Case No:74074
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Decision No: 153/16/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 breach of its notification obligations under Directive 98/34 as concerns technical regulations adopted in 2012

1 Introduction and correspondence

By a letter dated 11 December 2013 (Doc No 711563), the EFTA Surveillance Authority ("the Authority") informed the Icelandic Government that it had opened an own initiative case for the purposes of scrutinizing Iceland's fulfilment of its obligations under Directive 98/34 ("the Directive" or "Directive 98/34") as concerns technical regulations adopted in 2012.[1] In this letter, the Authority requested further details on several potentially non-notified technical regulations, within the meaning of the Directive, adopted in Iceland in 2012, in order to ascertain whether these were indeed of such a nature. Additionally, the Authority inquired about the fulfilment of other specific obligations under Directive 98/34, particularly relating to the lack of transposition of a rule of non-enforceabililty of technical regulations within the meaning of the Directive adopted without the due notification.

The Icelandic Government responded to this letter on 24 March 2014 (Doc No 728583).

After having analysed the Icelandic Government's submissions, the Authority issued a letter of formal notice concerning the subject matter on 16 July 2014 (Doc No 711563). The Icelandic Government responded to this letter on 5 November 2014 (Doc No 728583).

The case has been discussed at package meetings in Iceland in May 2014, May 2015 and June 2016.

Whereas two technical regulations have been notified,[2] one piece of legislation has been sufficiently accounted for as an implementation of a piece of EEA secondary law legislation,[3] and yet another regulation has been repealed,[4] Iceland still has not notified a number of the technical regulations in question, adopted in 2012, and is thus still in breach of its obligations under Directive 98/34 with respect to a number of these, as outlined below. Furthermore, Iceland has not enacted a rule of non-enforceability concerning technical regulations adopted without following the due notification procedure in Directive 98/34 and the corresponding Icelandic implementing measures.

2 Relevant EEA law

Article 1(1)-(5) and 1(10)-(11) of the Directive, as adapted to the EEA Agreement,[5] read:

Article 1

[1] The Act referred to at point 1 of Chapter XIX of Annex II to the EEA Agreement (*Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations*), as amended and as adapted to the EEA Agreement.

[2] DTR 2014/9018/IS and DTR 2016/9001/IS, the latter of which proposes a number of new rules on the advertisement of medicinal products and aims at repealing the regulation which *Reglugerð um (2.) breytingu á reglugerð nr. 328/1995 um lyfjaauglýsingar* amends.

[3] Lög 62/2012 um breytingu á lögum um fjarskipti og lögum um Póst- og fjarskiptastofnun (netöryggissveit, rekstrargjald o.fl.)

[4] Regulation No. 32/2012 amending Regulation no. 503/2005 on the labeling of foodstuffs, REGLUGERÐ um (7.) breytingu á reglugerð nr. 503/2005 um merkingu matvæla, með síðari breytingum, repealed by Regulation No 1294/2014.

[5] By Joint Committee Decisions No 146/1999 and No 16/2001.

For the purposes of this Directive, the following meanings shall apply:

(1) 'product', any industrially manufactured and any agricultural product, including fish products;

(2) 'service', any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

For the purposes of this definition:

— 'at a distance' means that the service is provided without the parties being simultaneously present,

— 'by electronic means' means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,

— 'at the individual request of a recipient of services' means that the service is provided through the transmission of data on individual request.

[…]

(3) 'technical specification', a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.

The term 'technical specification' also covers production methods and processes used in respect of products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 65/65/EEC, as well as production methods and processes relating to other products, where these have an effect on their characteristics;

(4) 'other requirements', a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;

(5) 'rule on services', requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point 2, in particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point.

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC [...].

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Annex VI to this Directive.

With the exception of Article 8(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 93/22/EEC or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

For the purposes of this definition:

— a rule shall be considered to be specifically aimed at Information Society services where, having regard to its statement of reasons and its operative part, the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner,

— a rule shall not be considered to be specifically aimed at Information Society services if it affects such services only in an implicit or incidental manner;

[...]

(10) 'draft technical regulation`, the text of a technical specification or other requirement, including administrative provisions formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made.

(11) 'technical regulation', technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 10, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider.

De facto technical regulations include:

— laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or to other requirements or to rules on services, compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions,

— voluntary agreements to which a public authority is a contracting party and which provide, in the general interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications,

> *— technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services linked to national social security systems are not included.*

Article 8(1) of the Directive, as adapted to the EEA Agreement,[6] reads:

> "*Subject to Article 10, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these have not already been made clear in the draft.*
>
> *[…]*
>
> *Where appropriate, and unless it has already been sent with a prior communication, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.*
>
> *Member States shall communicate the draft again under the above conditions if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive*."

3 The Authority's assessment

3.1 Non-notified technical regulations within the meaning of the Directive

Whereas the Icelandic Government, in its letters of 24 March 2014 and in its response to the letter of formal notice dated 5 November 2014, has provided satisfactory explanations for some of the seemingly non-notified technical regulations adopted in 2012, several technical regulations have not been adequately accounted for and/or have still not been notified to the Authority.

The Icelandic Government has acknowledged that a number of measures adopted in 2012 contain technical regulations within the meaning of the Directive. These measures are:

- Regulation No. 448/2012 on measures against animal diseases and infected products reaching the country, *REGLUGERÐ um varnir gegn því að dýrasjúkdómar og sýktar afurðir berist til landsins*[7]

[6] By Joint Committee Decisions No 146/1999 and No 16/2001.

[7] Section 7 of the regulation requires importers of agricultural machinery, tools and equipment, including trailers etc.to have an import licence. Section 5 of the regulation further submits the import of raw foods, meat and dairy products to a specific import scheme and a number of certification requirements etc.

- Regulation No. 186/2012 on the collection, recycling and deposit on disposable packaging for beverages, *REGLUGERÐ um breytingu á reglugerð nr. 368/2000, um söfnun, endurvinnslu og skilagjald á einnota umbúðir fyrir drykkjarvörur.*[8]

- Rules No. 496/2012 on the product selection and sales of tobacco and trade terms, *REGLUR um vöruval og sölu tóbaks og skilmálar í viðskiptum við birgja.*[9]

During package meetings in Iceland in May 2014, May 2015 and June 2016, it was discussed how this could be remedied. The Authority explained, by way of example, that a notification of a *draft* measure, substantively similar or identical to the abovementioned measures, and including a clause which would repeal the respective non-notified above measures upon entry into force (following the expiry of the standstill, and taking into account potential comments received), could be notified under the 98/34 procedure. However, as concerns the above mentioned measures, no such notification under Directive 98/34 has been received to date.

All of these measures contain technical regulations within the meaning of the Directive, which should have been notified to the Authority in accordance with Article 8(1) first subparagraph of the Directive, as adapted to the EEA Agreement.

3.2 Failure to implement a rule of non-enforceability

In case C-194/94 *CIA Security*, [10] the Court of Justice of the European Union ("the CJEU") held that Articles 8 and 9 of Directive 83/189 (i e. the predecessor of Article 98/34) are to be interpreted as meaning that national courts must decline to apply a national technical regulation which has not been notified in accordance with the directive vis-á-vis individuals and economic operators. The Authority notes, as specified in Case C-226/97 *Lemmens*, that the rule of non-enforceability does not have the effect of «*rendering unlawful any use of a product which is in conformity with regulations which have not been notified*».[11]

This case law finds its counterpart in the EFTA pillar in the EFTA Court's judgment in Case E-2/12 *HOB-vín*,[12] which concerned a notification arrangement under Directive

[8] Section 1 of the regulation provides for differentiated administration fees for different kinds of packaging, such as steel, glass and coloured plastic marterials.
[9] The Rules contain rules on the product selection of tobacco by the ÁTVR, pricing and specfic labelling and packaging provisions, constituting thus a technical regulation which should have been notified in accordance with Article 8(1) first subparagraph of the Directive.
[10] See, for example, Case C-194/94 *CIA Security*, judgment of 30 April 1996, ECLI:EU:C:1996:172, paragraph 55; Case C-443/98 *Unilever Italia SpA v Central Food SpA*, judgment of 26 September 2000, ECLI:EU:C:2000:496.
[11] Case C-226/97 *Lemmens*, judgment of 16 June 1998, ECLI:EU:C:1998:296, at paragraphs 34-35. In the case at hand where a driver accused of driving under the influence of alcohol made reference to the rule as concerned non-notified regulations regarding breath-analysis apparatus, and evidence obtained by such apparatus. However, the CJEU found that the «*Directive is to be interpreted as meaning that breach of the obligation imposed by Article 8 thereof to notify a technical regulation on breath-analysis apparatus does not have the effect of making it impossible for evidence obtained by means of such apparatus, authorised in accordance with regulations which have not been notified, to be relied upon against an individual charged with driving while under the influence of alcohol.*»
[12] Case E-2/12 *HOB-vín*, judgment of 11 December 2012, EFTA Ct. Rep. 1092, at paragraph 115.

2000/13, which has a comparable nature to that of Directive 98/34 and thus extends the principles developed in case C-194/94 *CIA Security* and subsequent judgments to the EEA. The consequence of this case law is that EEA States cannot allow measures that have not been duly notified, in accordance with the Directive, to be relied upon by the EEA State in question vis-à-vis individuals and economic operators.

In its response to the letter of formal notice of 5 November 2014, the Icelandic Government held that Directive 98/34 has been implemented into the Icelandic legal order by Act No 57/2000, and that this Act transposes the obligations therein in a sufficiently clear manner. The notification obligation for technical regulations within the meaning of Directive 98/34 indeed is clearly provided for in the aforementioned Icelandic implementing measures. However, the relative non-enforceability of measures that have not been duly notified in accordance with Iceland's legal obligations under Directive 98/34, as outlined above, has not been ensured.

Iceland enjoys a certain margin of appreciation in determining precisely how the obligations pursuant to Directive 98/34 in this regard are to be transposed into national law, as required by Article 7 EEA. The Authority would like to draw attention to Case E-15/12 *Jan Arnfinn Wahl v the Icelandic State*,[13] and recall that Iceland is obliged to ensure that directives are duly implemented with unquestionable binding force, precision and clarity. The EFTA Court stated that:

> "*[...] provisions of directives must be implemented with unquestionable binding force and the specificity, precision and clarity necessary to satisfy the requirements of legal certainty (compare, mutatis mutandis, Case C-159/99 Commission v Italy [2001] ECR I-4007, paragraph 32). EEA States must ensure full application of directives not only in fact but also in law.*
>
> *It is essential that the legal situation resulting from national implementing measures be sufficiently precise and clear and that individuals be made fully aware of their rights so that, where appropriate, they may rely on them before the national courts. The latter condition is of particular importance where the directive in question is intended to confer rights on nationals of other EEA States, as is the case here, as those nationals may not be aware of provisions and principles of national law (compare, mutatis mutandis, Case C-478/99 Commission v Sweden [2002] ECR I-4147, paragraph 18 and case law cited).*"[14]

In light of the above, the Authority concludes that Iceland is under an obligation not to enforce measures vis-à-vis individuals and economic operators, which have not been notified in line with the Directive and in line with the case-law of the EFTA Court, a rule to that effect has be to be laid down with precision and clarity in national law.

The Icelandic Government points out, in its reply to the letter of formal notice of November 2014, that the ruling of the District Court of Reykjavík in case E-2381/2011 (HOB-vín) demonstrates that Icelandic courts have abided by the EFTA Court's advisory opinion in Case E-2/12 *HOB-vín*, in confirming that non-respect of the obligation to notify is a fundamental procedural flaw. This, however, does not change the fact that in the Act implementing Directive 98/34, there is no explicit rule of non-enforceability which individuals can rely on directly before national courts.

[13] Case E-15/12 *Jan Arnfinn Wahl v the Icelandic State*, judgment of 22 July 2013, EFTA Ct. Rep. 534.
[14] Ibid at paragraphs 51-52.

In any case, the Authority is aware of conflicting case-law, e.g. Supreme Court case No 220/2005 of 6 April 2006, in which the decision of the Reykjavík District Court that a failure to comply with a notification obligation could not result in the technical regulation in question becoming inapplicable to individuals was confirmed by the Supreme Court.[15] The legal situation in this respect is thus, uncertain, and an explicit rule should be enacted in order to provide adequate legal certainty.

4 Conclusion

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

(i) by failing to comply with the procedure for the provision of information in the field of technical standards and regulations, laid down in the Act referred to at point 1 of Chapter XIX of Annex II to the EEA Agreement *(Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations)* as amended and adapted by the Agreement, Iceland has failed to fulfil its obligations under Article 8 of that Act in respect of the national legal acts adopted in 2012 referred to above in Section 3.1.

(ii) by failing to implement a specific rule of non-enforceability of measures not duly notified under the Act referred to at point 1 of Chapter XIX of Annex II to the EEA Agreement *(Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations)* as amended and adapted by the Agreement, Iceland has failed to fulfil its obligations under Articles 8 and 9 of that Act and under Article 7 of the EEA Agreement.

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, 13 July 2016

For the EFTA Surveillance Authority

Helga Jónsdóttir Carsten Zatschler

[15] Supreme Court case No 220/2005 of 6 April 2006.

College Member Director

This document has been electronically signed by Helga Jonsdottir, Carsten Zatschler on 13/07/2016