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EFTA Surveillance Authority
Rue Belliard 35
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Reykjavík, September 5, 2012
Reference: ANR12090262

Subject: Conditions of importation of raw meat into Iceland pursuant to Article 10 of act no 25/1993 on animal diseases and preventive measure against them. Case No: 70943 / Event No: 618214.

Dear Sirs,

Reference is made to the letter from the EFTA Surveillance Authority (ESA) to the Ministry of Fisheries and Agriculture of 12 June 2012, concerning a ban on the import of raw meat and raw animal products to Iceland and requesting replies to the following questions:

Attached are the Ministry's replies to the above-mentioned questions.

Ad 1: In the opinion of the Ministry, in general the same perspectives apply to Art. 13 of the EEA Agreement and Art. 36 of the Lisbon Treaty with regard to products covered by the EEA Treaty, i.e. those which are covered by Paragraph 3 of Art. 8 of the EEA Agreement. However, separate perspectives apply concerning the implementation of Art. 13 of the EEA Agreement regarding agricultural products.

Firstly, it should be pointed out that agricultural products are not included in the principal scope of application of the EEA Agreement, i.e. Paragraph 3 of Art. 8 of the Agreement, rather certain agricultural products are included in Annex I to the EEA Agreement. Here Art. 8 of the EEA Agreement applies and not Art. 11 of the EEA Agreement. This means that it can be assumed that the ban against any type of barrier to trade is not as extensive regarding those agricultural products which are covered by Art. 18 of the EEA Agreement as other products covered by Paragraph 3 of Art. 8 of the EEA Agreement.

Secondly, grounds can be presented for contending that Art. 13 of the EEA Agreement remains valid despite the harmonisation of laws through rules incorporated in Annex I to the EEA Agreement. Such an argument is supported in particular by the fact that the EEA Agreement does not apply to harmonisation of laws as EU law does, and in addition EEA law has no provisions similar to Art. 114 of the Lisbon Treaty (which assumes that Art. 36 of the Lisbon Treaty shall not apply when harmonisation of laws has taken place).

The reference of Art. 18 to Art. 13 of the EEA Agreement appears to be of little or no purpose unless it is understood in this manner. This is because the arrangements agreed upon in Annex I were equivalent right from the beginning in many cases to those EU Directives which were incorporated in it; in them harmonisation had precisely taken place in certain areas. As a result, it could be asked why reason was seen to refer to Art. 13 in Art. 18 of the EEA Agreement under these circumstances.

The Ministry also maintains that there is no authorisation in the EEA Agreement to derogate from the provisions of Art. 18 (which refers to Art. 13 of the EEA Agreement) even though new acts have been incorporated in Annex I on veterinary and phytosanitary matters unless amendments are made to the EEA Agreement itself as provided for in provisions of Art. 118 of the Agreement. Therefore it could be said that the EEA Agreement, in particular Art. 18 thereof, does not authorise derogations from the provisions of Art. 13 unless by amendment to the Agreement itself as provided for in Art. 118 thereof.

The Ministry is aware of the verdict of the EFTA Court in case no. E-4/04 (Perical AS) but considers its conclusions unclear with regard to the case at hand. It does, however, show that Art. 13 of the EEA Agreement and Art. 36 of the Lisbon Treaty cannot be applied in the same manner. The Ministry's opinion is simply that Art. 13 of the EEA Agreement applies to those Acts which are examined here. The phrase "other technical barriers to trade" applies only to barriers to trade which are technical. The said barriers are not covered by this phrase due to the fact that they can be justified by reference to Art. 13 of the EEA Agreement and thereby to recognised rules of European law.

Ad 2: The Ministry is of the opinion, on the basis of the precautionary principle, that the said question does not comprise the proper approach to the issue in dispute. In the Ministry's opinion, the precautionary principle can be applied when there is reason to expect a risk to the health of humans, animals or plants or the environment under a specific assumed scenario and, furthermore, that the scientific uncertainty regarding this risk or its consequences is such that it cannot be assessed with sufficient certainty. Accordingly, the rule can be applied even though only scientific uncertainty exists concerning the risk or its consequences.¹ In the context being considered here, the precautionary principle implies that if the conditions for its application exist, the onus of proof that a certain risk exists and that it is necessary to take certain measures is transferred to the party causing the risk. The rule thus implies a specific application of the principle of proportionality and reduces the onus of proof which generally rests with the Member States in these matters.

Verdicts of the European Court of Justice confirm this. According to those verdicts, in those instances where harmonisation of laws has not taken place the Member States may determine the

¹ Regarding the precautionary principle, COM(2000)1, 9 states: "(...) the principle will be applied where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection."

level of health which they consider appropriate for their citizens² and in which regard may be had for the health situation of a specific country.³ The Court does, however, carefully examine whether the Member States' specific measures and government policy comply with the objectives aimed at.⁴ It probably has a tendency to criticise more strongly Member States' measures of this sort which are not fully supported by the conclusions of international research on the risks and their consequences. Verdicts of the EFTA Court are in accordance with this.

Your question is responded to by saying that Iceland will gather and submit further reports on the subject of the question.

Ad 3: Annex I to the EEA Agreement originally provided for extensive co-operation in agriculture, including requiring border inspection posts concerning the products listed there. The Annex provisions concerning animal health discussed, for instance, live animals, the healthiness of various agricultural products, prevention of animal diseases, monitoring by and rules concerning reference laboratories, pure-bred animals and various administrative committees. Upon the entry into force of the EEA Agreement, all Member States except Iceland agreed to transpose the said rules. The reason for this position by Iceland was the unique position of Icelandic livestock breeds due to their centuries of isolation, including their vulnerability to communicable diseases.

These rules (exemptions) were approved by the EU at that time. Iceland's views were therefore recognised, including the need for an import ban on raw meat and eggs. In the estimation of the Ministry nothing has changed in this respect since that time, i.e. both the livestock breeds and public health are threatened by imports of this kind and the Directives mentioned in your letter are not sufficient to stave off the threat.

As a result of the above arguments, it is the Ministry's opinion that it is ESA which must demonstrate why it considers the remedies set out in the Directives sufficient, despite the fact that

² Cf. for example Case no. 87/83 *Melkunie* (ECR 2367) [1984], paragraph 18.

³ Cf. Case no. 94/83 *Albert Heijn BV* (ECR 3263) [1984], paragraph 16.

⁴ As an example of this, mention could be made of the verdict in Case C-322/01 *Deutscher Apothekerverband eV* (ECR 14887) [2003]. The circumstances of the case were such that German law prohibited the selling of pharmaceuticals by ordering, for instance, through the Internet with the result that it was impossible to obtain pharmaceuticals in pharmacies, whether a prescription was required or not. The court agreed that there were reasons of health which recommended limiting trade in prescription pharmaceuticals, but that the same was not true of pharmaceuticals not requiring a prescription. Paragraph 119 of the verdict states: "*Given that there may be risks attaching to the use of these medicinal products, the need to be able to check effectively and responsibly the authenticity of doctors' prescriptions and to ensure that the medicine is handed over either to the customer himself, or to a person to whom its collection has been entrusted by the customer, is such as to justify a prohibition on mail-order sales. As the Irish Government has observed, allowing prescription medicines to be supplied on receipt of a prescription and without any other control could increase the risk of prescriptions being abused or inappropriately used. Furthermore, the real possibility of the labelling of a medicinal product bought in a Member State other than the one in which the buyer resides being in a language other than the buyer's may have more harmful consequences in the case of prescription medicines.*" See also Case C-432/03 (*European Commission v Portugal*), where it is stated: "*44 It is settled case-law that, in the absence of harmonising rules, the Member States are free to decide on their intended level of protection of health and life of humans and on whether to require prior authorisation for the marketing of the products concerned (see Case C-293/94 Brandsma [1996] ECR I-3159, paragraph 11).*"

some years ago everyone agreed that it was necessary to protect the biosphere and public health with an import ban.

It should be pointed out here that, in the Ministry's estimation, it is the obligation of ESA to have regard for all aspects of the EEA Agreement in dealing with this case. It is not acceptable to establish a more or less free trade system with goods which affect both public health and livestock breeds in a specific area in such a manner that the risk of a mistake will be suffered by the area in question (in this case Iceland). Instead, ESA should be primarily offering support and assistance to small nations in maintaining their biosphere and public health. Here environmental perspectives come into consideration which have at least the same weight as trade perspectives.

Ad 4: The declaration referred to by ESA regards salmonella guarantees, which Iceland intended to apply, according to Article 8 of Regulation (EC) No 853/2004, in controls of trade in animal products (meat and eggs). However, when implementing JCD No 133/2007 - 137/2007, including the official control and hygiene package, by Act (IS) No 143/2009, the Icelandic parliament (*Althingi*) decided not to amend Article 10 of Act (IS) No 25/1993 on Animal Diseases and Preventive Measures Against Them. The provisions of this Act limit trade in raw meat and eggs. However, the responsible Minister can permit import of raw meat and eggs if certain criteria are fulfilled, as laid down in Regulation (IS) No 448/2012, as amended. One of these criteria is that the product has been tested and proven free from salmonella and that this is confirmed by a salmonella certificate. As a consequence, there is no need for Iceland to apply for special salmonella guarantees. The mentioned salmonella requirements apply to EEA trade and trade with third countries, but only products from third countries have to be controlled at BIPs.

Ad 5 Icelandic livestock breeds of cattle, horses, goats and sheep have been geographically isolated, ever since the settlement over 1100 years ago. It is broadly accepted that due to the long isolation and a unique health status, the native Icelandic farm animals are extremely vulnerable to a wide variety of transmissible agents, which are common in many parts of the world, (for further details see our former answers in a letter of 12 March 2012). Due to previous devastating disease outbreaks in livestock in Iceland, in connection with importation of live animals, Icelandic authorities have established several restrictions on the importation of live animals and animal products, which could carry serious infectious agents, including a ban on the importation of raw meat (for further details see our former answers in a letter of 12 March 2012).

It is well documented that untreated raw meat, even from clinically healthy animals, can contain infectious agents of various kinds. Disease outbreaks can occur if such products are fed to animals, either by accident or by intention. In modern times two outbreaks are known to have taken place in Iceland as a result of feeding animals with imported meat products, contaminated by infectious agents. During the Second World War, more precisely in 1942, pigs in the vicinity of Reykjavik showed symptoms of classical swine fever (pestivirus). The pigs became infected after being fed with leftovers (swill) from the US military occupation forces. The second outbreak was in 1955 when vesicular exanthema (calicivirus) was recorded on a large pig farm, in association with swill feeding from the US military base at Keflavik Airport. In both incidences the Icelandic veterinary authorities succeeded in containing the infections. The outbreaks had minor consequences in

Icelandic agriculture, as the infections were restricted to pigs, and the pig meat production was only a minor enterprise in Iceland in those days. This would not be the case with more severe infectious agents with a wider host range, for example Foot and Mouth Disease virus. In the past, outbreaks of FMD have on several occasions been linked to both illegally and legally imported contaminated meat and meat products, e.g. in the USA in 1929, in Taiwan in 1997 and in the UK in 1967 and 2001. An introduction of a virulent infectious agent such as the FMD virus could have catastrophic consequences in the presumably susceptible livestock of Iceland, probably leading to irreversible damages in the farming sector and could jeopardise the native heritage breeds, even to the brink of extinction. The native population of the Iceland Goat Breed, that only counts 830 animals and has an endangerment status, could easily face extinction in the case of an FMD epidemic. Dairy farming in Iceland is based entirely on the native Icelandic Dairy Breed. The population size is about 75.000 animals including 25.000 dairy cows. Huge losses in the dairy cow numbers would not only have serious effects on food security but also on the national breeding programme and thus, the potential for further genetic improvements. This could lead to the need for the importation of new genetic material and a subsequent erosion of valuable native breed resources. In the same manner, an FMD outbreak would have dramatic consequences for the traditional sheep farming and the Iceland Sheep Breed, also of native heritage merit, as well as the pig industry. Therefore, due to the high susceptibility of native Icelandic livestock to various infectious agents, it is not without reasons that Icelandic authorities are restrictive towards imports of live animals and untreated animal products which could carry infective agents, compromising food security in the country as well as animal health and breed conservation. Although various risk mitigation measures can minimize the exposure of Icelandic livestock to infectious agents, brought into the country with raw meat, it cannot be ignored that any import always entails some risk.

Thus, on the basis of the unique health status of livestock in Iceland, the Icelandic authorities cannot accept free import of raw meat into the country.

On behalf of the Minister



Sigurður Þorgeirsson