



JUDGMENT OF THE COURT

7 May 2025

(Failure by an EFTA State to fulfil its obligations – Failure to implement Regulation (EU) 2019/933 – Supplementary protection certificate for medicinal products)

In Case E-29/24,

EFTA Surveillance Authority, represented by Sigurbjörn Bernharð Edvardsson, Sigrún Ingibjörg Gísladóttir and Melpo-Menie Joséphidès, acting as Agents,

applicant,

v

Iceland, represented by Hendrik Daði Jónsson, and Gunnar Ingi Ágústsson, acting as Agents,

defendant,

APPLICATION seeking a declaration that Iceland has failed to adopt the measures necessary to make the act referred to at point 6 of Annex XVII to the Agreement on the European Economic Area (Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products), as adapted by Protocol 1 to the Agreement, part of its internal legal order,

THE COURT,

composed of: Páll Hreinsson, President, Bernd Hammermann and Michael Reiertsen (Judge-Rapporteur), Judges,

Registrar: Ólafur Jóhannes Einarsson,

having regard to the written pleadings of the parties,

having decided to dispense with the oral procedure,

gives the following

JUDGMENT

I INTRODUCTION

- 1 By an application lodged at the Court’s Registry on 16 October 2024, the EFTA Surveillance Authority (“ESA”) brought an action under 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 (“SCA”) seeking a declaration from the Court that Iceland has failed to adopt the measures necessary to make the act referred to at point 6 of Annex XVII to the Agreement on the European Economic Area (“EEA Agreement” or “EEA”) (Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products) (OJ 2019 L 153, p. 1, and Icelandic EEA Supplement 2022 No 47, p. 151) (“the Regulation”), as adapted by Protocol 1 to the EEA Agreement, part of its internal legal order, as required by Article 7 EEA.

II LEGAL BACKGROUND

- 2 Article 3 EEA reads, in extract:

The Contracting Parties shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Agreement.

They shall abstain from any measure which could jeopardize the attainment of the objectives of this Agreement.

...

- 3 Article 7 EEA reads, in extract:

Acts referred to or contained in the Annexes to this Agreement or in decisions of the EEA Joint Committee shall be binding upon the Contracting Parties and be, or be made, part of their internal legal order as follows:

(a) an act corresponding to an EEC regulation shall as such be made part of the internal legal order of the Contracting Parties;

...

- 4 Article 31 SCA reads:

If the EFTA Surveillance Authority considers that an EFTA State has failed to fulfil an obligation under the EEA Agreement or of this Agreement, it shall, unless

otherwise provided for in this Agreement, deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.

If the State concerned does not comply with the opinion within the period laid down by the EFTA Surveillance Authority, the latter may bring the matter before the EFTA Court.

- 5 Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 (OJ 2022 L 267, p. 50, and Icelandic EEA Supplement 2022 No 66, p. 48) (“JCD No 197/2022”) amended Annex XVII (Intellectual Property) to the EEA Agreement by adding the Regulation to point 6 of the Annex. Constitutional requirements were indicated by Norway. The requirements were fulfilled by 20 December 2022, and JCD No 197/2022 entered into force on 1 February 2023.

III FACTS AND PRE-LITIGATION PROCEDURE

- 6 On 22 September 2023, after prior correspondence, ESA sent a letter of formal notice to Iceland, concluding that, as Iceland had failed to take the necessary measures to make the Regulation part of its legal order, it had failed to fulfil its obligations under Article 7 EEA.
- 7 On 6 March 2024, in the absence of a response to the letter of formal notice from Iceland, ESA delivered its reasoned opinion maintaining the conclusion set out in the letter of formal notice. ESA requested Iceland to take the measures necessary to comply with the reasoned opinion within two months, i.e. no later than 6 May 2024.
- 8 Through informal communication, ESA was informed by the Icelandic Government that a draft legislative bill to implement the act as such into Iceland’s national legal order was scheduled to be presented to the Icelandic Parliament in October 2024.
- 9 On 16 October 2024, ESA decided, by way of College Decision No 170/24/COL, to bring the matter before the Court pursuant to Article 31 SCA.

IV PROCEDURE AND FORM OF ORDER SOUGHT

- 10 On 16 October 2024, ESA lodged the present application at the Court’s Registry, which was registered at the Court on the same date. ESA requests the Court to:
1. *declare that Iceland has failed to fulfil its obligations under Article 7 of the EEA Agreement by failing to make the Act referred to at point 6 of Annex XVII to the EEA Agreement (Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning, the supplementary protection certificate for medicinal products), as adapted by Protocol 1 to the EEA Agreement, part of its internal legal order, as such, and*
 2. *order Iceland to bear the costs of these proceedings.*

- 11 In its application, ESA notes that Iceland still has not made the Regulation part of its internal legal order, nor has it informed ESA of having done so.
- 12 On 18 December 2024, Iceland lodged its defence, registered at the Court on the same day, in which it submits that the facts of the case, as brought forward in the application, are correct and undisputed and that it does not dispute the declaration sought by ESA.
- 13 On 9 January 2025, the deadline for intervention expired pursuant to Article 113(1) of the Rules of Procedure (“RoP”). No applications to intervene were received.
- 14 A deadline of 20 January 2025 was set for the reply. In its reply dated 20 January 2025, registered at the Court on the same day, ESA observed that Iceland had not contested the declaration sought and emphasises that the case at hand concerns the implementation of a regulation, which under Article 7(a) EEA is to be implemented as such into the internal legal order of an EEA State. Further, ESA consented to the Court dispensing with the oral procedure should it wish to do so in the present case.
- 15 On 19 February 2025, the deadline for submitting written observations expired. No written observations were received.
- 16 On 24 February 2025, Iceland submitted its rejoinder, registered at the Court on the same day, in which it consented to the Court dispensing with the oral hearing pursuant to Article 70 RoP. In addition, Iceland informed the Court that a parliamentary bill completing the implementation of the Regulation was submitted to the Icelandic Parliament (*Alþingi*) on 15 February 2025 and is expected to be enacted during the current legislative session.
- 17 After having received the express consent of the parties, the Court, acting on a report from the Judge-Rapporteur, decided, pursuant to Article 70 RoP, to dispense with the oral procedure.

V FINDINGS OF THE COURT

- 18 Article 3 EEA imposes upon the EFTA States the general obligation to take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of the EEA Agreement (see the judgment of 2 April 2025, *ESA v Iceland*, E-21/24, paragraph 17 and case law cited).
- 19 Article 7(a) EEA provides that an act corresponding to an EU regulation, referred to in the Annexes to the EEA Agreement or a decision of the EEA Joint Committee, shall as such be made part of the internal legal order of an EEA State.
- 20 The Court notes that the lack of direct legal effect of acts referred to in decisions by the EEA Joint Committee makes timely implementation crucial for the proper functioning of the EEA Agreement. The EFTA States find themselves under an

obligation to implement regulations as such (see the judgment in *ESA v Iceland*, E-21/24, cited above, paragraph 19 and case law cited).

- 21 JCD No 197/2022 entered into force on 1 February 2023. The time limit for EFTA States to adopt the measures necessary to implement the Regulation expired on the same day.
- 22 The question of whether an EFTA State has failed to fulfil its obligations must be determined by reference to the situation as it stood at the end of the period laid down in the reasoned opinion (see the judgment in *ESA v Iceland*, E-21/24, cited above, paragraph 21 and case law cited). In this case, the relevant date is 6 May 2024.
- 23 It is undisputed that Iceland had failed to make the Regulation part of its internal legal order by the expiry of the time limit set in the reasoned opinion.
- 24 In its Reply, in response to its understanding of Iceland’s Defence, ESA argued that the requirement to incorporate regulations as such “is not simply a matter of formality or technicality, as the Icelandic Government suggests, but a substantive and integral element of the EEA Agreement”. In its Rejoinder, Iceland categorically objected to this allegation and stated that it had not made any statement which could, in good faith, be construed as trivialising the significance of the obligations of the Contracting Parties under Article 7(a) of the EEA Agreement. In this respect, the Court notes that the requirement to implement regulations as such is essential for ensuring substantive homogeneity and legal certainty.
- 25 In light of the above, it must be held that Iceland has failed to fulfil its obligations under Article 7 EEA by failing to make the Regulation, as adapted by Protocol 1 to the EEA Agreement, part of its internal legal order.

VI COSTS

- 26 Under Article 121(1) RoP, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party’s pleadings. Since ESA has requested that Iceland be ordered to pay the costs, the latter has been unsuccessful, and none of the exceptions in Article 121(2) RoP apply, Iceland must be ordered to pay the costs of the proceedings.

On those grounds,

THE COURT

hereby:

- 1. Declares that Iceland has failed to fulfil its obligations under Article 7 of the EEA Agreement by failing to make the act referred to at point 6 of Annex XVII to the EEA Agreement (Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products), as adapted by Protocol 1 to the EEA Agreement, part of its internal legal order.**
- 2. Orders Iceland to bear the costs of the proceedings.**

Páll Hreinsson

Bernd Hammermann

Michael Reiertsen

Delivered in open court in Luxembourg on 7 May 2025.

Ólafur Jóhannes Einarsson
Registrar

Páll Hreinsson
President