2. *Industrias Químicas del Vallés, SA shall bear the costs.*

(1) OJ C 254, 3.8.2015.

Action brought on 26 January 2016 — TestBioTech v Commission

(Case T-33/16)

(2016/C 136/51)

Language of the case: English

Parties

Applicant: TestBioTech eV (Munich, Germany) (represented by: K. Smith, QC, J. Stevenson, Barrister, R. Stein, Solicitor)

Defendant: European Commission

Form of order sought

The applicant claims that the Court should:

— declare the application admissible and well-founded;

— annul the Commission's decision dated 16 November 2015, which rejected the applicant's request for internal review of the Commission implementing decisions (EU) 2015/686 ([1]), (EU) 2015/696 ([2]) and (EU) 2015/698 ([3]) of 24 April 2015 granting three market authorisations under Regulation (EC) No 1829/2003 ([4]) (the 'GM Regulation') to Monsanto or Pioneer for their genetically modified soybeans MON 87769, MON 87705 and/or 305423;

— order the defendant to pay the applicant's costs; and

— order any other measure deemed appropriate.

Pleas in law and main arguments

In support of the action, the applicant relies on two pleas in law.

1. First plea in law, alleging that the Commission's conclusion that the vast majority of the request for internal review related to matters falling outside the scope of the Aarhus Regulation ([5]) violates Article 10(1) read in conjunction with Articles 2(f) and (g) and Recitals (11) and (18) to (21) of that Regulation.

   — A qualifying non-governmental organisation is entitled to make a request for internal review of an administrative act made under an environmental law. The GM Regulation is such a law. As a consequence, the organisation may request a review of any administrative act made under that law, including a market authorisation.

   — Taking into account both the terms and object and purpose of the United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters of 25 June 1998 (the 'Aarhus Convention') and the Aarhus Regulation, as well as the Aarhus Convention's implementation guide, there is no basis for the Commission's conclusions that it can carve up decisions made under the GM Regulation as being partly in-scope and outside the scope of the Aarhus Regulation.

   — Genetically modified organisms are elements of the environment. The Commission's argument that the impact of such organisms on human health is not an environmental matter and therefore not covered by the Aarhus Regulation is fundamentally flawed.

2. Second plea in law, alleging that the Commission's failure to respond to the request for internal review, submitted on 29 May 2015, before 16 November 2015 violated Article 10(3) of the Aarhus Regulation.

— The Commission issued the contested decision on 16 November 2015, some twenty-four weeks after the request for internal review was submitted. The Commission failed to provide an adequate explanation for breaching the normal requirement that a response be provided within twelve weeks and, in any event, failed to meet the absolute deadline for responding within eighteen weeks.

(1) Commission implementing decision (EU) 2015/686 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003 (OJ 2015 L 112, p. 16).
(2) Commission implementing decision (EU) 2015/696 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87705 (MON-877Ø5-6) pursuant to Regulation (EC) No 1829/2003 (OJ 2015 L 112, p. 60).
(3) Commission implementing decision (EU) 2015/698 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 (OJ 2015 L 112, p. 71).
(4) Regulation of the European Parliament and of the Council (EC) No 1829/2003 of 22 September 2003 on genetically food and feed (OJ 2003 L 268, p. 1).
(5) Regulation of the European Parliament and of the Council (EC) No 1367/2006 of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ 2006 L 264, p. 13).

Action brought on 23 February 2016 — Shire Pharmaceuticals Ireland v EMA

(Case T-80/16)

(2016/C 136/52)

Language of the case: English

Parties

Applicant: Shire Pharmaceuticals Ireland Ltd (Dublin, Ireland) (represented by: D. Anderson, QC, M. Birdling, Barrister, G. Castle and S. Cowlishaw, Solicitors)

Defendant: European Medicines Agency

Form of order sought

The applicant claims that the Court should:

— annul the decision of the European Medicines Agency dated 15 December 2015 and communicated to the applicant on 18 December 2015 refusing to validate an application pursuant to Regulation (EC) No 141/2000 (1) for designation as an orphan medicinal product; and

— order the defendant to pay the applicant's costs.

Pleas in law and main arguments

In support of the action, the applicant relies on one plea in law, alleging that the contested decision erred in its interpretation and application of Regulation (EC) No 141/2000. The applicant contends that the defendant:

— misapplied Article 5 of Regulation (EC) No 141/2000 by failing to appreciate the procedural nature of the validation process;

— should not have concluded that the conditions for designation were not (or could not be) established;

— erroneously elided the concepts of 'medicinal product' and 'active substance' contrary to Articles 3 and 5 of Regulation (EC) No 141/2000;