

**Request for a preliminary ruling from the Bayerischer Verwaltungsgerichtshof (Germany) lodged on 26 September 2014 — Davitas GmbH v Stadt Aschaffenburg**

(Case C-448/14)

(2014/C 448/10)

*Language of the case: German*

**Referring court**

Bayerischer Verwaltungsgerichtshof

**Parties to the main proceedings**

*Appellant:* Davitas GmbH

*Respondent:* Stadt Aschaffenburg

*Intervener:* Landesanstalt für Lebensmittelsicherheit Bayern

**Questions referred**

Is the product 'De Tox Forte' which is marketed by the appellant a food or a food ingredient with a new molecular structure within the meaning of Article 1(2)(c) of Regulation (EC) No 258/97 <sup>(1)</sup>?

In particular, does it suffice, in order to be able to answer this question in the affirmative, that that product, which contains the substance clinoptilolite in its particular primary molecular structure, was not yet being used as a food prior to 15 May 1997, or does that product, in addition, have to be produced via the production process by means of a procedure which results in a new or intentionally modified molecular structure, which means that it must be a substance which did not previously exist naturally in that form?

<sup>(1)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1).

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**Request for a preliminary ruling from the Consiglio di Stato (Italy) lodged on 29 September 2014 — Agenzia Italiana del Farmaco (AIFA), Ministry for Health v Doc Generici srl**

(Case C-452/14)

(2014/C 448/11)

*Language of the case: Italian*

**Referring court**

Consiglio di Stato

**Parties to the main proceedings**

*Applicants:* Agenzia Italiana del Farmaco (AIFA), Ministry for Health

*Defendant:* Doc Generici srl

**Questions referred**

1. Must Article 3(2)(a) of Council Regulation (EC) No 297/95 of 10 February 1995 <sup>(1)</sup>, in the version currently in force, be interpreted as meaning that Type I marketing authorisation variations — and, in particular, in respect of the case in the main proceedings, Type IA variations — where an identical variation affecting several authorisations belonging to the same holder are concerned, are subject to a single fee, to the extent specified therein, or to as many fees as there are authorisations affected by the variation?

2. In the circumstances in the present proceedings, may or must, as held by this Chamber, the question be referred to the Court of Justice?

<sup>(1)</sup> Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ 1995 L 35, 15.2.1995, p. 1).

**Action brought on 30 September 2014 — European Commission v Kingdom of Spain**

**(Case C-454/14)**

(2014/C 448/12)

*Language of the case: Spanish*

**Parties**

*Applicant:* European Commission (represented by: L. Pignataro-Nolin, E. Sanfrutos Cano and D. Loma-Osorio Lerena, acting as Agents)

*Defendant:* Kingdom of Spain

**Form of order sought**

The applicant claims that the Court should:

- declare that, by failing to adopt, for each of the landfill sites identified in point 26 of the present application (non-hazardous waste landfills in Urtuella in the Basque Country, and in Zurita and Juan Grande in the Canary Islands), the measures necessary to request the relevant operator to prepare a conditioning plan and ensure full implementation of that plan in accordance with the requirements of the directive, with the exception of those listed in Annex I, point 1, within eight years after the date laid down in Article 18(1) of Council Directive 1999/31/EC <sup>(1)</sup> of 26 April 1999 on the landfill of waste, the Kingdom of Spain has failed to fulfil its obligations under Article 14(c) of the directive in relation to each of the landfill sites listed.
- declare that, by failing to adopt, for each of the landfill sites identified in point 37 of the present application (9 non-hazardous waste landfills (Vélez Rubio (Almería), Alcolea de Cinca (Huesca), Sariñena (Huesca), Tamarite de Litera (Huesca), Somontano — Barbastro (Huesca), Barranco de Sedases (Fraga, Huesca), Barranco Seco (Puntallana, La Palma), Jumilla (Murcia) y Legazpia (Guipuzkoa)) and 19 inert waste landfills (Sierra Valleja (Arcos de la Frontera, Cádiz), Carretera Pantano del Rumblar (Baños de la Encina, Jaén), Barranco de la Cueva (Bélmez de la Moraleda, Jaén), Cerrajón (Castillo de Locution, Jaén), Las Canters (Jimena y Bed mar, Jaén), Hoya del Pine (Siles, Jaén), Bella vista (Finca El Coronel, Alcalá de Guadaira, Sevilla), El Patarín (Alcalá de Guadaira, Sevilla), Carretera de Arahal-Morón de la Frontera (Arahal, Sevilla), Carretera de Almadén de la Plata (Cazalla de la Sierra, Sevilla), El Chaparral (Écija, Sevilla), Carretera A-92, KM 57,5 (Morón de la Frontera, Sevilla), Carretera 3118 Fuente Leona — Cumbres mayores (Colina Barragona, Huelva), Llanos del Campo (Grazalema — Benamahoma, Cádiz) Andrada Baja (Alcalá de Guadaira, Sevilla), Las Zorreras (Aldeira, Granada), Carretera de los Villares (Andújar, Jaén) La Chacona (Cabra, Córdoba) and el Chaparral — La Sombrerera (Puerto Serrano, Cádiz))), the measures necessary to close as soon as possible, pursuant to Article 7(g) and Article 13 of Directive 1999/31, the sites which had not been granted, under Article 8 of that directive, a permit to continue to operate, the Kingdom of Spain has failed to fulfil its obligations in respect of each of the landfills listed in Article 14(b) of the directive.
- order the Kingdom of Spain to pay the costs.