ORIGINAL

MINISTRY FOR
FOREIGN AFFAIRS

Rauðarárstígur 25, 150 Reykjavík, Iceland
Tel: 354-545 9900, fax: 354-562 2373
external@utn.stjr.is · www.mfa.is

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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-2/17

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 (i) an authorisation system for the import of raw eggs and raw egg products such as the one laid down in Article 10 of Act No 25/1993 and Articles 3 (e) and 4 of Regulation (IS) No 448/2012; (ii) an authorisation system for the import of unpasteurised milk and dairy products processed from unpasteurised milk and additional requirements, such as laid down in Article 10 of Act No 25/1993 and Articles 3 (f), 4 and 5 of Regulation (IS) No 448/2012, and a prohibition of the marketing of imported dairy products processed from unpasteurised milk, such as laid down in Article 7a of Regulation (IS) No 104/2010; and (iii) an administrative practice of requiring importers to make a declaration and obtain an approval for the import of treated egg and dairy products, such as the one established in the context of the application 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"), in particular in the context of the EEA Agreement (hereinafter "EEA"). The Directive does not cover all, or at least some, of the precautionary measures mentioned in the application. The most obvious example is the ban of selling unpasteurised milk, which is unrelated to veterinary or border checks.

3. A marketing ban or restriction that extends to domestic and imported products alike cannot be a violation of the Directive, which seeks to prevent veterinary checks at frontiers and eliminate double-checking of health standards regulated by secondary legislation. 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 geographical location of Iceland, are moreover within the remit of the Icelandic Government, according to Article 18 and Article 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 great with regard to 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 in the European Union. Hence, animals in Iceland have never been exposed to vast amount of transmissible agents and thus have low level of immunological resistance. For this reason, a large number of 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 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)

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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**).

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.

14. The same rationale applies to restriction regarding milk and dairy products as well as egg products, as discussed below.

2.2. Milk and dairy products: Health risks and research

15. As regards raw (i.e. unpasteurised) milk and raw milk products experience shows that while it is possible to get foodborne illnesses from many different foods, raw milk "is one of the riskiest of all."[3] The risk is greater for infants, young children, the elderly, pregnant women and people with weakened immune systems. Milk may carry bacteria that causes serious illness, including Brucella, Campylobacter, Listeria, Mycobacterium bovis, Salmonella, Shiga toxin-producing E. coli, Shigella, Streptococcus pyogenes, and Yersinia enterocolitica.

16. *Products made from raw milk*, such as yogurt and cheeses, have the same ability to carry the bacteria.

17. While data on the frequency of outbreaks associated with raw milk is somewhat lacking within the EU, the United States Centres for Disease Control and Prevention has gathered extensive data and statistics related to the issue. This data has specific relevance as some states allow consumption of raw milk and raw milk products while others do not, thus it is possible to establish a link between outbreaks of diseases and the regulation of raw milk consumption.

18. In 1987, the United States Food and Drug Administration prohibited distribution of non-pasteurised dairy products in interstate commerce but some states allow sale

[3] See for further reference e.g.: https://www.cdc.gov/foodsafety/rawmilk/raw-milk-questions-and-answers.html

of these products. However, consumption of unpasteurised dairy products is uncommon.

19. Analytical studies from the United States confirm that foodborne disease outbreaks caused by contaminated dairy products occurred 122 times in the period between 1993 and 2006.[4] Most outbreaks (60%) involved raw milk (and raw milk products) despite the fact that consumption of such products only represented less than 1% of the total of dairy products.

20. The study furthermore reveals that the majority of disease outbreaks were caused by consumption of cheese (56%), whereas fluid milk caused 46% of the outbreaks. The conclusion is:

> "...the high incidence of outbreaks and outbreak-associated illness involving nonpasteurized dairy products is remarkable and greatly disproportionate to the incidence involving dairy products that were marketed, labelled, or otherwise presented as pasteurized."

21. The US authorities continue to recommend pasteurisation of raw milk and dairy products alike on basis of sound scientific evidence:

> "To protect the health of the public, state regulators should continue to support pasteurization and consider further restricting or prohibiting the sale and distribution of raw milk and other unpasteurized dairy products in their states."

22. The European Food Safety Authority (EFSA) has conducted a similar study within the EU. It concluded that the main hazards from raw drinking milk were Campylobacter, Salmonella as well as Escherichia Coli and that there were "clear links between drinking raw milk and human illness associated with these hazards". Interestingly, one of the findings was that risk assessment for these hazards *"could not be undertaken because country and EU-wide data are limited*".

23. A recent review, published in the International Dairy Journal, concentrated on microbiological hazards possibly present in raw dairy products, particularly cheese, butter, cream and buttermilk. The authors conclude:

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[4] Adam J. LAnger et. al: Nonpaseurized Dairy Products, Disease Outbreaks, and State Laws – United States, 1993-2006. Published by Emerging Infectious Diseases, Vol 18, No. 3, March 2012. **(ANNEX B.3)**

> "Pasteurisation ensures inactivation of vegetative pathogenic microorganisms, which increases the safety of products made thereof compared with *dairy products* made from raw milk."[5]

24. Consumption of raw milk and raw milk products poses a serious threat to human health. The precautionary measure of pasteurisation is simple and effective. Iceland has applied those measures for decades with good results and some of the micro biotical hazards related to the products are absent in Iceland.

3. THE LEGAL QUESTIONS – ICELAND'S SUBMISSIONS

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

25. The Icelandic Government submits that the aforementioned national rules relating to raw egg and egg products, as well as raw milk and dairy 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, non-discriminatory and proportionate.

26. During the earlier stages of the procedure (starting with the investigation of conditions relating to import of raw meat), 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 Ministry of Fisheries and Agriculture 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."

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[5] International Dairy Journal 50 (2015) 32-44 (41): Review of the microbiological hazards of dairy products made from raw milk (authored by C. Verraes, Staff Direction for Risk Assessment, DG, Control Policy and others), available at https://orbi.ulg.ac.be/bitstream/2268/185614/1/1-s2.0-S095869461500120X-main.pdf.

27. Iceland has accordingly submitted a 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.

28. 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."

29. 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. As regards the importation of raw meat, which falls under the same principle, the Icelandic Government submitted the Authority with scientific evidence and reports 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.

30. 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.

31. 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.

32. 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 …"

33. 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) …".

34. 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.

35. The mentioning of Article 13, at the end of Article 18 EEA, cannot be without a meaning under these circumstances. If the Authority is correct in its interpretation, i.e. that Article 13 can never apply when secondary legislation has harmonized the issue at stake, which would essentially be the result, since changes in Annex I always involve inclusion or amendments of secondary legislation.

36. 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.[6] As discussed below, a different construction of

[6] 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.

Article 18 would leave the EFTA States with a lower level of protection than the EU Member States within the EU pillar.

37. 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.

38. Paragraph 4 of Article 114 TFEU allow a Member State to maintain national provisions when, after the adoption of the harmonisation measure, a Member State deems it necessary on grounds of the *major needs* referred to in Article 36 TFEU[7]. 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".

39. When considering protection of public health, in the context of application of Article 36 TFEU, the EU Courts have been very fact-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". Finally, 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

[7] 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"

outweigh the inconvenience ... so far as the situation in Northern Ireland is concerned".

40. While it is necessary under Article 114, paragraph 6, TFEU, to follow certain notification procedure, it is interesting to note that the Commission will in essence verify whether the notified restrictions are based on arbitrary discrimination or a disguised restriction of trade and grant the exemption appropriately. 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."

41. 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 must, in the context of Article 18 EEA, be applied to allow for at least the same protection.

42. In this case, the contested measures involve restrictions of exposing humans to dangerous bacteria. As regards raw milk, and milk products, the same rules apply for national and imported products. Hence, there is no discriminatory element involved.

43. The EFTA-Court rightly 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 (EU) 178/2002.[8]

44. Based on all the aforementioned, the Icelandic Government submits that the Authority is, at the minimum, obliged to assess, based on Article 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.

45. 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.

46. Finally, it is also worth noting the EFTA Court judgment, Case E-4/04 *(Pedicel)* in which 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 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."

47. Thus, a substantive requirement like a ban is not the same kind of 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

[8] 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.

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. Milk and dairy products

48. The Authority claims that,

> "the Icelandic framework regarding imports of unpasteurised milk and dairy products processed from unpasteurised milk is in breach of Directive 89/662/EEC."

The Authority seeks a declaration that Iceland has failed to fulfil its obligations arising from Council Directive 89/662/EEC concerning veterinary checks by maintaining in force the alleged:

> "authorisation system for the import of unpasteurised milk and dairy products processed from unpasteurised milk and additional requirements, such as laid down in Article 10 of Act No 25/1993 and Articles 3 (f), 4 and 5 of Regulation (IS) No 448/2012 and a prohibition of the marketing of imported dairy products processed from unpasteurised milk, such as laid down in Article 7a of Regulation (IS) No 104/2010 ..."

49. The Authority first argues that Iceland is in breach by requiring importers of milk and dairy products to confirm that their products contain only pasteurised milk. Second, the Authority claims that any restrictions relating to raw milk, intended for further processing (dairy products), goes beyond the permission under Article 10.8 (a) of Regulation (EC) No 853/2004. The parties however agree that restrictions on the marketing of raw milk intended for "direct human consumption" is permissible under the aforementioned Regulation.

50. The Icelandic Government strongly objects to both arguments of the Authority and submits that:

a) Requiring an importer to identify the nature of imported goods and or seek an exemption from a ban is not by any means a *veterinary check* within the definition of Article 2 of the Directive 89/662/EC. The restriction of importation of raw milk and raw milk products is set out in Regulation (IS) 448/2012 in Article 3 (f) and involves no checking of any kind. Articles 4

and 5 of the same regulation allow for an exemption under special circumstances and set out procedural requirements for granting such exemptions.

b) The Authority does not interpret Article 10.8 (a) of Regulation (EC) No 853/2004 correctly in its Application. The logical reading of the exemption or flexibility for member states to regulate marketing of raw milk is that dairy products made of raw milk should be included. Contrary to the Authority's argument, this construction is supported by facts and scientific evidence.

Icelandic law prescribes heat treatment of milk and milk products in general

51. Icelandic law prescribed the pasteurising of all milk, intended for human consumption, in 1933. The purpose was to prevent the transmission of tuberculosis, and later salmonella through raw milk to consumers.

52. Icelandic law still prohibits marketing of all unpasteurised milk and milk products. Raw milk can carry dangerous microorganisms and pasteurisation is a process that kills the harmful bacteria by heating milk to a specific temperature for a set period.

53. According to *Regulation (IS) No 851/2012* all milk intended for human consumption is subjected to specific heat treatment (i.e. full or partial pasteurisation). Moreover, the regulation defines and fully regulates other dairy products (Annex I) under the same principle, i.e. that all milk, intended for production of dairy products shall be pasteurised. Hence, no distinction is made between milk and dairy products.

54. Thus, the total prohibition in Article 3 (f) of Regulation (IS) No 448/2012 is not an "authorisation procedure for the importation into Iceland of unpasteurised milk and dairy products" as the Authority claims in paragraph 58 of the Application. Neither is the procedure for obtaining an exemption set out in Articles 4 and 5 of the aforementioned Regulation.

National rules may restrict marketing of raw milk

55. Article 10 (8)(a) of Regulation (EC) No 853/2004 (the "Hygiene Regulation") provides flexibility for Member States to "maintain or establish national rules: prohibiting or restricting the placing on the market … of raw milk or raw cream intended for direct human consumption". Raw milk is defined in Annex I to the regulation as "milk … that has not been heated to more than 40° or undergone any treatment that has an equivalent effect", i.e. unpasteurised milk.

56. Accordingly, any precautions to enforce a "prohibition or restriction" on placing raw milk on the market is permissible under the regulation.

57. The Authority further states in paragraph 62 of the Application that the ban of importation of raw milk and dairy products goes further than permissible under Article 10.8 (a) of Regulation (EC) No 853/2004 as the latter only allows restriction on raw milk intended for *direct* human consumption.

58. The Icelandic Government first recalls that the alleged infringement relates to a breach of Article 5 of Directive 89/662/EEC concerning veterinary checks. The purpose of the Directive is to eliminate any double-checking of health or hygiene standards set out in secondary legislation.

59. 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."

60. A ban or restriction in the nature of Article 3 (f) of Regulation (IS) No 448/2012 is by no means a *"physical check and/or administrative formality which applies to the products ..."*. Any discrepancy or different interpretation regarding its compatibility with Article 10.8 (a) of Regulation (EC) No 853/2004 is a different issue. A restriction regarding physical checks or administrative formalities cannot be extended as legal ground to adjudicate whether substantive requirements or conditions conform to unrelated secondary legislation.

61. In any case Iceland maintains that any restrictions regarding importation of raw milk – intended for "direct human consumption" or otherwise - deemed in excess of what is permitted under Article 10.8 (a) of Regulation No 853/2004, are justified on basis of Article 18 read in conjunction with Article 13 of the EEA agreement.

62. First, there is no exhaustive harmonisation obligation as regards marketing of raw milk or milk products and the Member States have considerable discretion to regulate on basis of their own risk assessment. The Authority relies in essence on two court rulings, namely Case C-186/88 *(Commission v Germany)* and Case C-111/03 *(Commission v Sweden).* Both cases involve checks or health inspection of imported food products thus falling under "veterinary checks" as defined by the Directive and the Court.

63. 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 to be in place. 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.

64. 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.

65. 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 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.

66. 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. Next, 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 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.

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[9] The Directive was incorporated into the EEA Agreement by the EEA Joint Committee Decision No 166/2003. The Decision states that it does not apply to Iceland.

67. 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 pasteurization requirement.

68. It is the very essence of Article 18 EEA to allow the EFTA States to take measures that go beyond the total harmonization provided for by the acts incorporated into the EEA Agreement. Different reading of Article 18 EEA would render the provision superfluous. Given the sensitivity of the products concerned – which are in general outside the Agreement – the EFTA States retain the power to have recourse to Article 13 EEA.

Dairy products

69. In its Application the Authority reaches far to undermine the legitimate concerns raised by Iceland as regards dairy products. In paragraph 65 it is stated that:

> "Iceland has not provided factual or scientific elements to substantiate its argument, nor has it provided other justifications in light of the harmonised rules"

70. Dairy products made from raw milk pose the same and even greater risk to health than raw drinking milk. Logic and the scientific evidence, referred to above, both lead to that result. This is not an "expansive interpretation", as argued by the Authority, but a logical one supported by available scientific evidence as discussed above. The Authority, on the other hand, has not submitted any credible evidence to the contrary. Regulation (EC) No 853/2004 provides no explanation on the distinction between raw drinking milk and products made with such milk as an ingredient.

71. The policies of the Icelandic Government intend to maintain a good health standard based on effective measures to protect public health from a serious and increasing threat. It is a right that Iceland has never conceded. The Icelandic Government accordingly contends that the Application should be dismissed in this regard.

3.3. Eggs and egg products

72. The Authority argues, "Article 10 of Act No 25/1993 read in conjunction with Articles 3 to 5 of Regulation (IS) No 448/2012 imposes an authorisation procedure for the import into Iceland of raw eggs and raw egg products from other EEA states". The Authority specifically points to Article 4 of the latter Regulation.

73. The Icelandic Government argues the following in this regard: As stipulated in Recital 17 of Regulation (EC) No 853/2004 the adoption of the Regulation did not intend to threaten the "level of protection provided by the additional guarantees for Finland and Sweden on their accession to the Community." Moreover, competent authorities are allowed to impose national temperature requirements for egg storage facilities and for vehicles transporting eggs. The Regulation does thus recognise the unique status of certain states and allows special restrictions to maintain that status. Since 2004 the EU has adopted several programmes and restrictions on trade to limit and decrease the transmission of Salmonella through consumption of raw eggs and raw egg products.

74. 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 a low frequency of Salmonella bacteria and infections in Iceland. Salmonella is a dangerous bacterium that can be transferred to humans through consumption of raw or undercooked eggs. Most Salmonella illness cases occur through the consumption of such products. Eggs and egg products are a frequent cause of outbreaks of foodborne illnesses within the EU. A recent study showed:

> "In 2012, as in previous years, the most common single foodstuff category reported as a food vehicle was eggs and egg products, responsible for 168 (22%) out of 763 outbreaks. The majority of these outbreaks were associated with S (Salmonella) Enteridis (67%)"[10]

[10] EFSA Journal 2014; 12 (7): 3872: Public health risks of table eggs due to deterioration and development of pathogengs (p. 22) (**ANNEX B.4**)

75. The same study considered the underreporting of human salmonellosis within the EU to be very significant. For the EU in 2009 it was estimated at 6.2 million cases and in 2010 at 5.4 million cases. Total annual costs are estimated at EUR 2 billion.

76. Since 2007 the application of Salmonella control programmes at EU level has led to a decrease in incidences of infections in laying hen flocks and humans. This has been achieved through co-financing by the EU of national (veterinary) programmes, now under the legal framework of Regulation (EU) No 652/2014. However, the risk is considered unacceptable and even the EFSA itself has recommended further studies on the "effect of different temperatures of storage of eggs ... on the risk posed by egg borne pathogens such as S. Enteritidis." and further recommendations have been made for "investigate the occurrence and control of microorganisms during industrial production of egg products, including pasteurisation, if the storage of eggs is prolonged"[11]

77. According to the EFSA, reported cases of human salmonellosis within the EU in 2012 were 22.2 cases in population of 100.000 whereas the frequency in Iceland was 11,9.[12] This gives a good indication that the precautionary measures applied by Iceland are efficient and protect important health interests.

78. The efforts made within the EU to reduce Salmonella in poultry and humans within the last few years clearly demonstrates that the level of protection was unsatisfactory and needed overhauling. As discussed above the Commission has granted special guarantees to 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.[13]

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[11] Ibid, p. 109.

[12] See, EU summary report on zoonotic agents and food-borne outbreaks 2012, EFSA Journal 2014; 12 (2): 3547, p. 22. **(ANNEX B.5)**

[13] 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.

79. The relevant national authority in Iceland (Matvælastofnun, "MAST") requires an importer to submit data to prove that eggs and egg products have been treated (pasteurised), much in the same manner as in the instance of milk and dairy products. No licence is required but the importer needs to confirm that his products comply with the national regulation regarding treatment of eggs. The regulation and the administrative practice only stipulates a licence application and further documentation if an importer wishes to import untreated egg or egg products.

80. Iceland submits that Regulation (EC) No 853/2004 entails considerable flexibility for national authorities to regulate and monitor untreated eggs and egg products in order to battle the serious health hazards associated with Salmonella infections. Moreover, the vast reforms within the EU illustrate that the measures applied by Iceland have been necessary, effective and very proportionate to their objective.

4. CONCLUSION AND OTHER ISSUES

81. 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 requires. 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 to be obtained in accordance with Article 53 of the Rules of Procedure of the EFTA Court.

82. Finally, the Icelandic Government respectfully asks the Court to dismiss this 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	Adam J. Langer et. al: Nonpaseurized Dairy Products, Disease Outbreaks, and State Laws – United States, 1993-2006. Published by Emerging Infectious Diseases, Vol 18, No. 3, March 2012	7
B.4	Scientific Opinion on the public health risks of table eggs due to deterioration and development of pathogens, EFSA Journal 2014; 12 (7): 3872, p. 22.	2 (The full report of 143 pages will be lodged at the Registry, cf. Article 32(4) of Rules of Procedure)
B.5	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)