Case No: 77297
Document No: 809275
Decision No: 163/16/COL

REASONED OPINION

delivered in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning Iceland's failure to comply with its obligations under Council Directive 89/662/EEC by subjecting the import of egg and dairy products in Iceland to an authorisation procedure and additional requirements

1 Introduction

At the package meeting of 27 May 2015, the EFTA Surveillance Authority ("the Authority") informed the Icelandic Government that it had decided to open an investigation concerning the requirements imposed by Iceland for the import of egg and dairy products.

In the context of the proceedings in Case No 70943 – *Complaint against Iceland concerning imports of raw meat*, the Authority noted that the Icelandic legislation imposing restrictions on the import into Iceland of meat products was imposing similar restrictions on certain other products, in particular on egg and dairy products.

On 21 October 2015 (Doc No 757580), the Authority's Internal Market Affairs Directorate sent a pre-Article 31 letter to Iceland, in which it presented its preliminary conclusion that:

- by maintaining in force an authorisation system for the import of raw egg and dairy products and additional requirements, a prohibition of the marketing for direct human consumption of imported dairy products processed from unpasteurised milk and additional requirements for certain cheeses, as well as an administrative practice of requiring importers to make a declaration and obtain the approval of the Icelandic Food and Veterinary Authority (MAST) for the import of treated egg and dairy products, Iceland has failed to comply with *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*[1] ("Directive 89/662/EEC"), in particular Article 5 thereof;
- Alternatively, these requirements are in breach of Article 18 of the EEA Agreement.

On 10 February 2016 (Doc No 792343), the Authority sent a letter to Iceland, in which it invited it to inform the Authority of how it intended to comply with the EFTA Court's judgment of 1 February 2016 in case E-17/15 - *Ferskar kjötvörur ehf. v the Icelandic State*, in view of the conclusions concerning the incompatibility with Directive 89/662/EEC of the Icelandic authorisation system for raw meat imports.

On 10 March 2016 (IS ref. BRU15070011/89.A.410JBB), the Icelandic Government sent a reply to that letter, in which it stated in particular that it was in the process of evaluating possible adjustments to this authorisation system.

On 20 April 2016 (Doc No 793185), the Authority sent a letter of formal notice to Iceland, in which it concluded that, by maintaining in force an authorisation system for the import of raw eggs and raw egg products and additional requirements, an authorisation system for the import of unpasteurised milk and dairy products processed from unpasteurised milk and additional requirements, a prohibition of the marketing for direct human consumption of imported dairy products processed from unpasteurised milk as well as additional requirements for the import of certain cheeses, and an administrative practice of requiring importers to make a declaration and obtain an approval for the import of treated egg and dairy products, Iceland has failed to fulfil its obligations arising from Directive 89/662/EEC, and in particular Article 5 thereof.

[1] Act referred to at Point 1.1.1 of Chapter I of Annex I to the EEA Agreement.

The case was also discussed at the package meeting of 1 June 2016.

By a letter dated 21 June 2016 (IS ref. ANR15110013/20.5), the Icelandic government requested an extension of the deadline to reply to the Authority's letter of formal notice of 20 April 2016. By a letter dated 23 June 2016 (Doc No 809423), the Authority granted the Icelandic Government an extension of the deadline until 1 July 2016. By a letter dated 4 July 2016 (IS ref. ANR15110013/20.5), the Icelandic Government requested an additional extension of the deadline to reply to the letter of formal notice. By letter dated 5 July 2016 (Doc No 811072), the Authority granted the Icelandic Government an additional extension of the deadline until 11 July 2016.

On 14 July 2016 (IS ref. ANR15110013/20.5), the Icelandic Government sent a reply to the Authority's letter of formal notice of 20 April 2016.

In its reply, the Icelandic Government first referred, concerning the import authorisation system, to its legal arguments presented in its reply to the Authority's letter of formal notice in Case 70943 and the EFTA Court's judgment in case E-17/15 - *Ferskar kjötvörur ehf. v the Icelandic State*. It considered that, following the Advisory Opinion, it should wait for the procedure before the District Court of Reykjavík to be concluded before it takes further steps concerning the import system.

Then, concerning requirements relating to food contaminants and labelling foreseen in Article 5 (f) and (g) of Regulation (IS) No 448/2012, the Icelandic Government stated that these provisions did not impose additional requirements but were merely intended to reaffirm that importers must ensure that foodstuffs fulfil the rules on food contaminants and labelling. According to the Icelandic Government's interpretation, it follows from Article 5 of the said regulation that Iceland cannot demand certificates related to food contaminants or labelling from importers. In view of the above, the Authority will not pursue the infringement relating to Article 5 (f) and (g) of Regulation (IS) No 448/2012 in the present reasoned opinion.

Furthermore, concerning the Icelandic prohibition on marketing of dairy products processed from raw milk, the Icelandic Government stated in particular that in its view Article 10 (8) (a) of Regulation (EC) No 853/2004 cannot be understood as merely applying to raw milk, and not to dairy products produced from raw milk. As will be outlined below, the Authority does not agree.

2 Relevant national law

Article 10 of Act No 25/1993 on animal diseases and preventive measures against them, as amended, provides that:

> *"To prevent animal diseases from reaching the country it is prohibited to import the following types of goods:*
>
> *a. raw and lightly salted slaughter products, both processed and non-processed, raw eggs, non-disinfected raw skins and hides, feed for food producing animals (*in Icelandic: alidýraáburður*) and (*rotmassi*) mixed with feed for food producing animals,*

b. *meat meal, bone flour, blood meal, and fat that is distilled from the production of these materials,*
c. *hay and straw,*
d. *any type of used packaging, saddlery, machinery, device, instruments, and other objects that have been in contact with animals, animal products or animal waste,*
e. *any type of equipment used for angling.*

Despite the provision of paragraph 1, the Food and Veterinary Authority is authorised to allow the import of the products mentioned in items a-e, if it is considered proven that they will not transmit infectious agents that can cause animal diseases. The Minister can decide by regulation that paragraph 1 shall not apply to certain categories of the products listed therein, if the product is disinfected in production or a special disinfection is performed before importation and the product is accompanied with a satisfactory certificate of origin, processing and disinfection, in the case of producers outside of the European Economic Area. The Minister is authorised to prohibit by regulation the import of products, irrespective of their origin, which carry the risk of transmitting contaminating agents that could cause danger to the health of animals.[…]"[2]

Icelandic Regulation (IS) No 448/2012 of 23 May 2012 on measures to prevent the introduction of animal diseases and contaminated products to Iceland provides detailed provisions on the implementation of Article 10 of Act No 25/1993.

Article 3 of Regulation (IS) No 448/2012 provides that:

"The importation to Iceland of the following animal products and products that may carry infectious agents which cause diseases in animals and humans is not permitted, cf. however, further details in Chapter III.
(…)
e. *Untreated raw eggs, raw eggshells and raw egg products, which have not been treated by heating so that the product has been heated to 65°C for 5 minutes, or received other comparable treatment in the assessment of MAST.*

f. *Unpasteurised milk and dairy products processed from unpasteurised milk. However, up to 1 kg of cheese processed from unpasteurised milk from approved establishments in the European Economic Area may be imported for personal use; however, the Minister may authorise the import of a larger quantity for the same purpose."*

Article 4 of Regulation (IS) No 448/2012 provides that:

"The Minister of Fisheries and Agriculture is authorised to allow the import of products mentioned in Article 3, cf. Article 10 of [Act No 25/1993] and subsequent amendments, having received recommendations from the Food and Veterinary Authority, if it is considered proven that they will not transmit infectious agents that can cause diseases in animals and humans, and the conditions imposed for the import have been fulfilled, see however Article 7.

[2] Paragraph 2 of Article 10 of Act No 25/1993 on animal diseases and preventive measures against them was amended by Act No 71/2015, which entered into force on 20 July 2015 (unofficial translation by the Authority).

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

An importer of raw products shall in all cases apply for a permit to the Minister of Fisheries and Agriculture and submit, for the consideration of MAST, an import declaration, information on the country of origin and production, the type of product and producer, and the required certificates, as provided for in Article 5."

In practice, when the initial application has been processed, the importer has to apply for permission for the import of each individual consignment. This is satisfied by submitting all the necessary documentation to the office of import and export at MAST, where an evaluation of conformity takes place. If conformity is established, the documents are sent to the Ministry for final approval (the Authority understands that, upon the amendment of Article 10 paragraph 2 of Act No 25/1993 by Act No 71/2015, the approval is now granted by MAST). Upon such final approval, the importer may submit the documents to the customs authorities and have the consignments released.

Moreover, Article 5 of Regulation (IS) No 448/2012 provides that:

"Imported foods which are listed under classifications (CN Codes) 0202, 0203, 0204, 0207, 0208, 0210, 1601 and 1602[3]*, cf. Appendix I to the Customs Act, No 88/2005, which the Minister has authorised for import to Iceland as referred to in Article 4 and which have not received satisfactory heat treatment must be accompanied by the following certificates:*

a. an official certificate of origin and health, in the case of products from producers outside the European Economic Area;
b. an official certificate confirming that the animals from which the products derive were not given growth-promoting substances during rearing, in the case of products from producers outside the European Economic Area;
c. a certificate confirming that the products have been stored at a temperature of at least -18°C for a month prior to customs clearance;
d. an official certificate confirming that the animals from which the products derive were slaughtered in slaughterhouses and the products processed in processing plants authorised in the European Economic Area, in the case of products from producers outside the European Economic Area;
e. an official certificate confirming that the products are free of salmonella bacteria;
f. animal meat products and by-products, dairy products and raw eggs shall conform to the appropriate provisions of the current Regulation on food contaminants;
g. the product shall be labelled in conformity with current rules on labelling, advertising and promotion of foodstuffs.

[3] Description of the CN Codes: 0202: Meat of bovine animals, frozen, 0203: Meat of swine, fresh, chilled or frozen ; 0204: Meat of sheep or goats, fresh, chilled or frozen ; 0207: Meat and edible offal, of the poultry of heading 0105, fresh, chilled or frozen ; 0208: Other meat and edible meat offal, fresh, chilled or frozen ; 0210: Meat and edible meat offal, salted, in brine, dried or smoked; edible flours and meals of meat or meat offal ; 1601: Sausages and similar products, of meat, meat offal or blood; food preparations based on these products ; 1602: Other prepared or preserved meat, meat offal or blood.

> […] *Imported cheese in customs classifications (CN Codes) 0406.2000 and 0406.3000*[4] *must have received appropriate treatment so that the cheesecurd has been heat treated at least to 48°C, the product must have been stored for at least 6 months at a temperature of not less than 10°C and a humidity of less than 36%. The product must be accompanied by an official certificate of origin and health, in the case of producers outside of the European Economic Area, and confirmation that the product has received appropriate treatment.*"

The Authority considers that Article 10 of Act No 25/1993 and Articles 3 and 4 of Regulation (IS) No 448/2012 read together, impose a system of import authorisation for raw eggs and raw egg products and for unpasteurised milk and dairy products processed from unpasteurised milk, based on the production of certain documents. Article 5 of Regulation (IS) No 448/2012 further requires operators to establish, for the import of certain cheeses, that they have received a specific heat treatment and have been stored for at least 6 months at a temperature of not less than 10°C and a humidity of less than 36%.

The Authority understands that the products concerned are principally eggs and egg products, milk and dairy products. These products are defined and covered by *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*[5].

Furthermore, Article 7a of Regulation (IS) No 104/2010 on the incorporation of Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin provides that:

> "*In accordance with the provisions of Regulation No. 853/2004/EC, as amended, the following provisions shall apply with regards to the placing on the market of raw milk and raw cream, intended for distribution on the market, for direct human consumption:*
>
> *Milk that is distributed to consumers, shall be pasteurised and packaged in consumer packaging. Dairy products shall be produced from pasteurised milk. (…)*"

The Icelandic Government specified during the package meeting of 27 May 2015 that the marketing for direct human consumption of imported dairy products processed from unpasteurised milk was prohibited, even after the delivery of an import authorisation (except for certain cheeses complying with the requirements of Article 5 of Regulation (IS) No 448/2012).

Finally, the Icelandic Government also specified during the package meeting of 27 May 2015 that, for treated egg and dairy products (i.e. complying with the heat treatments mentioned in Article 3 (e) and (f) respectively of Regulation (IS) No 448/2012), importers

[4] Description of the CN Codes: 0406.2000 - grated or powdered cheese of all kinds; 0406.3000 - processed cheese, not grated or powdered.

[5] Annex I of Regulation (EC) No 853/2004 (act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement) defines 'raw milk' as "*milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect*"; 'eggs' as "*eggs in shell — other than broken, incubated or cooked eggs — that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products*"; 'dairy products' as "*processed products resulting from the processing of raw milk or from the further processing of such processed products*" and "egg products' as "*processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products*".

had to make a declaration and obtain the approval of MAST in order to get customs clearance. The Authority understands that this administrative practice results from the application of Article 3 of Regulation (IS) No 448/2012.

3 Relevant EEA law

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

Under Article 1 of that directive, veterinary checks to be carried out on products of animal origin covered by that directive, which are intended for trade between EEA States, are (subject to the provisions of Article 6 on products from third countries) no longer to be carried out at frontiers within the EEA, but are to take place in accordance with the provisions of Directive 89/662/EEC.

Article 2 of Directive 89/662/EEC specifies that the term 'veterinary check' within the meaning of the directive "*means any physical check and/or administrative formality which applies to the products covered by the directive and which is intended for the safeguarding, direct or otherwise, of public or animal health"*.

Chapter I of that directive, entitled 'Checks at origin', consists of Articles 3 and 4 which regulate veterinary checks in the EEA State of dispatch.

Under the first of those two provisions, the EEA State of dispatch is to ensure that the only products intended for intra-EEA trade are those which have been obtained, checked, marked and labelled in accordance with EEA rules for the destination in question and which are accompanied to the final consignee by the certificates required by the EEA veterinary rules.

In practice, this means that products of animal origin can only be placed on the market if they comply with the requirements laid down in the applicable EEA legislation, i.e. in particular the so-called "hygiene package" as well as the relevant animal health and welfare rules applicable in the EEA. Products of animal origin, including egg and dairy products, are subject in particular to the harmonised requirements of *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*[7] ("Regulation (EC) No 853/2004"), of *Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*[8] and *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*[9].

[6] Act referred to at Point 1.1.1 of Chapter I of Annex I to the EEA Agreement.
[7] Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement.
[8] Act referred to at Point 1.1.12 of Chapter I of Annex I to the EEA Agreement.
[9] Act referred to at Point 1.1.11 of Chapter I of Annex I to the EEA Agreement.

Then, Article 4(1) of Directive 89/662 provides that:

> "*Member States of dispatch shall take the necessary measures to ensure that operators comply with veterinary requirements at all stages of the production, storage, marketing and transport of the products referred to in Article 1* […]."

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

Article 5 defines – restrictively – the types of checks that can be carried out by the competent authority at the place of destination and states in particular in its paragraph 1 (a) that:

> *"Member States of destination shall implement the following measures:*
>
> *The competent authority may, at the places of destination of goods, check by means of non-discriminatory veterinary spot-checks that the requirements of Article 3 have been complied with; it may take samples at the same time.*
>
> *Furthermore, where the competent authority of the Member State of transit or of the Member State of destination has information leading it to suspect an infringement, checks may also be carried out during the transport of goods in its territory, including checks on compliance as regards the means of transport."*

It follows from these provisions that competent authorities of the EEA State of destination may only check, by means of non-discriminatory veterinary spot-checks, compliance with the relevant EEA legislation.

Articles 7 and 8 of Directive 89/662/EEC lay down the measures to be taken and the procedure to be followed if, during a check carried out at the place of destination of a consignment, the competent authority establishes the existence of an epizootic disease, any new serious and contagious disease or other cause likely to constitute a serious hazard to animals or to human health.

Article 9 of Directive 89/662/EEC provides that, in cases of an outbreak in its territory of any zoonoses, disease or other cause likely to constitute a serious hazard to human or animal health, Member States may adopt safeguard measures[10].

Finally, it should be mentioned that, concerning dairy products, Regulation (EU) No 853/2004 provides in its Article 10.8 that:

> *"A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:*

[10] Directive 89/662/EEC was incorporated into the EEA Agreement with an adaptation to Article 9, according to which this provision does not apply and any reference to it must be read as a reference to paragraph 3 of the Introductory Part of Annex I, Chapter I thereto, which concerns safeguard and protective measures.

(a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption;
or
(b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation."

4 The Authority's assessment

4.1 Introduction

The rules concerning the intra-EEA trade of products of animal origin and veterinary checks have been harmonised in the EEA.

According to Directive 89/662/EEC, veterinary checks are to take place at the place of dispatch, and the competent authority at the place of destination may carry checks only by means of non-discriminatory spot-checks. In addition, Article 5 of Directive 89/662/EEC provides that the veterinary checks at the place of destination are limited to verifying the fulfilment of the requirements of EEA legislation. Hence veterinary checks on imports of egg and dairy products can only be aimed at verifying compliance with the requirements of relevant EEA legislation.

The EFTA Court stated, in its judgment of 1 February 2016 in case E-17/15 *Ferskar kjötvörur ehf.* v *the Icelandic State* ("the *Ferskar kjötvörur ehf.* judgment") that:

"*65 The harmonised system of veterinary checks [under Directive 89/662/EEC] is based on full inspection of the goods in the EEA State of dispatch. The system is intended to replace, as a rule, inspection in the EEA State of destination. Considerations related to the need to protect public or animal health cannot justify additional specific constraints imposed by an EEA State when the frontier is crossed (see, for comparison, judgment in Commission v Sweden, C-111/03, EU:C:2005:619, paragraph 51).*

66 The objective of the Directive could not be realised, nor its effectiveness achieved, if the EEA States were free to go beyond its requirements. Maintaining or adopting national measures other than those expressly provided for in the Directive must therefore be regarded as incompatible with the Directive's purpose".

Furthermore, the EFTA Court stated in paragraph 76 of that judgment that: "*The aim to protect human and animal health in EEA trade mentioned in Article 13 EEA cannot be invoked to justify measures banning or restricting imports when a Directive provides for the harmonization of the measures necessary to guarantee the protection of animal and human health and when they establish procedures to check that they are observed*".

It also follows from the consistent interpretation made on several occasions by the Court of Justice of the European Union ("the CJEU" or "the Court of Justice") that Directive 89/662/EEC has exhaustively harmonised veterinary checks that can take place in the

State of destination[11]. The CJEU stated that a detailed and harmonised system of health inspections, based on harmonised rules at EEA level, replaces all other inspection systems existing within the country of destination, whatever the place where such inspections may be carried out[12].

A review of the Icelandic legal framework, in light of the above and in particular of the *Ferskar kjötvörur ehf.* judgment, has led the Authority to reach the conclusion that the authorisation procedure and the additional requirements imposed by the Icelandic legislation on imports of egg and dairy products are not in line with Directive 89/662/EEC, and in particular Article 5 thereof. The Authority also notes that the amendment of Article 10 paragraph 2 of Act No 25/1993 by Act No 71/2015 mentioned above does not alter this conclusion.

4.2 The Icelandic legal framework regarding imports of raw eggs and raw egg products is in breach of Directive 89/662/EEC

First of all, 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.

In particular, Article 4 of Regulation (IS) No 448/2012 requires all operators to submit an initial application and then – systematically and for each consignment – an application for the import of raw eggs and raw egg products.

The EFTA Court concluded in the *Ferskar kjötvörur ehf.* judgment that:

"*It is not compatible with the provisions of Directive 89/662/EEC for an EEA State to enact rules demanding that an importer of raw meat products applies for a special permit before the products are imported* […]."

The authorisation system for the import of raw eggs and raw egg products is similar to the one for raw meat products. Therefore the same conclusion must be made, i.e. that these requirements are not compatible with the provisions of Directive 89/662/EEC, and in particular Article 5 thereof, as they constitute obligations that go beyond the controls permitted at the place of destination.

4.3 The Icelandic legal framework regarding imports of unpasteurised milk and dairy products processed from unpasteurised milk is in breach of Directive 89/662/EEC

First of all, 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 unpasteurised milk and dairy products processed from unpasteurised milk from other EEA States.

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[11] See, in particular, *Commission* v *Germany*, C-186/88, ECLI:EU:C:1989:601; *Commission* v *Germany*, C-102/96, ECLI:EU:C:1998:529; *Danske Slagterier v Bundesrepublik Deutschland*, C-445/06, ECLI:EU:C:2009:178 and *Commission* v *Sweden*, C-111/03, ECLI:EU:C:2005:619.

[12] See, in particular, *Commission* v *Sweden*, C-111/03, cited above, paragraph 51 and joined cases *Ligur Carni Srl and Genova Carni Srl v Unità Sanitaria Locale n. XV di Genova and Ponente SpA v Unità Sanitaria Locale n. XIX di La Spezia and CO.GE.SE.MA Coop a r l* , C-277/91, C-318/91 and C-319/91, ECLI:EU:C:1993:927, paragraph 26.

Article 4 of Regulation (IS) No 448/2012 requires all operators to submit an initial application and then – systematically and for each consignment – an application for the import of unpasteurised milk and dairy products processed from unpasteurised milk, and Article 5 imposes additional requirements concerning certain cheeses, including a heat treatment and a storage for at least 6 months.

In view of the EFTA Court's *Ferskar kjötvörur ehf.* judgment as presented above, the authorisation procedure for the import of unpasteurised milk and dairy products processed from unpasteurised milk, which is similar to the one for raw meat products, is not compatible with the provisions of Directive 89/662/EEC, and in particular Article 5 thereof.

In addition, it results from Article 7a of Regulation (IS) No 104/2010 that dairy products, including the imported ones, must be produced from pasteurised milk. Consequently, the marketing of imported dairy products processed from unpasteurised milk is prohibited, even after obtaining an import authorisation.

It follows from Article 5 of Directive 89/662/EEC read in conjunction with its Article 3, that veterinary checks on dairy products can only be aimed at verifying that these products comply with relevant EEA rules, and in particular the harmonised requirements applicable to dairy products set by Regulation (EC) No 853/2004.

In this regard, the Authority considers that the Icelandic measure does not find a legal basis, as a matter of EEA law, in Article 10.8 (a) of Regulation (EC) No 853/2004, as it goes beyond what is permitted under this provision, which only allows restrictive measures on raw milk or raw cream for direct human consumption. In this respect, the Authority disagrees with the argument of the Icelandic Government that Article 10.8 (a) of Regulation (EC) No 853/2004 would extend to dairy products processed from raw milk. Indeed, this provision allows EEA States to maintain or establish national rules prohibiting or restricting the placing on the market of solely two specific products, i.e. raw milk and raw cream, and solely for a specific use, i.e. the marketing for direct human consumption. This interpretation appears to be further confirmed by Recital 23 of the said regulation, which states that:

"*This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption, if appropriate measures are taken.* ***As regards raw milk and raw cream intended for direct human consumption, it is appropriate to enable each Member State to maintain or establish appropriate health measures to ensure the achievement of the objectives of this Regulation on its territory.***" (emphasis added)

It follows from the above that the prohibition of the marketing of imported dairy products processed from unpasteurised milk cannot be based on Article 10.8 (a) of Regulation (EC) No 853/2004 and is not compatible with the provisions of Directive 89/662/EEC and in particular Article 5 thereof.

4.4 The Icelandic legal framework regarding imports of treated egg and dairy products is in breach of Directive 89/662/EEC

The Authority understands that importers of treated egg and dairy products (i.e. complying with the heat treatments mentioned in Article 3, paragraphs (e) and (f) respectively of Regulation (IS) No 448/2012) are not subject to the authorisation procedure of Article 4 of Regulation (IS) No 448/2012, but still have to make a declaration and obtain the approval of MAST in order to get customs clearance.

Although there does not appear to be an express provision in Act No 25/1993 or Regulation (IS) No 448/2012 providing for this obligation, this practice was confirmed by the Icelandic Government during the package meeting of 27 May 2015.

In view of the judgment of the EFTA Court mentioned above and relevant case-law of the CJEU, the Authority considers that this obligation of declaration and approval by MAST goes beyond the checks allowed under Article 5 of Directive 89/662/EEC. This administrative practice is thus incompatible with Directive 89/662/EEC, and in particular Article 5 thereof.

FOR THESE REASONS,

THE EFTA SURVEILLANCE AUTHORITY,

pursuant to the first paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, and after having given Iceland the opportunity of submitting its observations,

HEREBY DELIVERS THE FOLLOWING REASONED OPINION

That by:

- maintaining in force an authorisation system for the import of raw eggs and raw egg products such as the ones laid down in Article 10 of Act No 25/1993 and Articles 3 (e) and 4 of Regulation (IS) No 448/2012,

- maintaining in force 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,

- maintaining in force an administrative practice, such as the one applicable in the context of the application of Regulation (IS) No 448/2012, of requiring importers to make a declaration and obtain an approval for the import of treated egg and dairy products,

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 adaptations in Annex I thereto, and in particular Article 5 of that directive.

Pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the EFTA Surveillance Authority requires Iceland to take the measures necessary to comply with this reasoned opinion within *two months* of its receipt.

Done at Brussels, 14 September 2016

For the EFTA Surveillance Authority

Helga Jónsdóttir
College Member

Carsten Zatschler
Director

This document has been electronically signed by Helga Jonsdottir, Carsten Zatschler on 14/09/2016