Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

11 June 2015*

(Failure of a Member State to fulfil obligations — Public health — Directive 2004/23/EC — Directive 2006/17/EC — Directive 2006/86/EC — Exclusion of reproductive cells, foetal tissues and embryonic tissues from the scope of national legislation transposing those directives)

In Case C-29/14,

ACTION under Article 258 TFEU for failure to fulfil obligations, brought on 21 January 2014,

European Commission, represented by C. Gheorghiu and M. Owsiany-Hornung, acting as Agents, with an address for service in Luxembourg,

applicant,

v

Republic of Poland, represented by B. Majczyna, acting as Agent,

defendant,

THE COURT (Third Chamber),

composed of M. Ilešič, President of the Chamber, A. Ó Caoimh, C. Toader, E. Jarašiūnas and C.G. Fernlund (Rapporteur), Judges,

Advocate General: M. Wathelet,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 By its action, the European Commission requests the Court to declare that the Republic of Poland has failed to fulfil its obligations under Article 31 of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ

* Language of the case: Polish.

2004 L 102, p. 48), under Articles 3(b), 4(2) and 7 of, and Annex III to, Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (OJ 2006 L 38, p. 40) and under Article 11 of Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ 2006 L 294, p. 32) by excluding reproductive cells and foetal and embryonic tissue from the scope of the provisions of national law transposing those directives.

Legal context

EU law

Directive 2004/23

2 Recitals 1, 2 and 4 in the preamble to Directive 2004/23 are worded as follows:

‘(1) The transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases.

(2) The availability of human tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use.

…

(4) There is an urgent need for a unified framework in order to ensure high standards of quality and safety with respect to the procurement, testing, processing, storage and distribution of tissues and cells across the Community and to facilitate exchanges thereof for patients receiving this type of therapy each year. It is essential, therefore, that Community provisions ensure that human tissues and cells, whatever their intended use, are of comparable quality and safety. The establishment of such standards, therefore, will help to reassure the public that human tissues and cells that are procured in another Member State, nonetheless carry the same guarantees as those in their own country.’

3 According to recital 7 in the preamble to that directive, the latter should ‘apply to … reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells’.

4 Article 31 of Directive 2004/23, entitled ‘Transposition’, provides:

‘1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 7 April 2006. They shall forthwith inform the Commission thereof.

When Member States adopt these measures they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

…

3. Member States shall communicate to the Commission the texts of the provisions of national law that they have already adopted or which they adopt in the field governed by this Directive.'

Directive 2006/17

5 Article 3 of Directive 2006/17 provides:

'The competent authority or authorities shall ensure that donors comply with the selection criteria set out in:

…

(b) Annex III for donors of reproductive cells.'

6 Article 4 of that directive, entitled 'Laboratory tests required for donors', provides in paragraph 2:

'The competent authority or authorities shall ensure that:

(a) donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Annex III;

(b) the tests referred to in point (a) above are carried out in compliance with the general requirements set out in point 4 of Annex III.'

7 Under Article 7 of that directive, entitled 'Transposition':

'1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 November 2006, at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.'

8 Annex III to Directive 2006/17 lays down the selection criteria and laboratory tests required for donors of reproductive cells as referred to in Article 3(b) and Article 4(2) of that directive.

Directive 2006/86

9 Article 10 of Directive 2006/86, entitled 'European coding system', provides:

'1. A single European identifying code shall be allocated to all donated material at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and to provide information on the main characteristics and properties of tissues and cells. The code shall incorporate at least the information set out in Annex VII.

2. Paragraph 1 shall not apply to partner donation of reproductive cells.'

10 Article 11 of that directive, entitled 'Transposition', provides:

'1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 September 2007, at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 10 of this Directive, by 1 September 2008.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.'

Polish law

11 The directives at issue were transposed into the Polish internal legal order principally by the Law relating to the removal, storage and transplantation of cells, tissues and organs (ustawa o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów) of 1 July 2005 (Dz. U. 2005, No 169, position 1411), as subsequently amended ('the principal transposing act').

12 Article 1(2)(1) of the principal transposing act provides that it does not apply to 'the removal and transplantation of reproductive cells, gonads, foetal tissues, embryonic tissues and reproductive organs and the elements thereof'.

13 The Republic of Poland also adopted, on the basis of the principal transposing act, a series of implementing acts, including several orders of the Minister for Health, designed also to transpose into Polish law the majority of the provisions of the directives at issue ('the implementing acts'). Those implementing acts also do not apply to the removal and transplantation of the cells and tissues referred to in paragraph 12 of the present judgment.

Pre-litigation procedure

14 After establishing that the principal transposing act applied neither to reproductive cells nor to foetal and embryonic tissues ('the tissues and cells at issue'), the Commission, by letters of 14 February 2008 and 23 February 2009, requested the Republic of Poland to provide clarification as to what the Commission considered to be an incomplete transposition, in the internal legal order, of the directives at issue and as to the progress in regard to the full transposition of those directives.

15 In its replies to those letters, the Republic of Poland, first, confirmed that the principal transposing act excluded the tissues and cells at issue from its scope and, secondly, informed the Commission of the existence of a draft amendment to that act which was designed to ensure the full transposition of those directives.

16 As the Republic of Poland failed to send to the Commission either the text of that draft amendment or the legislative timetable relating thereto, the Commission, on 1 October 2010, sent a letter of formal notice to the Republic of Poland. On 28 February 2012, an additional letter of formal notice was

received by that Member State, intended to correct a mistake in the first letter of formal notice concerning a reference to the types of tissues and cells excluded from the scope of the principal transposing act.

17 In the meantime, the Republic of Poland sent to the Commission information concerning the legislative timetable relating to a draft law concerning *in vitro* fertilisation. That timetable was not respected.

18 In its reply of 27 April 2012 to the additional letter of formal notice, the Republic of Poland sent to the Commission the text of a draft law amending the principal transposing act, which extended the scope thereof, as well as nine draft implementation orders and an indicative timetable concerning the entry into force of those implementation orders. The time-limits set out in that timetable were also not respected.

19 On 25 January 2013, the Commission sent a reasoned opinion to the Republic of Poland, requesting the latter to take the measures necessary to fulfil, within two months, its obligations under the directives at issue.

20 By letter of 20 March 2013, the Republic of Poland replied to the reasoned opinion by stating that the detailed rules relating to the tissues and cells at issue were still in the process of being drafted.

21 In those circumstances, the Commission decided to bring the present action.

The action

Arguments of the parties

22 The Commission contends that the transposition of the directives at issue into Polish law is incomplete, in view of the fact that the texts adopted by the Republic of Poland with a view to ensuring that transposition exclude the tissues and cells at issue from their scope. Moreover, by stating that the provisions of those directives are, as regards the tissues and cells at issue, to a large extent applied in daily clinical practice, the Republic of Poland implicitly but necessarily acknowledges that the implementation of those provisions in the internal legal order is merely partial. In any event, according to the Commission, it cannot be disputed that clear and precise binding acts ensuring the full transposition of those directives did not enter into force within the period laid down in the reasoned opinion.

23 The Republic of Poland disputes the alleged failure and contends that the Commission has not established the existence of such a failure.

24 The Republic of Poland contends that, despite the exclusion of the tissues and cells at issue from the scope of the principal transposing act, the legislation in force in the internal legal order guarantees, as regards those tissues and cells, a correct and proper implementation of the obligations under the directives at issue. In order to substantiate that claim, it invokes the existence of approximately 20 acts, including laws regulating the medical professions, the provision of certain types of health care, laboratory medicine, the rights of patients, and the protection of personal data, as well as various orders of the Minister for Health, a programme adopted by that Minister entitled ‘Treatment of infertility by *in vitro* fertilisation for the period 2013–2016’, and a number of rules adopted by national organisations of medical practitioners.

25 In that regard, the Republic of Poland contends that the objectives defined by the directives at issue must be fulfilled by professional organisations responsible for providing medical care and which must be subject to appropriate rules. Consequently, in contrast to the situation of directives which seek to create specific rights for individuals and the implementation of which requires the adoption of a single act having legislative force, it is permissible to ensure the effectiveness of the directives at issue by means of rules in the medical field, including non-legislative rules adopted by national organisations of medical practitioners. Furthermore, those medical rules, even if they do not have legislative force, are sufficiently incorporated into the Polish legal system, as is evident from the fact that the Law on the medical and dental professions obliges medical and dental practitioners to exercise their profession in compliance with rules of good practice and due diligence, or the fact that medical practitioners may be subject to criminal and disciplinary liability in cases where they fail to comply with those medical rules.

26 The Commission considers that the arguments set out by the Republic of Poland before the Court are at variance with those which that Member State presented in the context of the pre-litigation procedure. The latter, according to the Commission, has failed to explain how the transposition of the directives at issue by means of a specific law, namely the principal transposing act, was necessary for certain tissues and cells, and not for others. In any event, on the assumption that the transposition, as regards the tissues and cells at issue, could have been effectively carried out on the basis of specific provisions or by means of the 'general legal context', the express exclusion of those tissues and cells from the scope of the principal transposing act and the absence of specific rules in their regard results in a situation of manifest legal uncertainty.

27 The Commission takes issue with the contention that the acts referred to by the Republic of Poland in its defence, and which, moreover, were not communicated to the Commission in the context of the pre-litigation procedure, were capable of ensuring appropriate transposition of the directives at issue. In particular, neither the programme adopted by the Minister for Health relating to the 'Treatment of infertility by *in vitro* fertilisation for the period 2013–2016' nor the algorithms, proposals, recommendations, requirements, guidelines or information formulated by organisations which are not authorised to adopt legal acts could be classified as mandatory provisions.

28 Moreover, the Commission claims that the Republic of Poland has not shown that its general legal context guarantees effectively that the directives at issue will be applied in a manner which is sufficiently clear and precise.

29 In the alternative, the Commission responds to the arguments of the Republic of Poland relating to the transposition of each of the directives at issue in order to reject their relevance. Essentially, the Commission submits that the acts relied upon by that Member State for the purpose of maintaining that it had duly fulfilled the obligations resulting from those directives either are not appropriate in scope or do not contain binding rules genuinely corresponding to the specific requirements of those directives.

30 With regard to the Commission's argument that the transposing acts invoked by the Republic of Poland in its defence do not constitute mandatory provisions, that Member State replies that it is necessary to distinguish between, on the one hand, administrative practice, which may be freely amended and is not always properly disseminated, and, on the other hand, the procedures defined by means of medical rules, which function as a body of written rules based on scientific foundations and the application and validity of which are widely acknowledged by the medical profession and by patients. Those rules, the Republic of Poland submits, constitute a written frame of reference for procedures applicable to all persons involved in the provision of health care services and may, in principle, be amended only in accordance with developments in medical science. Thus, contrary to what is claimed by the Commission, those rules could not be treated as amounting to a mere administrative practice and regarded as lacking, in themselves, all binding character. Moreover, the programme of the Minister for Health entitled 'Treatment of infertility by *in vitro* fertilisation for the

period 2013–2016' has an express legislative basis and provides for the organisation of actions in line with a defined plan setting priorities in the context of the development of solutions in the field of health protection.

Findings of the Court

31 It must be noted at the outset that the Republic of Poland does not contest the fact that the principal transposing act and the implementing acts, which sought to implement the directives at issue in Polish law, failed to ensure the transposition of the provisions of those directives in so far as they concern the tissues and cells at issue. By contrast, it contends, in essence, that the transposition of those provisions in that regard was ensured by means of a body of texts issued by the legislative authority, the regulatory authority or even national organisations of medical practitioners.

32 In that regard, it should be noted that the Republic of Poland referred to those transposition measures for the first time at the stage of the defence, a fact which cannot be reconciled with the duty of sincere cooperation imposed on Member States under Article 4(3) TEU (see, to that effect, judgment in *Commission* v *Spain*, C-151/12, EU:C:2013:690, paragraph 49).

33 The Court has already held that, while, in proceedings under Article 258 TFEU for failure to fulfil obligations, it is incumbent on the Commission to place before the Court the information needed to enable the Court to establish that an obligation has not been fulfilled, it is also incumbent on the Member States, pursuant to Article 4(3) TEU, to facilitate the achievement of the Commission's tasks. Moreover, the information concerning the transposition of a directive which the Member States are obliged to provide to the Commission must be clear and precise, and it must unequivocally indicate the legislative, regulatory and administrative measures by which the Member State considers that it has fulfilled the various obligations imposed on it by the directive. In the absence of such information, the Commission is not in a position to determine whether the Member State has genuinely and fully implemented the directive. The failure of a Member State to fulfil that obligation, whether by providing no information at all or by providing insufficiently clear and precise information, may of itself justify recourse to the procedure under Article 258 TFEU in order to establish that failure to fulfil the obligation (see, to that effect, judgment in *Commission* v *Italy*, C-456/03, EU:C:2005:388, paragraphs 26 and 27).

34 In the present case, however, it should be noted that, although the transposition measures invoked by the Republic of Poland at the stage of the defence were not mentioned by it during the pre-litigation procedure, the present action concerns, not a failure to fulfil the obligation to provide information, but a failure to fulfil the obligation to transpose the directives at issue into Polish national law, with respect to the tissues and cells at issue. It follows that the mere fact that the Republic of Poland failed to inform the Commission, during the pre-litigation procedure, that, in its opinion, those directives had already been fully transposed into the national law in force cannot suffice to establish the alleged failure to fulfil obligations (see, to that effect, judgment in *Commission* v *Poland*, C-478/13, EU:C:2014:2253, paragraph 33 and the case-law cited).

35 As a consequence, in so far as the measures invoked by the Republic of Poland in its defence were in force when the period laid down by the reasoned opinion expired, the Court must take them into account when determining whether that obligation has not been fulfilled (judgment in *Commission* v *Poland*, C-478/13, EU:C:2014:2253, paragraph 34 and the case-law cited).

36 In the present case, it is apparent from the documents in the file that all of those acts, with the exception of the order of the Minister for Health of 14 June 2013 establishing a register of medically assisted procreation, were in force at the end of the period laid down by the reasoned opinion. It is

therefore necessary to establish whether those acts may be considered to have ensured transposition of the directives at issue, as regards the tissues and cells at issue, as is claimed by the Republic of Poland.

37 In that regard, it follows from settled case-law that the provisions of a directive must be implemented with unquestionable binding force, and with the specificity, precision and clarity necessary to satisfy the requirements of legal certainty (see, inter alia, judgment in *Commission* v *Greece*, C-81/07, EU:C:2008:172, paragraph 19 and the case-law cited). That principle of legal certainty requires appropriate publicity for the national measures adopted pursuant to EU rules in such a way as to enable the persons concerned by such measures to ascertain the scope of their rights and obligations in the particular area governed by EU law (judgment in *Commission* v *Belgium*, C-415/01, EU:C:2003:118, paragraph 21).

38 It is none the less the case that, according to the actual wording of the third paragraph of Article 288 TFEU, Member States may choose the form and methods for implementing directives which best ensure the result which they seek to achieve. It is also apparent from that provision that the transposition of a directive into national law does not necessarily require legislative action in each Member State. Thus, it is not always necessary formally to enact the requirements of a directive in a specific express legal provision, since the general legal context may be sufficient for implementation of a directive, depending on its content. In particular, the existence of general principles of constitutional or administrative law may render superfluous transposition by specific legislative or regulatory measures, provided, however, that those principles actually ensure the full application of the directive by the national administrative authorities and that, where the relevant provision of the directive seeks to create rights for individuals, the legal situation arising from those principles is sufficiently precise and clear and that the persons concerned are placed in a position to know the full extent of their rights and obligations and, where appropriate, to be able to invoke them before the national courts (see, inter alia, judgment in *Commission* v *France*, C-296/01, EU:C:2003:626, paragraph 55 and the case-law cited).

39 It is necessary to examine the Commission's complaint in the light of that case-law.

40 First of all, the Court has already held that it is necessary in every case to determine the nature of the provisions of a directive to which infringement proceedings relate, in order to assess the extent of the obligation as to transposition which is imposed on the Member States (judgment in *Commission* v *Luxembourg*, C-32/05, EU:C:2006:749, paragraph 36).

41 In the present case, it should be noted that the directives at issue are characterised by their highly technical nature and by the fact that they impose very specific obligations on the Member States with a view to ensuring a high level of protection of public health.

42 The Republic of Poland nevertheless contends that the general legal context existing in Poland is sufficient to permit attainment of the objectives pursued by those directives and emphasises, in its rejoinder, that the provisions in those directives relating to the tissues and cells at issue do not create rights for patients but seek to ensure their safety and protection when those tissues and cells are being handled. In that regard, that Member State contends that, from the point of view of safeguarding the legal interests of patients, it is above all necessary that, on the basis of national legislation, they should have at their disposal sufficient means in the event that their rights and safety are adversely affected.

43 It follows from recitals 1, 2 and 4 in the preamble to Directive 2004/23 that the directives at issue, taken together, seek to ensure a high level of protection of public health, in so far as they are intended to create a unified framework in order to ensure high standards of quality and safety with respect to the procurement, testing, processing, storage and distribution of human tissues and cells, in order, inter alia, to prevent the transmission of diseases.

44 The directives at issue also seek to impose a number of specific obligations on persons and establishments which use human tissues and cells covered by those directives. In that regard, Article 27 of Directive 2004/23 provides that the national provisions adopted pursuant to that directive must provide for a system of effective, proportionate and dissuasive penalties.

45 In the present case, it is common ground that the principal transposing act expressly excludes the tissues and cells at issue from its scope, that gap being, however, according to the Republic of Poland, filled by the existence of several acts which are already in force within the national legal order.

46 However, it should be noted that some of those acts amount, according to their actual titles, to no more than 'guidelines' or 'recommendations' and do not therefore have the unquestionable binding force required by the case-law referred to in paragraph 37 of the present judgment.

47 In addition, it is apparent from the pleadings lodged by the Republic of Poland before the Court that the acts relied upon by that Member State in order to claim that it duly transposed the directives at issue vary in their legal nature and include both non-binding acts and provisions of general application in the fields of criminal and civil law. In the light of the specific scope of the obligations imposed by the directives at issue and the objective of protecting public health which they pursue, the transposition of those directives by a multitude of acts combined with the exclusion of certain types of tissues and cells from the scope of the principal transposing act, even though those tissues and cells are covered by those directives, fails to satisfy the requirements of specificity, precision and clarity resulting from the case-law referred to in paragraph 37 of the present judgment. In those circumstances, the individuals concerned by the unified framework provided for by the directives at issue are not in a position, on the basis of those acts alone, to know the full extent of their rights and obligations with the legal certainty required by the Court's case-law.

48 It must therefore be held that the Republic of Poland has failed to show that a transposition of those directives by the adoption of specific legislative or regulatory measures would have been superfluous with regard to the tissues and cells at issue.

49 Finally, it was in any event necessary for the Republic of Poland to adopt specific transposition measures given that Article 31 of Directive 2004/23, Article 7 of Directive 2006/17 and Article 11 of Directive 2006/86 expressly require Member States to ensure that their measures transposing those directives include a reference to them or that such reference is made when they are officially published (see, to that effect, judgment in *Commission* v *Spain*, C-360/95, EU:C:1997:624, paragraph 13).

50 In the present case, it must be noted that, with respect to the tissues and cells at issue, the Republic of Poland has failed to fulfil that obligation.

51 In the light of all of the foregoing, it must be held that, by excluding reproductive cells and foetal and embryonic tissue from the scope of the provisions of national law transposing the directives at issue, the Republic of Poland has failed to fulfil its obligations under Article 31 of Directive 2004/23, under Articles 3(b), 4(2) and 7 of, and Annex III to, Directive 2006/17, and under Article 11 of Directive 2006/86.

Costs

52 Under Article 138(1) of the Rules of Procedure of the Court of Justice, the unsuccessful party must be ordered to pay the costs if they have been applied for in the other party's pleadings. Since the Commission has applied for costs and the Republic of Poland has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds, the Court (Third Chamber) hereby:

1. **Declares that the Republic of Poland has failed to fulfil its obligations under Article 31 of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, under Articles 3(b), 4(2) and 7 of, and Annex III to, Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, and under Article 11 of Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, by excluding reproductive cells and foetal and embryonic tissue from the scope of the provisions of national law transposing those directives;**

2. **Orders the Republic of Poland to pay the costs.**

[Signatures]