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Reykjavík, 10 April 2017

TO THE PRESIDENT AND MEMBERS OF THE EFTA COURT

STATEMENT OF DEFENCE

submitted pursuant to Article 35 of the Rules of Procedure of the EFTA Court by the

GOVERNMENT OF ICELAND

Represented by Ms. Helga Hauksdóttir, Director General at the Ministry for Foreign Affairs, as Agent, Dr. Sigurgeir Þorgeirsson, Senior Adviser at the Ministry of Industries and Innovation, as Co-Agent, and Mr. Jóhannes Karl Sveinsson, Attorney to the Supreme Court of Iceland, as Counsel.

Case E-3/17

EFTA Surveillance Authority

v

Iceland

The Government of Iceland has the honour of lodging the following Defence.

1. INTRODUCTION

1. By this action, the EFTA Surveillance Authority ("the Authority") seeks a declaration from the EFTA Court that:

> "by maintaining in force an authorisation system for the import of fresh meat and meat products such as laid down in Article 10 of Act No 25/1993 and Articles 3, 4 and 5 of Regulation (IS) No 448/2012, Iceland has failed to fulfil its obligations arising from 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* as amended and as adapted to the EEA Agreement by Protocol 1 thereto and by the sectoral adaptions in Annex I thereto, and in particular Article 5 of that directive"

2. The Icelandic Government contends that the claim is misconceived. The Authority has not recognised the true nature and extent of the obligations imposed by Council Directive 89/662/EEC (hereinafter the "Directive"), particularly in the context of the EEA Agreement (hereinafter "EEA"). The Directive does not cover the precautionary measures mentioned in the application.

3. The long-standing measures, designed to maintain a unique standard of health and safety, and protect against hazards which may be particularly dangerous due to the isolation of Iceland, are moreover within the remit of the Icelandic Government, per Articles 18 and 13 EEA.

4. The Icelandic Government accordingly submits that this application is without merit and should be dismissed.

2. THE BACKGROUND FACTS

2.1. General

5. It is common ground that the isolated geographical location of Iceland has caused the development of particular breeds of livestock. These native breeds, apart from

the horse and a few sheep, do not exist in other parts of the world and Iceland is obliged to protect these breeds under the 1992 Rio Convention on Biological Diversity. The Icelandic Government has applied various measures to protect and preserve this unique status.

6. Since the country's settlement, the import of live animals and untreated animal products has been small. Since the year 1882, there has been a general ban on the import of livestock to Iceland with provisions for exemptions subject to very strict quarantine requirements. Because of 1100 years of virtual isolation from the outside world, the risk entailed in imports is particularly and unusually high as regards diseases against which Icelandic domestic animal populations have not developed immunity. This is not only theoretical; but on the contrary, Iceland has a tragic history of sporadic imports of sheep with catastrophic consequences, the last one in 1933 which resulted in 600 thousand sheep having to be slaughtered to eradicate three serious neurological / lung diseases (Maedi-Visna and Jaagziekte).

7. Consequently, serious epidemics with unusually serious consequences could easily emerge in Iceland, which would otherwise not cause the same harm in other EEA States. This main principle is undisputed in the opinion of the Icelandic Government, albeit different opinions may exist regarding the degree of risk and the acceptable level of allowing such risks.

8. Moreover, the low frequency of diseases in the Icelandic livestock is unusual compared with that of other countries. Animals in Iceland are free of numerous infectious agents known to be endemic in many parts of the world including the European Union. Hence, animals in Iceland have never been exposed to vast number of transmissible agents and thus have a low level of immunological resistance. For this reason, many known and unknown infectious agents have the potential to start epidemics in animals in Iceland.

9. As a remote island in the North Atlantic, the circumstances allow the national authorities the possibility to effectively limit the risk caused by the isolation.

10. The negotiations of the EEA Agreement took note of these facts and arguments, as will be discussed below. Moreover, 23 years after the entry into force of the EEA

Agreement, Iceland still does not participate fully in Annex I of the EEA Agreement on veterinary and phytosanitary matters. In particular do the provisions on import of live animals do not apply to Iceland.

11. Animal and public health can be put at risk not only by live animals. Animal products such as raw meat can also transmit pathogens, for instance through swill-feeding, leftovers left in the countryside where there are free range animals, transmission from humans and rodents feeding on garbage.[1]

12. During its consultation with the Authority, at earlier stages of this case, the Icelandic Government acquired and presented two detailed reports regarding the risk associated with import of meat and meat products.[2] The authors are renowned scientists and scholars in the field. The reports state that increased importation, without necessary precautionary measures, may

> "have grave consequences for human and animal health in Iceland" (antimicrobial resistance)

and

> "uncontrolled importation of fresh meat and meat products will significantly increase the incidence of human campylobacteriosis and probably also of EHEC/VTEC and MRSA infections."

13. Against that background, Iceland has restricted the import of meat; and if allowed, the import is subjected to conditions of heat treatment or freezing.

2.2. The nature and effect of the national measures on importation of raw meat

14. The safeguard measures concerning the import of raw meat products to Iceland greatly reduce the possible risk to public and animal health in Iceland. The rules

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[1] Messenger AM, Barnes AN, Gray GC. Reverse Zoonotic Disease Transmission (Zooanthroponosis): A Systematic Review of Seldom-Documented Human Biological Threats to Animals. PLoS One. 2014 Feb 28;9(2). Murrell KD, Djordjevic M, Cuperlovic K, Sofronic Lj, Savic M, Djordjevic M, Damjanovic S. Epidemiology of Trichinella infection in the horse: the risk from animal product feeding practices. Vet Parasitol. 2004 Sep 2;123(3-4):223-33. OIE - Terrestrial Animal Health Code 2015, chapter 6.3. The control of hazards of animal and public health importance in animal feed. Runólfsson H, Alfreðsson GÁ, Lund NÁ, Sigurmundsson S. Skýrsla starfshóps um Salmonella og Campylobacter í dýrum og umhverfi á Suðurlandi. Landbúnaðarráðuneytið 15. mars 2002
(http//www.mast.is/library/Salmonella/skyrsla_salmonella_camp.pdf)

[2] Professor Karl G. Kristinsson: Risk associated with import of meat and meat products (**ANNEX B.I**) and Vilhjálmur Svansson: The risk to human and animal health associated with free import of raw meat and measures to reduce such risk (**ANNEX B.2**).

have been efficient, as for decades there has been no record of transmission of pathogens from imported food to the *animal population*.[3]

15. Most importantly, the requirement to freeze the products for a certain period provides scope to react in case of contamination in the relevant animal population or in slaughter animals ("quarantine effect").

16. If such rules were to be abandoned, this would increase the risk of infections and in order to minimize the risk of such infections, very extensive controls would be required to limit the risk involved to any meaningful extent. The only other viable option to safeguard the current situation in Iceland is to keep tight controls on imports of raw and untreated animal products potentially carrying transmissible agents.

17. To illustrate the imminent and real threat, it must be emphasised that outside Iceland numerous incidents are known, where foodstuffs infected livestock. Foot-and-mouth disease has caused extensive harm. The virus is highly contagious, hardy and infects pigs, cattle and sheep. Transmission to pigs usually marks the onset of new epidemics. There are many examples where infected meat started epidemics of foot-and-mouth disease, as well as other diseases. In Iceland, there are three known incidents where infectious diseases have been transmitted to animals through animal products: Anthrax (Bacillus anthracis), classical swine fever (Classical swine fever virus) and vesicular exanthema (Vesicular exanthema of swine virus).

18. Human diseases include campylobacter, salmonella and E. coli, O157:H7, sometimes referred to as the hamburger bacteria, which does not cause illness in animals, but can cause serious diseases and even fatalities in humans. Increased imports of raw bovine products can be expected to introduce this bacteria to Iceland, carrying it into the biota and transmitting it to Icelandic livestock.

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[3] The main point here is that certain pathogens do not exist in Iceland and other agents are more rare and/or found in smaller quantities in foodstuffs or animals in Iceland. Research from 2010 established that all samples from 845 cattle tested negative for E. coli (Eschierichia coli), strain O157:H7, and salmonella. The use of antibiotics for animals in Iceland is only a fraction of that used in Europe according to information from the European Medicines Agency.

19. Other transmissible agents include trichina, which might possibly be introduced into Iceland, but it is currently unknown in the country. In humans, it causes sickness and even death. It could also be pointed out that Icelandic poultry farmers are now worldwide in the forefront in fighting campylobacteriosis, and that this success should not be jeopardised.

20. In Iceland, various transmission routes from foodstuffs to animals are possible. Most frequently these stem from leftover food which free-roaming outdoor animals have access to, including infections from rodents that may have become infected through leftover food/waste. As stated above, transmission also occurs from humans to animals, e.g. to cattle, and in particular E. coli O157, Salmonella Derby and Salmonella Dublin. Agents could possibly also be transmitted to pets if their feed consists of raw or minimally treated meat, such as trichina and echinococcosis.

21. The rules on import of raw meat do not seek to discourage imports of meat to Iceland. Iceland is currently not self-sufficient with meat and importers have entered the market with considerable success.

22. Meat imports have thus steadily been on the rise for the past years. For instance, the volume of imports in 2003/2004 was at 161 tons for a period of one year, while in 2014 the comparable number was 2357 tons.

23. The numbers show a clear upward trend. Currently, imports are twenty times the volume of ten years ago. There is a slight decline during and immediately after the financial crisis in Iceland, attributable to the overall decrease in consumption and devaluation of the Icelandic currency (contributing to uncompetitive prices).

24. Moreover, the practical application of the rules does not discourage imports of raw meat. Over the past decade, the Icelandic authorities made physical inspections of imported consignments only in less than a handful of cases. Iceland does not in any way seek to double-check requirements that have been checked in the country of dispatch.

25. Concerning the "freezing certificate", which is at the core of the case, it must be noted that in practice no certificate is required, as long as it is clear from the documentation that the meat is frozen, for instance, when it appears from the invoice that the slaughtering date lies one month back in time.

26. The sole objective of the rules is to preserve Iceland's unique disease-free status. By achieving this objective, Iceland is in full compliance with EEA law. The Icelandic Government is of the firm opinion that these special and unique circumstances, which are described above and which pose serious risks to human and animal health in Iceland and impose an obligation on the government to protect its citizens.

27. Further, the EEA States are entitled to protect the health of humans and animals, taking into account the specific situations in their respective countries, and to adopt the required measures, as reflected in Article 18 EEA in conjunction with Article 13 EEA, recital ten of the preamble of the EEA Agreement, as well as the precautionary principle.

28. The point of departure - is that the EU's common agricultural policy was exempted from the scope of application of the EEA Agreement. Thus, the product at stake *is not entitled to free movement within the EEA*, as it is excluded from the product scope of the EEA Agreement.

3. THE LEGAL QUESTIONS – ICELAND'S SUBMISSIONS

3.1. Plea based on Article 18 EEA and the precautionary principle

29. The Icelandic Government submits that the aforementioned national rules relating to conditions of imported meat and meat products are within the scope of Article 18 EEA, i.e. by virtue of its reference to Article 13. Accordingly, the Icelandic Government argues that it has full permission to enact national rules that prohibit or restrict trade of goods with the aim to protect the life and health of humans and

animals. Such rules must be justified by scientific rationale, be non-discriminatory and proportionate.

30. During the pre-litigation procedure in this case, the Authority seemed to agree with the Icelandic Government that the national measures could be justified under Article 13 EEA, subject to submission of appropriate facts and reasons. For instance, in its letter dated 12 December 2011, the Authority invited the Icelandic Government to:

> "... provide detailed information in support of the claim that these arrangements are justified under Article 13 EEA. In particular, the Authority [requested] Iceland (1) to demonstrate 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."

31. Iceland has accordingly submitted vast amount of scientific evidence to the Authority to support the measures. It appears that the Authority has abandoned the prior position and now rejects that the reference to Article 13 in Article 18 EEA has any relevance. This inconsistency discredits the legal arguments presented in this context in the application.

32. The inconsistency of the Authority in this context is moreover demonstrated in its letter dated 20 February 2013 to the Icelandic Government which stated for example:

> "The Icelandic legislation ... is in breach of EEA law in so far as the Icelandic legal and regulatory framework: [...] Constitutes "technical barriers to trade" that compromise relevant arrangements in Annex I and thus in breach of Article 18 EEA regarding trade in agricultural products which prohibits [sic!]. The Directorate considers, at this point, that Iceland has not yet demonstrated that the measures are justified under Article 13 EEA. Iceland needs to bring forth additional information demonstrating that the measures are necessary and the objective cannot be achieved by any less restrictive means on trade".

33. It seems that the Authority thus fully accepted at the earlier stages of the proceedings that the justifications for more stringent measures could be justified by grounds falling under the scope of Article 13. The Icelandic Government submitted scientific evidence and reports to the Authority that gave full details of

the health hazards related to unrestricted importation. The Authority never responded materially to those submissions. The Application in this case does not explain why the common legal understanding of Article 18 during the pre-litigation procedure is now considered irrelevant.

34. As regards the applicability of Articles 18 and 13 EEA, it should first be acknowledged that the agricultural products do not fall under the EEA Agreement and do not enjoy the general principle of free movement within the EEA. They are not a part of the internal market in that context. Moreover, the EU common agricultural policy does not apply within the EEA. Furthermore, the EFTA States do not have access to any common resources available to the EU pillar in case of outbreaks of diseases.

35. Chapter 2 of the EEA Agreement, however, provides for further liberalisation in trade of agricultural products and "opens the door" to special arrangements – agreed methodology - without extending the EEA Agreement to cover those products.

36. The EEA Joint Committee Decision No 133/2007 of 26 October 2007 amended Chapter I of Annex I to the EEA and provided:

> "The provisions contained in this Chapter shall apply to Iceland …"

37. This decision did thus not widen the scope of the EEA Agreement to agricultural and fishery products but used the mechanism of Chapter 2 of the Agreement to provide for "arrangements [that] apply to products other than those covered by Article 8 (3) …" as provided for in Article 18 EEA.

38. In this situation, Article 18 provides that such arrangements may not be compromised by other technical barriers to trade. Moreover, Article 13 *"shall apply"*. The Decision of the EEA Joint Committee did not amend the EEA Agreement in this regard. Iceland has not limited its sovereign rights to enact national rules to protect its legitimate interests as provided for in Article 13 EEA.

39. The mentioning of Article 13, at the end of Article 18 EEA, cannot be without a meaning under these circumstances. However, if Article 13 can never apply when secondary legislation has harmonized the issue at stake, it would be, as amendments to Annex I always involve inclusion or amendments of secondary legislation.

40. As the EFTA States are not a part of the EU's common agricultural policy and institutional mechanism inside the EU pillar, it seems logical that in such instances the EFTA States should retain the right to protect health and lives, if unacceptable risks are involved in the trade at hand. Article 13 is thus a safeguard measure, which has never been abandoned.[4] As discussed below, a different construction of Article 18 would leave the EFTA States with a lower level of protection than the EU Member States within the EU pillar.

41. To substantiate Iceland's interpretation of Article 13 further, in the context of Article 18 EEA, it needs to be recognised that EU Member States can, according to Article 114 TFEU (previously Article 95 TEC and 100a of the EC Treaty), adopt different or additional measures than required under the implemented directives.

42. Paragraph 4 of Article 114 TFEU allows a Member State to maintain national provisions when, after the adoption of the harmonisation measure, if a Member State deems it necessary on grounds of the *major needs* referred to in Article 36 TFEU[5]. Moreover, paragraph 5 of Article 114 TFEU allows a Member State to introduce its own national provisions, if the Member State deems it necessary, inter alia on the basis of a problem *specific to that Member State*. Paragraph 8 allows a Member State to raise "a specific problem on public health in a field which has been the subject of prior harmonization measures".

43. When considering protection of public health, in the context of an application of Article 36 TFEU, the Court of Justice of the European Union have been very fact-

[4] The incorporation of the Directive into the EEA Agreement excluded Article 9 of the Directive. Article 9 concerns safeguard measures to be taken in the event of an outbreak of any zoonoses, diseases or other cause likely to constitute a serious hazard to animals or to human health.

[5] Article 36 TFEU provides that *major needs* or justifications entail, inter alia: "prohibitions or restrictions on imports … justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals and plants …[and] shall not, however constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States"

specific. For instance, in Case C-40/92 *(Commission* v *UK)* emphasis was put on the fact that restriction on imports of poultry products into Northern Ireland had been substantially unchanged since 1933 and based upon an order made before the United Kingdom's accession to the Community. In that case, it was also deemed important that *"the poultry flock of Northern Ireland, unlike that of other parts of the United Kingdom, has not been subject to a system of vaccination against Newcastle disease. Instead, the disease has been combated there by the compulsory slaughter of contaminated birds in the event of an outbreak..."* However, the Court concluded that in the light of scientific evidence, that the risk of infection was "extremely slight" and could not justify a "complete prohibition". The Court then went on to allow the licencing arrangements for imports into Northern Ireland, as it had "not been established that those dangers and risks cannot under certain circumstances outweigh the inconvenience ... so far as the situation in Northern Ireland is concerned".

44. While it is necessary under Article 114, paragraph 6, TFEU, to follow a certain notification procedure, it is interesting to note that the Commission will verify whether the notified restrictions are based on arbitrary discrimination or a disguised restriction on trade and approve or reject the national measures accordingly. The legal basis for granting a derogation under Article 114 (4) and (6) is described in Case C-426/13 P(R) *(Commission* v *Germany)* as follows:

> "Member State may base a request to maintain its pre-existing national provisions on an assessment of the risk to public health different from that accepted by the EU legislature when it adopted the harmonisation measure from which the national provisions derogate. To that end, it falls to the requesting Member State to prove that those national provisions ensure a level of protection of public health which is higher than that of the EU harmonisation measure and that they do not go beyond what is necessary to attain that objective."

45. The EEA Agreement does not contain safeguard provisions, similar to paragraphs 4 and 5 of Article 114 TFEU. However, that cannot lead to the result that the EFTA States have less rights to "maintain pre-existing national provisions on an assessment of risk ... different from what accepted by the EU legislature". Article 13 EEA must, in the context of Article 18 EEA, be applied to allow for at least the same protection.

46. As the EFTA Court stated in its judgment (Advisory Opinion) in case E-17/15 *(Ferskar kjötvörur ehf.* v *The Icelandic State)* that EEA States are not "free to go beyond its requirements ...[of Directive 89/662/EC]". The Icelandic Government does not submit that it is completely "free" to apply any measures on the basis of Article 13, read in conjunction with Article 18 EEA. Such measures need to be a result of scientific risk assessment that indicates possibility of harmful effects on health. The precautionary measures must be proportionate and no more restrictive of trade than is required to achieve the level of health protection sought, as for example permitted under Article 7 of Regulation (EC) No 178/2002.[6]

47. Based on all the aforementioned, the Icelandic Government submits that the Authority is, at the minimum, obliged to assess, based on Articles 18 and 13 EEA, whether Iceland has provided justifications in compliance with the principles discussed above. The Authority has not exhausted or allowed that process, but relies entirely on the plea that no justifications can be provided under Article 13, under any circumstances when the issue at stake concerns an area, which has been regulated by a Directive. Thus, the Application must fail.

48. The Icelandic Government is responsible for preventing exposure of animal and human life to danger. In case of uncertainty as to precise danger, the precautionary principle must apply.

49. Finally, it is also worth noting the judgment of the EFTA Court in Case E-4/04 (*Pedicel*). The EFTA Court held in paragraph 27 (emphasis added):

> "The Court cannot accept the Appellant's suggestion to construe the term "technical barriers to trade" in Article 18 EEA as being synonymous with "measures having equivalent effect" to quantitative restrictions in Article 11 EEA. Already the explicit difference in wording speaks against such a conclusion. Moreover, the purpose of Protocol 47, to which Article 18 EEA refers via Article 23(b) EEA, is to facilitate trade in wine products insofar as they are in conformity with the EC legislation as set out in Appendix 1 to the Protocol. Hence, 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 under the implemented EC legislation shall be imposed. The object is not, directly or indirectly, to

[6] 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 lays down procedures in matters of food safety.

make Article 11 EEA applicable to wine and thereby bypass the product coverage rules as established under the EEA Agreement. In that context, the Court notes that the last sentence of Article 18 EEA provides that Article 13 EEA shall apply, while there is no corresponding reference to Article 11 EEA."

50. Thus, a substantive requirement like a ban is not the same kind of a requirement as a procedural requirement. The fact that a substantive requirement by its very nature would be caught by Article 11 EEA as a measure equivalent to a quantitative restriction does not entail in itself that the measure is within the scope of Article 18 EEA and therefore must be justified under Article 13 EEA.

3.2. The alleged infringement of the Icelandic Government

51. The Authority seeks a declaration from the EFTA Court that Iceland has failed to fulfil its obligations arising from Council Directive 89/662/EEC concerning veterinary checks by maintaining in force "the authorisation procedure and the additional requirements imposed by the Icelandic legislation on imports of fresh meat and meat products".[7] The Authority then elaborates on a "few legal issues" concerning: 1) the alleged import authorisation system; and 2) specific requirements, i.e. the freezing requirement, the salmonella certificate, food contaminants and labelling, all as set out in Regulation (IS) No 448/2012. The Icelandic Government would like to submit the following regarding some of those matters.

The freezing requirement

52. As concerns the *"freezing certificate"*, the certificate does not seek to double-check compliance with requirements that have been checked in the State of dispatch; there is no double-checking of compliance with Article 3 of the Directive, neither at border nor systematically afterwards. Iceland is thus in compliance with the Directive. The "freezing certificate", which is not disruptive to trade, seeks to take care of the very special situation of Iceland – an objective that lies beyond the EEA rules.

[7] Application, para. 52.

53. Against this background, it must be held that the requirement that a "freezing certificate" be presented at import does not come within the scope of the Directive.

54. In any event, the requirement, as will appear from the following, complies with Article 18 EEA in conjunction with Article 13 EEA, which allow EEA Member States to deviate and/or complement the arrangements governing trade in agricultural products. As explained below, the freezing requirement does not compromise the overall arrangements governing trade in agricultural products and is in conformity with Article 13 EEA. Moreover, it is effective and proportionate.

55. The Icelandic Government in this regard first recalls that the alleged infringement Article 5 of Directive 89/662/EEC concerning checks on arrival at the destination. The purpose of the Directive is to eliminate any double-checking of health or hygiene standards set out in secondary legislation.

56. According to Article 2 of the Directive, which provides the definitions necessary for the reading of the Directive:

> "For the purposes of this Directive:
>
> 1. '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;"

Article 1, to which Article 2 refers, provides:

> "Member States shall ensure that the veterinary checks to be carried out on products of animal origin which are covered by the Directives listed in Annex A or by Article 14 and which are intended for trade are no longer carried out, without prejudice to Article 6, at frontiers but are carried out in accordance with this Directive."

57. A ban or restriction in the nature of Article 5 of Regulation (IS) No 448/2012 is by no means a *"physical check and/or administrative formality which applies to the products ..."*. A restriction regarding physical checks or administrative formalities

cannot be extended as legal grounds to adjudicate whether substantive requirements or conditions conform to unrelated secondary legislation.

58. The Authority relies on two court rulings, namely Case C-186/88 *(Commission* v *Germany)* and Case C-111/03 *(Commission* v *Sweden).* [8] Both cases involve checks or health inspection of imported food products thus falling under "veterinary checks" as defined by the Directive and the Court.

59. In the first place, Case C-186/88 concerns mainly a different directive than Directive 89/662/EEC. It is first after having ruled that the other directive had harmonized the substantive matter at issue, *'pronounced sexual odour in uncastrated male pigs'*, that the Court found an infringement of Directive 89/662/EEC. In other words, the German ruling may be read as supporting Iceland's position on the first condition above, i.e. Directive 89/662/EEC is concerned with checks and not substantive requirements.

60. Case C-111/03 concerned checks and not substantive requirements. It was in that context that the Court held that Member States were not *'free to go beyond the requirements contained'* in Directive 89/662/EEC (paragraph 63 of the ruling). Iceland would be able to agree, as Iceland accepts that the Directive rules out systematic checks and only allows spot-checks. Thus, the ruling does not support the Authority on the question whether a substantive requirement in itself falls within the scope of Directive 89/662/EEC.

61. It is worth mentioning that Directive 2002/99/EC, consolidated through Directive 2013/20/EU, lays down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.[9] Article 6(1) and (2) provides:

> 1. Pending adoption of Regulations of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and rules for controls applicable to foodstuffs and animal feed, Member States shall ensure that official animal health controls are carried out by their competent authorities to ensure compliance with this Directive, its

[8] Application, para 58-61.
[9] The Directive was incorporated into the EEA Agreement with the Decision of the EEA Joint Committee No 166/2003. The Decision states that it does not apply to Iceland.

implementing rules and any safeguard measures relating to products of animal origin adopted pursuant to this Directive. As a general rule, inspections must be unannounced and checks carried out in accordance with the provisions of Directive 89/662/EEC.

2. Pending adoption of Regulations of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and rules for controls applicable to foodstuffs and animal feed, where infringements of animal health rules are identified, Member States shall take the necessary measures to remedy the situation in accordance with the provisions of Directive 89/662/EEC.

62. The quoted text seems to indicate that there is no exhaustive harmonization of the hygiene rules for food of animal origin and the controls applicable to foodstuffs. In addition, it is worth noting the mention of Directive 89/662/EEC in paragraph 1, in contrast to the mention of the Directive in paragraph 2. When paragraph 1 states that the checks of Member States must, *as a general rule,* be in accordance with Directive 89/662/EEC, it is hard to believe that Directive 89/662/EEC should be exhaustive on the checks; the term 'as a general rule' indicates that there may be checks that are not in accordance with Directive 89/662/EEC.

63. Against this background, the conclusion on the second condition for ruling out the applicability of Article 13 EEA must be: If Directive 89/662/EEC is exhaustive, it is not at all clear that it is exhaustive in relation to a substantive requirement such as the freezing requirement.

The salmonella certificate, conformity with Regulation on food contaminants and labelling

64. As the Icelandic Government has previously submitted in its consultation with the Authority, it considers it important to prevent transmission of the salmonella bacteria and maintain the exceptional status Iceland currently enjoys in that regard. The Icelandic Government seeks to maintain the good status of low frequency of Salmonella bacteria and infections in Iceland. Salmonella is a dangerous bacterium that can be transferred to humans through consumption of raw meat.

65. According to the European Food Safety Authority (EFSA), reported cases of human salmonellosis within the EU in 2012 were 22.2 cases in a population of

100.000, whereas the frequency in Iceland was 11,9.[10] This gives a good indication that the precautionary measures applied by Iceland are efficient and protect important health interests.

66. The efforts made within the EU to reduce Salmonella within the last few years clearly demonstrate that the level of protection was unsatisfactory and needed overhauling. The Commission has granted special guarantees to EU Member States where prevalence of Salmonella is very low and strict national control programmes apply. The guarantees include extended monitoring showing the absence of Salmonella before sending consignment to those Member States.[11]

67. Iceland submits that the condition of point e. of Article 5 of Regulation No 448/2012, i.e. to require an importer to submit an official certificate of salmonella free product, is within its powers under Articles 13 and 18 EEA. The measures are effective, necessary and proportionate. The intention is – just as has been the case within the EU – to protect important interests from an unacceptable risk.

68. The duty of an importer to only import products that are in conformity with Regulation on food contaminants, per point f. of Article 5 of Regulation No 448/2012, is not a requirement for a check or the submission of a certificate. The labelling requirement in point g. of the same Article is not an imposition of a veterinary check nor an inspection either.

69. As explained in a letter from the Icelandic Government to the Authority on 13 July 2016 (Annex A.9 to the Authority's Application in Case E-2/17 (imports of eggs and dairy products)) the said rules serve as

> "…reaffirmation of the importers obligation to ensure that foodstuffs fulfil the rules on food contaminants and on labelling."

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[10] See, EU summary report on zoonotic agents and food-borne outbreaks 2012, EFSA Journal 2014; 12 (2): 3547, p. 22. **(ANNEX B.3)**

[11] Commission Regulation (EC) No 1688/2005 as regards special guarantees concerning salmonella in certain meat and eggs; Council Decision 95/410/EC as regards poultry for slaughter intended for Finland and Sweden, 2003/644/EC: Commission Decision 2003/644/EC regarding consignments to Finland and Sweden of breeding poultry and day-old chicks for introduction into flocks of breeding poultry or flocks of productive poultry; Commission Decision 2004/235/EC regarding consignments to Finland and Sweden of laying hens.

70. Accordingly, points f. and g. of Article 5 of the Regulation do not seem to impose additional requirements and thus not any checks within the context of the Directive. The claim of the Authority should thus be dismissed.

4. CONCLUSION AND OTHER ISSUES

71. The Icelandic Government intends to submit further evidence in form of scientific reports, documents, witness statements and data, all as subsequent submission of other parties require. In case the Court is of the opinion that the parties have submitted contradicting scientific data and evidence, it may appropriate to order an expert's report be obtained in accordance with Article 53 of the Rules of Procedure of the EFTA Court.

72. Finally, the Icelandic Government respectfully asks the Court to dismiss the application. It further seeks an order that the Authority should pay its costs.

For the Government of Iceland,

Helga Hauksdóttir
Agent

Sigurgeir Þorgeirsson
Co-Agent

5. SCHEDULE OF ANNEXES

No	Description	Number of pages
B.1	Professor Karl G. Kristinsson: Risk associated with import of meat and meat products (2015)	13
B.2	Vilhjálmur Svansson: The risk to human and animal health associated with free import of raw meat and measures to reduce such risk (2015)	37
B.3	The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2012, EFSA Journal 2014; 12 (2): 3547, p. 22.	2 (The full report of 312 pages will be lodged at the Registry, cf. Article 32(4) of Rules of Procedure)