



JUDGMENT OF THE COURT

1 February 2016

*(Failure by an EEA/EFTA State to fulfil its obligations – Failure to implement –
Directive 2010/53/EU)*

In Case E-23/15,

EFTA Surveillance Authority, represented by Clémence Perrin, Officer, and Marlene Lie Hakkebo, Officer, Department of Legal & Executive Affairs, acting as Agents,

applicant,

v

The Principality of Liechtenstein, represented by Dr Andrea Entner-Koch, Director, and Frederique Lambrecht, Senior legal Officer, EEA Coordination Unit, acting as Agents,

defendant,

APPLICATION for a declaration that by failing to adopt the measures necessary to implement Articles 15 and 16 of the Act referred to at point 15zn of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, as corrected), as adapted to the Agreement by way of Protocol 1 thereto and by Joint Committee Decision No 164/2013 of 8 October 2013, within the time prescribed, the Principality of Liechtenstein has failed to fulfil its obligations under Article 31 of that Act and under Article 7 of the Agreement.

THE COURT,

composed of: Carl Baudenbacher, President, Per Christiansen and Páll Hreinsson (Judge-Rapporteur), Judges,

Registrar: Gunnar Selvik,

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 Registry on 17 August 2015, 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, by failing, within the time prescribed, to adopt the measures necessary to implement Articles 15 and 16 of the Act referred to at point 15zn of Chapter XIII of Annex II to the Agreement on the European Economic Area (“EEA”), that is Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, (OJ 2010 L 207, p. 14, as corrected by OJ 2010 L 243, p. 68) (“the Directive” or “the Act”) as adapted to the Agreement by way of Protocol 1 thereto and by Joint Committee Decision No 164/2013 of 8 October 2013 (OJ 2014 L 58, p. 17, and EEA Supplement 2014 No 13, p. 19) (“Decision No 164/2013”), Liechtenstein has failed to fulfil its obligations under Article 31 of the Act and under Article 7 EEA.

II Law

- 2 Article 3 EEA reads:

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:

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:

...

(b) an act corresponding to an EEC directive shall leave to the authorities of the Contracting Parties the choice of form and method of implementation.

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 EEA Joint Committee Decision No 164/2013 of 8 October 2013 amended Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement by adding the Directive to point 15zn of Chapter XIII of the Annex. As for Liechtenstein, the Directive should not apply to it, with the exception of Articles 15 and 16. The definitions in Article 3 and the general provisions in Articles 17(2)(h) and 23 should only apply to Liechtenstein as far as necessary for transposing Articles 15 and 16 of the Directive. Constitutional requirements were indicated by Iceland and Liechtenstein for the purposes of Article 103 EEA. By 27 May 2014 both States had notified the fulfilment of constitutional requirements. Consequently, Decision No 164/2013 entered into force on 1 July 2014. The time limit for the EEA/EFTA States to adopt the measures necessary to implement the Directive expired on the same date.

III Facts and pre-litigation procedure

6 By a letter of 9 July 2014, ESA reminded Liechtenstein of its obligation to implement the Directive. Liechtenstein did not reply to this letter.

7 On 8 October 2014, having received no further information from Liechtenstein, ESA issued a letter of formal notice, concluding that Liechtenstein had failed to fulfil its obligations under Article 31 of the Act and Article 7 EEA by failing to take, or in any event, to notify ESA of the necessary measures to ensure implementation of Articles 15 and 16 of the Act. Liechtenstein was invited to submit its observations on the content of the letter of formal notice, within two months of receipt of the letter.

- 8 On 5 December 2014, Liechtenstein replied to the letter of formal notice. In the reply, Liechtenstein informed ESA that the transposition of the Directive was ongoing and that it would be combined with the transposition of Commission Implementing Directive 2012/25/EU of 9 October 2012, laying down information procedures for the exchange, between Member States, of human organs intended for transplantation. Furthermore, Liechtenstein informed that it expected the measures to transpose the Directive to enter into force in March 2016.
- 9 On 11 February 2015, ESA delivered a reasoned opinion maintaining the conclusion set out in its letter of formal notice. Pursuant to the second paragraph of Article 31 SCA, ESA required Liechtenstein to take the necessary measures to comply with the reasoned opinion within two months following the notification, that is no later than 11 April 2015.
- 10 On 10 April 2015, Liechtenstein replied to the reasoned opinion and reiterated that it expected the measures to transpose the Directive to enter into force in March 2016.
- 11 On 15 July 2015, having received no further information, ESA decided to bring the matter before the Court pursuant to the second paragraph of Article 31 SCA.

IV Procedure and forms of order sought

- 12 ESA lodged the present application at the Court Registry on 17 August 2015. Liechtenstein's statement of defence was registered at the Court on 19 October 2015. By a letter of 27 November 2015, ESA waived its right to submit a reply and consented to dispense with the oral procedure should the Court wish to do so. By a letter of 3 December 2015, Liechtenstein also consented to dispense with the oral procedure.
- 13 The applicant, ESA, requests the Court to:
 1. *Declare that by failing to adopt the measures necessary to implement Articles 15 and 16 of the Act referred to at 15zn of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2010/53/EU of 7 July 2010 of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation, as corrected) as adapted to the Agreement by way of Protocol 1 thereto, within the time prescribed, Liechtenstein has failed to fulfil its obligations under Article 31 of that Act and under Article 7 of the EEA Agreement.*
 2. *Order Liechtenstein to bear the costs of these proceedings.*

- 14 The defendant, Liechtenstein, submits that the facts of the case as set out in the application are correct and undisputed. Liechtenstein does not contest the declaration sought by ESA. However, Liechtenstein underlines its willingness to implement the Directive as swiftly as possible. As to the costs, the Liechtenstein

Government requests the Court to order each party to pay its own costs of the proceedings.

- 15 After having received the express consent of the parties, the Court, acting on a report from the Judge-Rapporteur, decided, pursuant to Article 41(2) of the Rules of Procedure (“RoP”), to dispense with the oral procedure.

V Findings of the Court

- 16 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 (Case E-18/15 *ESA v Iceland*, judgment of 16 December 2015, not yet reported, paragraph 17 and case law cited).
- 17 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. An obligation to implement the Directive also follows from Article 31 of the Directive. 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 also in Liechtenstein. The EEA/EFTA States find themselves under an obligation of result in that regard (see, *inter alia*, *ESA v Iceland*, cited above, paragraph 18 and case law cited).
- 18 Decision No 164/2013 entered into force on 1 July 2014. The time limit for the EEA/EFTA States to adopt the measures necessary to implement the Directive expired on the same date.
- 19 The question 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 (see, *inter alia*, *ESA v Iceland*, cited above, paragraph 20 and case law cited). It is undisputed that Liechtenstein had not adopted the measures necessary to implement relevant provisions of the Directive by the expiry of the time limit set out in the reasoned opinion.
- 20 It must therefore be held that by failing, within the time prescribed, to adopt the measures necessary to implement Articles 15 and 16 of the Act referred to at point 15zn of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, as corrected), as adapted to the Agreement by way of Protocol 1 thereto, Liechtenstein has failed to fulfil its obligations under Article 31 of the Act and Article 7 EEA.

VI Costs

- 21 Under Article 66(2) 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 Liechtenstein be ordered to pay the costs, and the latter has been unsuccessful, and none of the exceptions in Article 66(3) RoP apply, Liechtenstein must therefore be ordered to pay the costs.

On those grounds,

THE COURT

hereby:

- 1. Declares that, by failing, within the time prescribed, to adopt the measures necessary to implement Articles 15 and 16 of the Act referred to at point 15zn of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, as corrected), as adapted to the Agreement by way of Protocol 1 thereto, Liechtenstein has failed to fulfil its obligations under Article 31 of that Act and under Article 7 of the EEA Agreement.**
- 2. Orders Liechtenstein to bear the costs of the proceedings.**

Carl Baudenbacher

Per Christiansen

Páll Hreinsson

Delivered in open court in Luxembourg on 1 February 2016.

Gunnar Selvik
Registrar

Carl Baudenbacher
President