

## DECISION OF THE EEA JOINT COMMITTEE

No 164/2013

of 8 October 2013

## amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

- (1) 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<sup>(1)</sup>, as corrected by OJ L 243, 16.9.2010, p. 68, is to be incorporated into the EEA Agreement.
- (2) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1*

The following is inserted after point 15zn (Commission Regulation (EC) No 668/2009) of Chapter XIII of Annex II to the EEA Agreement:

'15zn. **32010 L 0053**: 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 L 207, 6.8.2010, p. 14), as corrected by OJ L 243, 16.9.2010, p. 68.

The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptation:

This Directive shall not apply to Liechtenstein, with the exception of Articles 15 and 16. The definitions in Article 3 and general provisions in Articles 17(2)(h) and 23 shall only apply to Liechtenstein as far as necessary for transposing Articles 15 and 16 of the Directive.'

*Article 2*

The texts of Directive 2010/53/EU, as corrected by OJ L 243, 16.9.2010, p. 68 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

*Article 3*

This Decision shall enter into force on 9 October 2013, provided that all the notifications under Article 103(1) of the EEA Agreement have been made to the EEA Joint Committee (\*).

*Article 4*

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 8 October 2013.

For the EEA Joint Committee

The President

Thórir IBSEN

<sup>(1)</sup> OJ L 207, 6.8.2010, p. 14.

<sup>(\*)</sup> Constitutional requirements indicated.

**Declaration by the EFTA States to Decision No 164/2013 of 8 October 2013 incorporating 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 into the EEA Agreement**

'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, based on Article 168 of the Treaty on the Functioning of the European Union, constitutes an important part of European health legislation and corresponds to the health policy of the EFTA States. The EEA Agreement does not provide a legal basis for public health equivalent to that of Article 168 of the Treaty on the Functioning of the European Union. The incorporation of this Directive is thus without prejudice to the scope of the EEA Agreement.

This declaration is without prejudice to Article 118 of the EEA Agreement.'

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