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: Landesanwaltschaft 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 ([1])?

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?

([1]) 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).

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 ([1]), 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?