot be excluded.[9] Accordingly, it must be assessed on a case-by-case basis to what extent the EEA regulatory framework leaves discretion for the EEA States to have specific national regulations.

49. The Government of Norway proposes that the first question should be answered as follows:

> *The regulatory discretion of the EEA States is limited by the provisions of the EEA Agreement, also as regards agricultural products, but only within the scope of the Agreement and to the extent that the relevant rules in the Agreement apply in the case at hand.*

ESA

50. ESA submits that agricultural products and foodstuffs remain subject to the provisions of Chapter 2 and 4 of Part II of the Agreement. Article 17 EEA refers to Annex I, which includes the Directive as well as the foodstuffs legislation known as the "Hygiene Package" and relevant animal health and welfare rules applicable in the EEA.[10] Those legal acts harmonised the conditions under which products of animal origin are produced and placed on the market and circulated in the EEA. Furthermore, Article 23(a) EEA refers to Annex II on technical regulations, standards, testing and certification, which contains a specific chapter related to foodstuffs.

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7 OJ 1999 L 158, p. 1, and EEA Supplement 1999 No 27, p. 1.

8 Reference is made to Case E-4/04 *Pedicel* [2005] EFTA Ct. Rep. 1, paragraph 27.

9 Reference is made to Joined Cases E-9/07 and E-10/07 *L'Oréal* [2008] EFTA Ct. Rep. 259, paragraph 27.

10 Reference is made to Regulation (EC) No 853/2004 and Regulation (EC) No 854/2004 forming part of the "Hygiene Package" and Regulation (EC) No 882/2004 on animal welfare, referred to at point 17 of subchapter 6.1, point 12 of subchapter 1.1 and point 11 of subchapter 1.1, respectively, of Chapter I of Annex I to the EEA Agreement.

51. ESA submits that the inclusion of Chapters 2 and 4 and the legal acts referred to in Annexes I and II would be devoid of any meaning and effectiveness if EEA States were free not to apply those provisions. Pursuant to Article 7 EEA, Iceland is bound to ensure the full implementation of the relevant acts.[11] Thus, any national measure related to veterinary checks on raw meat has to be compatible with the Directive and related legislation on animal products.

52. ESA proposes that the Court should answer the first question as follows:

> *The field of application of the free movement of goods under the EEA Agreement, as it results from Articles 8, 17 and 23(a) and (b) thereof, entails that an EEA State is bound by the provisions of the EEA Agreement and the acts based thereon in setting rules on the importation of raw meat products.*

The Commission

53. The Commission submits that Chapters 2 and 4 of Part II of the EEA Agreement extend the scope of the agreement to include agricultural and food products. Articles 17 and 23(a) refer to Annexes I and II, respectively, thereby giving effect to the Directive and related legislation. The inclusion of those articles of the EEA Agreement would be rendered ineffective and meaningless if the EEA States could elect not to apply them. It is in this context that the scope of Article 8(3) EEA must be understood.

54. Furthermore, the Commission continues, an uncertainty concerning the scope of those articles is dispelled by Article 18 EEA, which specifically provides that those articles apply to products other than those covered by Article 8(3) EEA, and that they shall not be compromised by other technical barriers to trade.

55. As the Commission understands it, it is therefore clear from the intention of the EEA Agreement that agricultural and food products may be captured by specific provisions incorporated into Part II of the EEA Agreement.[12] Consequently, an EEA State is obliged to fully apply and implement the provisions of Chapters 2 and 4 of Part II of the EEA Agreement and the legal acts referred to in Annexes I and II. With regard to veterinary checks on raw meat, the provisions of the Directive apply. An EEA State does not have discretion to substitute or supplement those provisions with its own national rules.

56. The Commission proposes the following answer to the first question:

> *The field of application of the EEA Agreement, as defined in Article 8 thereof, does not entail that a Member State of the Agreement has discretion regarding the setting of rules on the importation of raw meat products but is, in this respect bound by the provisions of the Agreement and the acts based thereon.*

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[11] Reference is made to Case E-2/12 *HOB-vín* [2012] EFTA Ct. Rep. 1092, paragraph 46.

[12] Reference is made to *HOB-vín*, cited above, paragraph 27.

Question 2

57. By its second question, which arises in the case of a negative answer to the first question, the referring court asks, in essence, whether requirements imposed on the importer of raw meat, such as those contained in Articles 3 to 5 of the Icelandic Regulation, are compatible with the Directive.

The plaintiff

58. The plaintiff argues that it is clear from the wording of the Directive and the consistent interpretation of its Article 5 that the Directive exhaustively harmonises the veterinary checks that can take place in the State of destination of the products covered by the Directive.[13] The Directive does not contain any provision that would allow EEA States to impose stricter rules, save "protective measures" which are temporary by nature and strictly circumscribed. Furthermore, the European Court of Justice ("the ECJ") has held that a detailed and harmonised system of health inspections of fresh meat replaces all other inspection systems existing within the country of destination.[14]

59. In this regard, the plaintiff argues that, in areas where European legislation provides for harmonisation, recourse to justification under Article 36 of the Treaty on the Functioning of the European Union ("TFEU"), corresponding to Article 13 EEA, is not available.[15]

60. In the plaintiff's view, the administrative formalities mentioned in the question referred constitute veterinary checks within the meaning of Article 2 of the Directive. As those requirements constitute obligations that go beyond the controls permitted at the place of destination under Article 5 of the Directive, they are not permitted.

61. The plaintiff contends that the ECJ has ruled that similar additional veterinary checks placed on imports of animal products are not compatible with harmonised rules on veterinary checks.[16] The reasoning in those cases shows that even a prior notification system is not in line with the requirements of the Directive. Thus, it must be clear that a prior authorisation system, such as the one at issue, is incompatible with the Directive.

62. Moreover, the plaintiff submits that the administrative formalities require importers to fulfil certain substantive conditions. That is not permitted under Article 5 of the Directive, as veterinary checks in the State of destination can only aim at

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[13] Reference is made to Cases C-186/88 *Commission* v *Germany* [1989] ECR 3997; C-102/96 *Commission* v *Germany* [1998] ECR I-6871; C-111/03 *Commission* v *Sweden* [2005] ECR I-8789; and C-455/06 *Danske Slagterier* [2009] ECR I-2119.

[14] Reference is made to *Commission* v *Sweden*, cited above, and Joined Cases C-277/91, C-318/91 and C-319/91 *Ligur Carni and Others* [1993] ECR I-6621.

[15] Reference is made to Cases C-52/92 *Commission* v *Portugal* [1993] ECR I-2961, 251/78 *Denkavit Futtermittel* [1979] ECR 3369 and C-1/96 *Compassion in World Farming* [1998] ECR I-1251.

[16] Reference is made to Case C-186/88 *Commission* v *Germany* and *Commission* v *Sweden*, both cited above.

verifying, by means of non-discriminatory veterinary spot-checks, that the requirements of Article 3 of the Directive have been complied with, that is whether the product has been obtained, checked, marked and labelled in accordance with EEA rules. EEA States cannot therefore impose checks that do not find their basis in EEA rules. In the plaintiff's view, there is no basis in those rules for the requirement in Article 5(c) of the Icelandic Regulation to demonstrate that products have been stored frozen for a certain period of time prior to customs clearance.

63. Against that background, the plaintiff concludes that the administrative formalities at issue and the imposition of substantive requirements on the importers, such as the obligation to freeze raw meat, are in breach of Article 5 of the Directive.

The defendant

64. The defendant submits that the Directive was enacted with a view to completing the internal market and pursuing the common agricultural policy.[17] In the EEA there is no internal market for the products at issue and there is no common agricultural policy. The products at issue do not enjoy a right to free movement within the EEA. The isolated geographical location of Iceland and the immunological vulnerability of the country's animal population is also reflected by the numerous acts in Annex I to the EEA Agreement that are not applicable to Iceland. Thus, the specific EEA context of the Directive and the special circumstances of Iceland must be taken into account when interpreting the Directive.[18]

65. The defendant observes that the matter in dispute in the main proceedings concerns the "freezing certificate". However, it is not clear from the reference from the District Court for what reason all the Icelandic rules concerning the import of raw meat should be reviewed in the light of the Directive in the present proceedings.

66. As regards the "freezing certificate" at issue, the defendant submits that the certificate does not discourage imports of raw meat, as can be seen from the increasing volume of imported meat over the last ten years. Moreover, the certificate does not seek to double-check compliance with requirements that have been checked in the State of dispatch. Iceland has full trust in the veterinary checks that are conducted in other EEA States by virtue of the common EEA rules. The certificate only seeks to take care of the very special situation of Iceland. That objective lies beyond the EEA rules.

67. Against that background, the defendant submits that the requirement that a "freezing certificate" be presented at import does not come within the scope of the Directive.

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[17] Reference is made to Case C-102/96 *Commission* v *Germany*, paragraph 27, and *Commission* v *Sweden*, paragraph 42, both cited above.

[18] Reference is made to Case C-128/94 *Hönig* [1995] ECR I-3389, paragraph 9, and *L'Oréal*, cited above, paragraph 28.

ESA

68. ESA essentially shares the observations on the second question submitted by the plaintiff. In addition, it has submitted observations on the compatibility with the Directive of Article 5(e), (f) and (g) of the Icelandic Regulation.

69. In relation to the salmonella certificate required under Article 5(e) of the Icelandic Regulation, ESA observes that, according to Article 8 of Regulation (EC) No 853/2004, EEA States may impose additional guarantees in respect of salmonella only if they meet certain requirements. Such additional guarantees have been established for Finland and Sweden, and there is a possibility for other EEA States to apply them if they have a control programme recognised as equivalent to that approved in Finland and Sweden. Iceland has submitted to ESA a national control programme for salmonella in poultry and poultry products, but it has not applied for a recognition of equivalence to that approved in Finland and Sweden. Iceland may therefore not apply the additional guarantees provided for in Article 8 of that regulation.

70. In relation to Article 5(f) of the Icelandic Regulation and the requirement that the products mentioned therein conform to the regulation on food contaminants, ESA notes that the EEA legislation on contaminants in food sets out maximum levels for certain contaminants.[19] That legislation does not contain any provisions giving EEA States a legal basis to impose on importers the completion of a systematic procedure to demonstrate that food products are in conformity with the current legislation on food contaminants.

71. ESA understands Article 5(g) of the Icelandic Regulation to the effect that this entails a systematic obligation for the importer to present to the Food and Veterinary Authority photographs/pdf documents illustrating the packaging. ESA notes that the EEA legislation on the labelling of foodstuffs[20] does not provide a legal basis for EEA States to impose on importers the completion of a systematic procedure to demonstrate that food products are in conformity with legislation on labelling.

72. Consequently, ESA submits that the substantive requirements imposed on the importer under Article 5(c), (e), (f) and (g) of the Icelandic Regulation do not find a legal basis in EEA law and go beyond the veterinary checks allowed under Article 5 of the Directive.

73. ESA rejects Iceland's argument that, since there remain border controls in the EEA in the form of customs controls, the Directive cannot be read as excluding systematic border controls. In ESA's view, the existence of customs controls on agricultural goods by EFTA States cannot justify the existence of additional veterinary

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[19] Reference is made to Regulation (EEC) No 315/93 and Regulation (EC) No 1881/2006, referred to at points 54f and 54zzzz, respectively, of Chapter XII of Annex II to the EEA Agreement.

[20] Reference is made to Regulation (EU) No 1169/2011, referred to at point 86 of Chapter XII of Annex II to the EEA Agreement.

checks. Customs controls and veterinary checks follow different purposes and operate in different spheres of the EEA Agreement.

74. ESA proposes that the Court should answer the second question as follows:

> *It is not compatible with the provisions of [the Directive] that an EEA State requires an importer of raw meat products to apply for a special permit before the products are imported, and to submit, for this purpose, of an import declaration, information on the country of origin and production, the type of product and the producer, and certain certificates, including a certificate confirming that the products have been stored frozen for a certain period prior to customs clearance.*

The Commission

75. The Commission submits that the rules and requirements in question fall within the definition of veterinary checks under Article 2 of the Directive. The Directive's aim, expressed in recital 4 of its preamble, to harmonise the basic requirements relating to the safeguarding of public health and animal health is incompatible with the notion that an EEA State has discretion to impose additional rules or alternative requirements on those trading in animal products.[21]

76. In the Commission's view, the Directive provides for a uniform, harmonised method for the application of EEA rules relating to veterinary checks of animal products traded within the area to which the EEA Agreement applies.[22] Within the context of this harmonised system, the scope for an EEA State to impose additional controls or requirements with respect to products being imported into its territory is strictly limited.[23] The checks that may be carried out at the place of destination are described in Article 5 of the Directive. EEA States are given no discretion to impose more rigorous measures, save for "protective measures" which are temporary in nature and are required to control an established outbreak of a zoonosis or disease or a cause likely to constitute a serious hazard to animals or humans. Furthermore, as the Directive has exhaustively harmonised the regulatory regime for veterinary checks for animal products, the imposition of additional requirements or rules by the EEA State of destination cannot be justified under Article 13 EEA or Article 36 TFEU.[24]

77. According to the Commission, the kind of rules and requirements described by the national court appear not to fall within the type of checks permitted by Article 5 of the Directive. Insofar as the requirements are systematic, they cannot be described as

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[21] Reference is made to *Commission* v *Sweden*, cited above, paragraph 63.

[22] Reference is made to Cases C-186/88 *Commission* v *Germany*, C-102/96 *Commission* v *Germany*, paragraphs 26 and 27, and *Commission* v *Sweden*, paragraph 51, all cited above.

[23] Reference is made to *Commission* v *Sweden*, cited above, paragraph 52.

[24] Reference is made to *Commission* v *Portugal*, paragraph 17, *Denkavit Futtermittel*, paragraph 14 and *Compassion in World Farming*, paragraph 47, all cited above.

spot-checks, and as such go beyond what is permissible pursuant to Article 5. In particular, the requirement that the product must have been stored frozen for a certain period of time prior to customs clearance is wholly outside and beyond what is required under the Directive or any act to which it refers.

78. Furthermore, the Commission maintains that the ECJ has held that rules similar to those set out in the question referred are not compatible with harmonised rules on veterinary checks.[25]

79. The Commission proposes that the second question should be answered as follows:

> *It is not compatible with the provisions of [the Directive] that a Member State of the EEA Agreement should set rules demanding that an importer of raw meat products applies for a special permit before the products are imported, and require the submission, for this purpose, of an import declaration, information on the country of origin and production, the type of products and the producer, and the required certificates, including a certificate confirming that the products have been stored frozen for a certain period of time prior to customs clearance.*

Question 3

80. By its third question, the referring court asks whether the provisions of the Regulation are relevant in answering the second question.

The plaintiff

81. The plaintiff submits that the disputed administrative formalities must be considered in the light of the aim of food law, laid down in Article 5(2) of the Regulation, that is to achieve the free movement in the EEA of food and feed manufactured or marketed according to the general principles and requirements in Chapter II of the Regulation. According to the plaintiff, the disputed measures fail to satisfy the requirements of risk analysis and risk assessment laid down in Article 6(1) and (2) of the Regulation.

82. The plaintiff also challenges the defendant's application of the precautionary principle in Article 7 of the Regulation. Neither the conditions in Article 7(1) for provisional risk management measures, nor the limits applying under Article 7(2) to the contents and duration of such measures, have been respected as regards the disputed measures.

83. Finally, the plaintiff refers to Chapter III of the Regulation, establishing the European Food Safety Authority ("EFSA"). In the plaintiff's view, the EFSA undoubtedly plays an important role in maintaining harmonisation concerning food

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[25] Reference is made to *Commission* v *Sweden*, cited above, paragraphs 58 and 63.

safety and relevant criteria concerning food and feed safety in the internal market. Therefore, the responsibility concerning this matter rests with EFSA, not unilaterally with individual EEA States.

The defendant

84. The defendant submits that the Regulation lays down general principles and requirements for food law with which Iceland complies. The requirement of a "freezing certificate" is nevertheless not affected by the Directive. Accordingly, the defendant submits that the Regulation does not alter the answer to the second question.

ESA

85. ESA submits that the Regulation sets out the general principles and requirements of food safety legislation, and that it relies on more specific EEA legislation setting requirements destined to ensure the safety of foodstuffs placed on the market in the EEA. It is primarily those specific rules, such as the Hygiene Package, which determine, as far as food safety is concerned, whether foods of animal origin can be placed on the market. That is confirmed by Article 14(7) of the Regulation. It also follows from case law that the Regulation is inapplicable to the extent to which an EEA rule contains specific provisions for certain categories of foodstuffs.[26] ESA submits therefore that the Regulation is not relevant as such for the purpose of assessing the conformity of national measures with the Directive.

86. ESA proposes that the Court should answer the third question as follows:

> *The provisions of [the Regulation] are not relevant in answering the second question.*

The Commission

87. The Commission submits that the Regulation is not intended to supersede more specific regulation. In fact it relies on more specific regulation to determine whether food meets the requisite standard in order to be placed on the market, cf. Article 14(7) of the Regulation.[27] Accordingly, any provision of the Regulation concerning checks on meat products is precluded to the extent to which a specific provision in the Directive applies.

88. The Commission proposes that the third question should be answered as follows:

> *The provisions of [the Regulation] are not relevant in answering the second question.*

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[26] Reference is made to Joined Cases C-211/03, C-299/03 and C-316/13 to C-318/03 *HLH Warenvertrieb and Orthica* [2005] ECR I-5141, paragraph 39.

[27] Reference is made to *HLH Warenvertrieb and Orthica*, cited above, paragraphs 38 and 39.

Question 4

89. By its fourth question, the referring court asks, in essence, whether a national prohibition on the import of raw meat constitutes a technical barrier to trade under Article 18 EEA.

The plaintiff

90. The plaintiff submits that the requirement of a "freezing certificate" is in breach of Article 18 EEA, in that it constitutes a technical barrier to trade, in other words, it imposes a requirement of the same kind as the arrangements laid down in Annex I to the EEA Agreement.

91. Annex I contains numerous acts dealing with animal health protection, which serve the same purpose as the obligation to freeze all meat products. These acts constitute a coherent and harmonised approach to animal health protection so that individual EEA States do not need to adopt restrictive national measures. By maintaining the requirement of a "freezing certificate", Iceland departs from this harmonised approach and compromises the objectives of this body of rules. The same applies to other additional requirements for importing meat to Iceland, for example the obligation to demonstrate that the imported product is free of salmonella, requirements concerning food contaminants and labelling, etc.

The defendant

92. The defendant submits that a prohibition, or a conditional prohibition, on the import of raw meat must be assimilated to a quantitative restriction within the meaning of Article 11 EEA.[28] However, the prohibition on technical barriers to trade laid down in Article 18 EEA cannot be equated with the terms of Article 11 EEA.[29] This means that the obligation under Article 18 EEA to refrain from technical barriers to trade is not relevant for the determination of Iceland's compliance with EEA law in the present case.

93. The defendant further submits that a ban on imports does not constitute a measure of the same kind as veterinary checks envisaged by the Directive. The import prohibition is not a veterinary check of any kind, as it relates to the protection of a unique status in the country of import, allowing ample time to prevent irreparable harm and not physically examining the imported goods. In the defendant's view, since Article 18 EEA deals with products which are not included within the scope of the free movement of goods, it allows EEA States to introduce other measures. In this context, Article 13 EEA is applicable.

94. According to the defendant, the term technical barriers to trade must primarily

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[28] Reference is made to Case 34/79 *Henn and Darby* [1979] ECR 3795, paragraphs 11 to 13.

[29] Reference is made to *Pedicel*, cited above, paragraph 27.

mean a situation where the State concerned uses remedies or measures to discriminate against the import of agricultural products for the benefit of domestic production of the same type. The defendant submits that this is not the case here, as the disputed measures are only adopted to protect animal populations and public and animal health.

ESA

95. ESA stresses its conclusion that the Icelandic legislation breaches the Directive and cannot be justified under Article 13 EEA. A response to the fourth, fifth and sixth question is therefore strictly not necessary and the observations related to Article 18 and 13 EEA should be considered only in the event that the Court were not to consider the Directive to exhaustively harmonise veterinary checks and/or the Court were not to find a breach of Article 5 of the Directive. ESA furthermore considers the combination of the provisions referred to in the fourth and fifth questions to establish an authorisation procedure. It therefore provides a joint answer to those two questions.

96. ESA submits that the Icelandic measures are technical barriers to trade, in that they entail requirements of the same kind as those imposed in acts referred to in Annex I to the EEA Agreement.[30] The authorisation system constitutes veterinary checks for fresh meat which are additional to those provided for in the harmonised system for veterinary checks on products of animal origin traded in the EEA established by the Directive. Furthermore, the requirements laid down in Article 5(c), (e), (f) and (g) of the Icelandic Regulation all constitute additional requirements of the same kind as those provided for and implemented in the EEA legislation.

97. Consequently, ESA submits that the authorisation procedure and related requirements represent technical barriers to trade within the meaning of Article 18 EEA.

98. ESA proposes the following answer to the fourth and fifth questions:

> *A measure, such as that in Article 10 of [the Act] read in conjunction with Articles 3 to 5 of [the Icelandic Regulation] in place in Iceland, in the form of a systematic authorisation procedure for operators who want to import raw meat into Iceland, constitutes an obstacle to trade in the form of a "technical barrier" within the meaning of Article 18 EEA.*

The Commission

99. The Commission submits that the reference in Article 18 EEA to other technical barriers to trade should be construed as any additional rules or requirements imposed of the same kind as the arrangements or acts cited in the relevant annexes.[31] The Directive is such an arrangement referred to in Article 18 EEA. It provides a comprehensive and harmonised system for veterinary checks for products of animal origin traded within the

[30] Reference is made to *Pedicel*, cited above, paragraph 27.

[31] Reference is made to *Pedicel*, cited above, paragraph 27.

EEA. It thus follows that rules or technical requirements imposed concerning veterinary checks for raw meat, which come in addition to those provided for in the Directive, should be considered as other technical barriers to trade.

100. The Commission proposes the following answer to the fourth question:

> *It constitutes a technical barrier to trade in the sense of Article 18 EEA if an EEA State sets rules under which the importation to that State of raw meat products is not permitted.*

Question 5

101. The essence of the fifth question referred is whether it affects the answer to the fourth question if the rules of the EEA State of destination permit the granting of exceptions from the general prohibition on the import of raw meat.

The plaintiff

102. The plaintiff maintains that applicable Icelandic law provides no exception from the prohibition on the import of raw meat products to Iceland. Even if there were such an exception, the main rule of prohibition would still constitute a technical barrier to trade. Nevertheless, a case-by-case assessment would be necessary, and the scope of such exception or exceptions could influence that assessment.

The defendant

103. For the purposes of the present case, the defendant interprets the fifth question as asking whether the requirement that a "freezing certificate" be presented at import amounts to a technical barrier to trade within the meaning of Article 18 EEA. Such a requirement would, in the defendant's view, be a physical barrier to trade rather than a technical barrier, at least according to the terminology that was current when the EEA Agreement was negotiated.

The Commission

104. The Commission stresses the fact that any rule which imposes further requirements of the same kind as those requirements provided for under the acts set out in Annexes I or II, in so far as they relate to trade in raw meat, must be considered a technical barrier to trade pursuant to Article 18 EEA. In connection with Article 13 EEA, the Commission submits that the rules concerning veterinary checks of products of animal origin traded within the EEA have been fully harmonised by the Directive. Accordingly, an EEA State is not permitted to impose rules or requirements concerning the import of raw meat that go beyond the requirements under the Directive.[32] An EEA State cannot circumvent the legal effects of harmonisation by invoking either the

[32] Reference is made to *Danske Slagterier*, cited above, paragraph 25.

precautionary principle or Article 13 EEA.[33] A rule imposed by an EEA State of destination prohibiting the import of raw meat cannot therefore be justified on the grounds that it constitutes an exception to the general prohibition on technical barriers to trade.

105. The Commission proposes the following answer to the fifth question:

> *It does not affect the answer to the fourth question if it is permitted, under the rules of the EEA State of destination, to grant exceptions from the general prohibition referred to in that question.*

Question 6

106. By its sixth question, which arises if Article 18 EEA is considered to apply, the referring court asks, in essence, whether and under what circumstances a system such as that described in the fourth and fifth question could be justified under Article 13 EEA, and what the requirements of proof are in that regard, particularly in the light of the precautionary principle of EEA law.

The plaintiff

107. The plaintiff submits that even though EEA States may decide on the level of protection they intend to provide for the legitimate interest pursued, they must nevertheless comply with the principle of proportionality.[34] An EEA State imposing a national ban or an authorisation system for a particular product must therefore show that the restriction is limited to what is necessary to attain the legitimate aim of protection of public health, and that the aim cannot be achieved by any other means that would have a less restrictive effect on intra-EEA trade.[35] Furthermore, according to settled case law, decision makers may not base their decisions on a "zero risk" approach.[36]

108. In the plaintiff's view, the restrictions placed on the import of meat to Iceland, for example the "freezing requirement", are not proportionate to the risk addressed. In relation to the pathogens identified in the risk assessments presented by Iceland, harmonised measures have already been laid down in current EEA legislation.[37] Those

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[33] Reference is made to Case C-102/96 *Commission* v *Germany*, paragraphs 21 and 22, and *Commission* v *Sweden*, paragraph 51, both cited above.

[34] Reference is made to Cases E-3/06 *Ladbrokes* [2007] EFTA Ct. Rep. 86 and C-41/02 *Commission* v *Netherlands* [2004] ECR I-11375.

[35] Reference is made to Cases C-270/02 *Commission* v *Italy* [2004] ECR I-1559 and 104/75 *de Peijper* [1976] ECR 613.

[36] Reference is made to Cases T-257/07 *France* v *Commission* [2011] ECR II-5827, T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305 and T-70/99 *Alpharma* v *Council* [2002] ECR II-3495.

[37] Reference is made by way of example to Regulation (EC) No 853/2004 and Regulation (EC) No 2160/2003 (as regards salmonella), Directive 2002/60/EC (as regards African swine fever), Directive 2001/89/EC (as regards classical swine fever), and Directive 2005/94/EC (as regards avian influenza), referred to at point 17

measures minimise the risk of products originating in the EEA introducing a number of the diseases identified in the risk assessment.

109. The plaintiff contends that restrictions imposed on the basis of the precautionary principle should only be of a provisional nature, pending the availability of more reliable scientific data.[38] However, the Icelandic rules on import of meat are not provisional in nature and do not depend on the development of scientific knowledge.

110. Finally, the plaintiff submits that the burden of proof regarding the legal and factual basis for measures under Article 13 EEA, is borne by the EEA State. An EEA State banning the import of raw meat must prove beyond any doubt that the import of such meat would seriously jeopardise human health and the wellbeing of animals. The plaintiff contends that Iceland has failed to demonstrate such a risk. Consequently, the plaintiff argues that the measures at issue are not justified under Article 13 EEA.

The defendant

111. According to the defendant, an EEA State may aim at a very high level of protection of public and animal health and biodiversity.[39] The measures adopted must nevertheless be suitable and necessary for attaining that level of protection. As the referring court is closer to the matters of law and fact in the main proceedings, that court is in a better position to conduct the proportionality review.[40] This conclusion is also supported by the clear separation of functions on which Article 34 SCA is based.

112. The defendant contends that when applying Article 13 EEA concerning agricultural products, it must be kept in mind, first, that the EU agricultural policy does not as such fall within the scope of the EEA Agreement. The EEA Agreement was never intended nor drafted to reduce or concede the health requirements that apply to Iceland for specific reasons. Second, Article 13 EEA and related case law apply primarily to products for which there is an internal market in the EEA. In the defendant's view, Article 13 EEA cannot therefore be interpreted in the same stringent manner in the field of agricultural products as it is in relation to goods covered by the provisions on free movement.

113. The defendant argues further that where there is uncertainty as to the existence or extent of risks to public or animal health, an EEA State is entitled to take protective measures without having to wait until the reality of those risks become fully apparent. It suffices therefore to demonstrate that it is reasonable to assume that the measure can

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of subchapter 6.1, point 8b of subchapter 7.1, point 9b of subchapter 3.1, point 3 of subchapter 3.1 and point 5a of subchapter 3.1, respectively, of Chapter I of Annex I to the EEA Agreement.

[38] Reference is made to Case C-504/04 *Agraproduktion Staebelow* [2006] ECR I-679.

[39] Reference is made to Cases C-67/97 *Bluhme* [1998] ECR I-8033, paragraph 33, and E-16/10 *Philip Morris Norway* [2011] EFTA Ct. Rep. 330, paragraph 77.

[40] Reference is made to *Philip Morris Norway*, cited above, paragraph 86, and Case C-405/98 *Gourmet* [2001] ECR I-1795, paragraph 33.

contribute to the protection of public and animal health.[41]

114. The defendant submits that when the harmonisation of rules is absent and there is scientific uncertainty with regard to the risk in question, it is for the EEA States to decide what degree of protection of human health they intend to assure, having regard to the fundamental requirements of EEA law, notably the free movement of goods. It is within the discretion of the EEA State to decide as to the level of risk it considers appropriate.[42] The defendant argues that the discretion should be even wider where the principle of free movement of goods does not apply.

115. The defendant asserts therefore that it maintains all its rights to safeguard full public and animal health in conformity with Article 18 EEA read in conjunction with Article 13 EEA. Iceland is not obliged to bear the risk of incidents that may cause irreparable harm to the animal populations in Iceland and/or considerably undermine public and animal health. When there is scientific uncertainty concerning risk, the onus of proof is on the party causing the risk to show that Iceland has gone to unnecessary lengths in its decision to counteract the risk.

116. According to the defendant, the measures at issue do not serve to ensure perfect absence of risk. However, Iceland can best safeguard its interests by maintaining protection in accordance with new scientific data on the causes of the dangers for animal populations and human health. The expert opinions obtained and submitted to ESA during the earlier infringement proceedings demonstrate that scientific research and evaluation support the measures taken by Iceland. However, this is for the national court to assess.

117. The defendant consequently submits that the objectives pursued by the requirement of a "freezing certificate" are fully justifiable under Article 13 EEA and that it is for the referring court to review the proportionality of the requirement.

ESA

118. ESA asserts that in harmonised fields of European legislation, recourse to justifications under Article 13 EEA is not available.[43] However, if the Directive is considered not to harmonise veterinary checks exhaustively, ESA submits that the Icelandic rules on the import of raw meat products cannot be justified under Article 13 EEA.

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41 Reference is made to *Philip Morris Norway*, cited above, paragraphs 82 and 83.

42 Reference is made to Case E-3/00 *ESA* v *Norway* [2000-2001] EFTA Ct. Rep. 73.

43 Reference is made to *Compassion in World Farming*, cited above, paragraph 47.

119. ESA notes that Article 13 EEA, being an exception from Article 18 EEA, should be interpreted narrowly, and the burden to prove that the measure is justified lies with the EEA State.[44] Although the EEA States can decide on the level of protection they intend to provide for the legitimate interest pursued,[45] they must comply with the principle of proportionality.[46] EEA States imposing a ban on a product or subjecting it to an authorisation system must show that the measure is appropriate and limited to what is necessary to attain the legitimate aim pursued, in this case the protection of public and animal health.[47] This includes an obligation to provide the relevant evidence.[48]

120. ESA alleges that the two risk assessments submitted by Iceland during the infringement procedure, dealing with animal health and public health respectively, do not support the view that unrestricted import 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. As decisions may not be based on a "zero risk" approach, ESA maintains that the Icelandic measures are not proportionate to the objective pursued.[49]

121. With regard to animal health, ESA submits that, according to the risk assessment, the main risk of spreading pathogens is linked to the keeping of hobby pigs or backyard poultry, which appears to be a growing trend in Iceland. On the other hand, the risk to the commercial herds is negligible. Furthermore, most of the pathogens posing a non-negligible risk would survive freezing for a 30-day period. Therefore, the "freezing requirement" does not appear to be suitable and necessary to eliminate the risk of infection of Icelandic livestock.

122. With regard to public health, ESA considers that, although the risk assessment concludes that the possibility cannot be excluded that the import of raw beef, pork and broiler meat from the EU could have a negative impact on public health in Iceland, the report does not address the question of the necessity and appropriateness of a general and highly restrictive authorisation system such as the one at issue, nor the substantive requirements necessary in order to obtain an import authorisation.

123. ESA submits further that, as regards the pathogens identified in the risk assessments presented by Iceland, there are already harmonised measures laid down in current EEA legislation.[50] As also Iceland acknowledges, these measures minimise the risk that products originating in the EEA will introduce a number of the diseases

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[44] Reference is made to *Commission* v *Italy*, paragraph 22, and *Commission* v *Netherlands*, paragraph 47, both cited above.

[45] Reference is made to *Ladbrokes*, cited above, paragraph 42.

[46] Reference is made to *Commission* v *Netherlands*, cited above, paragraph 46.

[47] Reference is made to *de Peijper*, cited above, paragraph 17.

[48] Reference is made to *Commission* v *Italy*, cited above.

[49] Reference is made to *France* v *Commission*, paragraph 79, *Pfizer Animal Health* v *Council*, paragraphs 139 and 141, and *Alpharma* v *Council*, paragraphs 152 and 154, all cited above.

[50] Reference is made by way of example to Directive 2002/60/EC (as regards African swine fever), Directive 2001/89/EC (as regards classical swine fever) and Directive 2005/94/EC (as regards avian influenza).

identified in the risk assessment. However, Iceland has not provided information establishing that the freezing requirement is appropriate and necessary in this context and that no less restrictive measures are available.

124. ESA contends that resort to the precautionary principle is conditional upon an identification of the potentially negative consequences for health and a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research.[51] Measures taken must be based on scientific evidence, and they must be proportionate, non-discriminatory, transparent and consistent with similar measures already taken.[52]

125. In ESA's view, Iceland has not provided information in the present case that would establish a scientific uncertainty. The measures are based solely on the hypothesis that the possibility cannot be excluded that the import of fresh meat and meat products from the EEA could have a negative impact on the public and animal health in Iceland. However, a preventive measure cannot be based on a hypothetical approach, founded on a mere assumption which has not been scientifically verified.[53]

126. Finally, ESA notes that there is nothing to indicate that the Icelandic rules on import of meat are provisional in nature and that maintenance of the measures depends on the development of scientific knowledge, as required in the case of measures adopted under the precautionary principle.[54]

127. ESA concludes that, if Article 18 EEA is considered applicable, the information provided in the request for an Advisory Opinion as well as in the course of the infringement proceedings strongly indicates that the national measures fail to meet the proportionality test inherent in Article 13 EEA.

128. ESA proposes that the sixth question is answered in the following manner:

> *In case Article 18 EEA applies, a measure, such as that in Article 10 of [the Act] read in conjunction with Article 3 to 5 of [the Icelandic Regulation], as it is not suitable, necessary and proportionate to attain the aim of protecting public and animal health, cannot be regarded as being justified under Article 13 EEA.*

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[51] Reference is made to Cases C-333/08 *Commission* v *France* [2010] ECR I-757, paragraph 92, and C-343/09 *Afton Chemical* [2010] ECR I-7027, paragraph 60.

[52] Reference is made to *ESA* v *Norway*, cited above, paragraphs 26, 30 and 32.

[53] Reference is made to *Pfizer Animal Health* v *Council*, paragraph 143, and *Commission* v *France*, paragraph 91, both cited above, and to Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 106.

[54] Reference is made to *Agraproduktion Staebelow*, cited above, paragraph 40, Case C-601/11 P *France* v *Commission*, judgment of 11 July 2013, published electronically, paragraph 110, and Communication from the Commission of 2 February 2000 on the precautionary principle, COM(2000) 1 final, p. 1.

The Commission

129. The Commission considers the sixth question to be moot and suggests that it should not be considered by the Court.

Per Christiansen
Judge-Rapporteur