

**Judgment of the Court (Fifth Chamber) of 17 December 2009 — Commission of the European Communities v Kingdom of Belgium**

(Case C-120/09) <sup>(1)</sup>

*(Failure of a Member State to fulfil obligations — Directive 1999/31/EC — Landfilling of waste — Concept of ‘underground storage’, of ‘landfill gas’ and ‘eluate’ — Obligation to determine the trigger levels from which it can be considered that the location of the landfill has a significant adverse effect on groundwater quality — Failure to transpose within the prescribed time limit with regard to the Walloon Region)*

(2010/C 51/18)

Language of the case: French

**Parties**

*Applicant:* Commission of the European Communities (represented by: M. van Beek and J.-B. Laignelot, Agents)

*Defendant:* Kingdom of Belgium (represented by T. Materne, Agent)

**Re:**

Failure of a Member State to fulfil obligations — Failure to transpose fully into Walloon law Article 2(f), (j) and (k) of, and point 4C of Annex III to, Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ 1999 L 182, p. 1) — Concept of ‘underground storage’, of ‘landfill gas’ and ‘eluate’- Obligation to determine the trigger levels from which it can be considered that the location of the landfill has a significant adverse effect on groundwater quality

**Operative part of the judgment**

1. By failing to ensure the transposition with regard to the Walloon Region of Article 2(f), (j) and (k) of, and point 4C of Annex III to, Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, the Kingdom of Belgium has failed to fulfil its obligations under that directive.
2. The Kingdom of Belgium shall bear the costs.

<sup>(1)</sup> OJ C 141 of 20.06.2009

**Order of the Court (Seventh Chamber) of 9 November 2009 (References for a preliminary ruling from the Tribunale Amministrativo Regionale del Lazio (Italy)) — Roche SpA (C-450/07), Federazione nazionale unitaria dei Titolari di Farmacia italiani (Federfarma) (C-451/07) v Agenzia Italiana del Farmaco (AIFA), Ministero della Salute**

(Joined Cases C-450/07 and C-451/07) <sup>(1)</sup>

*(First subparagraph of Article 104(3) of the Rules of Procedure — Directive 89/105/EEC — Transparency of measures regulating the prices of medicinal products for human use — Article 4 — Price freeze — Price reduction)*

(2010/C 51/19)

Language of the case: Italian

**Referring court**

Tribunale Amministrativo Regionale del Lazio

**Parties to the main proceedings**

*Applicant:* Roche SpA

*Defendants:* Agenzia Italiana del Farmaco (AIFA), Ministero della Salute

**Re:**

Reference for a preliminary ruling — Tribunale Amministrativo Regionale del Lazio — Interpretation of Article 4(1) and (2) of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ 1989 L 40, p. 8) — Price freeze imposed on medicinal products — Procedures to follow in the case of a price reduction

**Operative part**

1. Article 4(1) of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems is to be interpreted as meaning that, provided the requirements laid down by that provision are met, the competent authorities of a Member State may adopt general measures reducing the prices of all, or of certain categories of, medicinal products, even if the adoption of those measures is not preceded by a freeze on those prices.
2. Article 4(1) of Directive 89/105 is to be interpreted as meaning that, provided the requirements laid down by that provision are met, the adoption of measures reducing the prices of all, or of certain categories of, medicinal products is possible more than once a year and for several years.

3. Article 4(1) of Directive 89/105 is to be interpreted as meaning that it does not preclude measures controlling the prices of all, or of certain categories of, medicinal products from being adopted on the basis of predicted expenditure, provided that the requirements laid down by that provision are met and that the predictions are based on objective and verifiable data.
4. Article 4(1) of Directive 89/105 is to be interpreted as meaning that it is for the Member States to determine, in compliance with the objective of transparency pursued by that directive and the requirements laid down by that provision, the criteria on the basis of which the review of the macro-economic conditions referred to in that provision is to be conducted and that those criteria may consist in pharmaceutical expenditure alone, in health expenditure overall or even in other types of expenditure.
5. Article 4(2) of Directive 89/105 is to be interpreted as meaning that:
- the Member States must, in all cases, provide for the possibility for an undertaking, which is concerned by a measure freezing or reducing the prices of all, or of certain categories of, medicinal products, of applying for a derogation from the price imposed pursuant to such measure;
  - they are to ensure that a reasoned decision on any such application is adopted, and
  - the genuine participation of the undertaking concerned consists, first, in the submission of an adequate statement of the particular reasons justifying its application for derogation and, second, in the provision of detailed additional information if the information supporting the application is inadequate.

(<sup>1</sup>) OJ C 297, 8.12.2007.

**Order of the Court of 24 November 2009 — Landtag Schleswig-Holstein v Commission of the European Communities**

(Case C-281/08 P) (<sup>1</sup>)

**(Appeal — Action for annulment — Access to documents — Capacity of a regional parliament to be a party to legal proceedings)**

(2010/C 51/20)

Language of the case: German

**Parties**

Appellant: Landtag Schleswig-Holstein (represented by: S.R. Laskowski, Privatdozentin, and J. Caspar, Professor)

Other party to the proceedings: Commission of the European Communities (represented by: P. Costa de Oliveira and B. Mertenczuk, acting as Agents)

**Re:**

Appeal brought against the order of the Court of First Instance (Second Chamber) of 3 April 2008 in Case T-236/06 *Landtag Schleswig-Holstein v Commission*, by which the Court rejected as inadmissible an application for annulment of the Commission's decisions of 10 March 2006 and 23 June 2006 refusing to grant the applicant access to the document SEK(2005) 420, of 22 March 2005 containing a legal analysis of a draft framework decision, under discussion in the Council, on the retention of data processed and stored in relation to the provision of publicly available electronic communications services or of data transmitted by means of the public communications networks, for purposes of the prevention, investigation, detection and prosecution of crime and criminal offences, including terrorism — Capacity of a regional parliament to be a party to legal proceedings — Right to be heard before a court — Notion of 'legal person' in the fourth paragraph of Article 230 EC

**Operative part of the order**

1. The appeal is dismissed.
2. The Landtag Schleswig-Holstein is ordered to pay the costs.

(<sup>1</sup>) OJ C 260, 11.10.2008.

**Order of the Court (Seventh Chamber) of 9 November 2009 (reference for a preliminary ruling from the Tribunale Amministrativo Regionale del Lazio — Italy) — A. Menarini — Industrie Farmaceutiche Riunite Srl, FIRMA Srl, Laboratori Guidotti SpA, Menarini International Operations Luxembourg SA, Istituto Lusofarmaco d'Italia SpA, Malesi Istituto Farmacobiologico SpA v Ministero della Salute, Agenzia Italiana del Farmaco (AIFA)**

(Case C-353/08) (<sup>1</sup>)

**(First subparagraph of Article 104(3) of the Rules of Procedure — Directive 89/105/EEC — Transparency of measures regulating the prices of medicinal products for human use — Article 4(1) — Price freeze — Price reductions)**

(2010/C 51/21)

Language of the case: Italian

**Referring court**

Tribunale Amministrativo Regionale del Lazio