

Brussels, 16 October 2024  
Case No: 92995  
Document No: 1490158

**ORIGINAL**

## **IN THE EFTA COURT**

### **APPLICATION**

submitted pursuant to Article 31 (2) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by

### **THE EFTA SURVEILLANCE AUTHORITY**

represented by Sigurbjörn Bernharð Edvardsson, Sigrún Ingibjörg Gísladóttir  
and Melpo-Menie Joséphidès

Department of Legal & Executive Affairs,  
acting as Agents,

### **AGAINST**

### **ICELAND**

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.

**Table of Contents**

1	INTRODUCTION .....	3
2	PRE-LITIGATION PROCEDURE.....	3
3	LAW .....	4
4	SUBMISSIONS .....	5
5	CONCLUSION .....	5
6	SCHEDULE OF ANNEXES .....	7

## 1 INTRODUCTION

1. By this Application, the EFTA Surveillance Authority (“**ESA**”) brings an action under Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance and a Court of Justice (“**SCA**”). The Act in this application concerns a supplementary protection certificate for medicinal products.<sup>1</sup>
2. ESA seeks 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**” or “**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*) (“**the Act**”), as adapted by Protocol 1 to that Agreement, part of its internal legal order, as such, as required by Article 7 of the EEA Agreement.

## 2 PRE-LITIGATION PROCEDURE

3. On 22 September 2023, after correspondence,<sup>2</sup> ESA sent a letter of formal notice to Iceland, concluding that as Iceland had failed to take the necessary measures to make the Act part of Iceland’s legal order, as such, it had failed to fulfil its obligations under Article 7 of the EEA Agreement.<sup>3</sup>
4. The Icelandic Government did not reply to the letter of formal notice. Accordingly, ESA delivered a reasoned opinion on 6 March 2024.<sup>4</sup> Iceland was given two months in which to take the measures necessary to comply with the reasoned opinions, i.e. no later than 6 May 2024.
5. Through informal communication, the Authority was informed by the Icelandic Government that a draft legislative bill to implement the Act as such into Iceland’s national legal order is scheduled to be presented to the Icelandic Parliament in October 2024.
6. When the deadline set in the reasoned opinion expired, Iceland had neither informed ESA that it had implemented the Act, nor was ESA in the possession of any other information which indicated that the Act had been made part of Iceland’s internal legal order.

---

<sup>1</sup> This application is based on College Decision 170/24/COL (**Annex A.1** to this Application).

<sup>2</sup> Details of the prior correspondence between ESA and Iceland are set out in the letter of formal notice, see footnote 3 below.

<sup>3</sup> Document No 1392734; **Annex A.2** to this Application.

<sup>4</sup> Document No. 1435876; **Annex A.3** to this Application.

7. Since Iceland had not complied with the reasoned opinion by the deadline set therein (i.e. 6 May 2024), ESA on 16 October 2024, by Decision No 170/24/COL, decided to bring the matter before the Court pursuant to Article 31 SCA.<sup>5</sup>
8. For the sake of completeness, ESA notes that at the point of lodging the present application, Iceland has not informed ESA of any measures it has adopted to make the Act part of its internal legal order. Moreover, ESA is not in possession of any other information which indicates that the Act has been made part of Iceland's legal order.

### 3 LAW

9. Article 3, first and second paragraph, EEA provides:

*“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.”*

10. Article 7 EEA provides:

*“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.*

*[...]*“

11. Article 31 SCA provides:

*“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.”*

---

<sup>5</sup> College Decision 170/24/COL.

## 4 SUBMISSIONS

12. Article 3 EEA imposes upon the EEA 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.<sup>6</sup>
13. Under Article 7 EEA, the EEA EFTA States are obliged to implement all acts referred to in the Annexes to the EEA Agreement, as amended by decisions of the EEA Joint Committee. According to settled case-law, 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 also in Iceland. The EEA EFTA States find themselves under an obligation of result in that regard.<sup>7</sup>
14. Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 amended Annex XVII to the EEA Agreement by, *inter alia*, adding the Act. Decision No 197/2022 entered into force on 1 February 2023.<sup>8</sup> The time limit for the EEA EFTA States to adopt the measures necessary to make the Act part of their internal legal orders expired on the same day.
15. The question of whether an EEA 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.<sup>9</sup> The Icelandic Government has not thus far sought to contest ESA's assertion that Iceland had not adopted the measures necessary to make the Act a part of its internal legal order by the expiry of the time limit set in the reasoned opinion.
16. As a result, ESA submits that Iceland has failed to fulfil its obligations under Article 7 EEA, by failing to make the Act part of its internal legal order, as such.

## 5 CONCLUSION

17. Accordingly, 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*

---

<sup>6</sup> See, *inter alia*, Case E-6/18 *ESA v Iceland*, judgment of 14 May 2019, paragraph 16.

<sup>7</sup> *Ibid.*, paragraph 17.

<sup>8</sup> Constitutional requirements were indicated by Norway. The constitutional requirements were fulfilled on 20 December 2022. The confirmed entry into force of the Joint Committee Decision No 197/2022 was 1 February 2023.

<sup>9</sup> See, *inter alia*, Case E-6/06 *ESA v The Principality of Liechtenstein* [2007] EFTA Ct. Rep. 238, paragraph 20.

*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.

Sigurbjörn Bernharð Edvardsson

Sigrún Ingibjörg Gísladóttir

Mel-po-Menie Joséphidès

Agents of the EFTA Surveillance Authority

**6 SCHEDULE OF ANNEXES**

<b>No</b>	<b>Description</b>	<b>Referred to in this Application at paragraph(s)</b>	<b>Number of pages</b>
A.1	College Decision 170/24/COL	1, 7	3
A.2	Letter of Formal Notice	3	2
A.3	Reasoned Opinion	4	4