



Reports of Cases

Case C-282/15

Queisser Pharma GmbH & Co. KG
v
Bundesrepublik Deutschland

(Request for a preliminary ruling
from the Verwaltungsgericht Braunschweig)

(Reference for a preliminary ruling — Free movement of goods — Articles 34 TFEU to 36 TFEU — Purely domestic situation — Food safety — Regulation (EC) No 178/2002 — Article 6 — Principle of risk analysis — Article 7 — Precautionary principle — Regulation (EC) No 1925/2006 — Member State legislation prohibiting the manufacture and sale of food supplements containing amino acids — Situation in which a temporary derogation to that prohibition is at the discretion of the national authority)

Summary — Judgment of the Court (Fourth Chamber), 19 January 2017

Approximation of laws — Food safety — Regulation No 178/2002 — Risk assessment and application of the precautionary principle — Adoption, without a comprehensive risk analysis, of national legislation prohibiting the manufacturing and marketing of certain food supplements — No possibility to derogate at the discretion of the competent authority and for a limited period, even in cases where the substances at issue are safe

(Regulation (EC) No 178/2002 of the European Parliament and of the Council, Arts 6 and 7)

Articles 6 and 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which prohibits the manufacture, processing or marketing of any food supplement containing amino acids, unless a derogation has been issued by a national authority with discretion in that respect, where that legislation is based on a risk analysis which concerns only certain amino acids, which it is for the referring court to verify. In any event, those articles must be interpreted as precluding such national legislation, where that legislation lays down that the derogations to the prohibition covered by it may only be granted for a specific period even in cases where the safety of a substance is established.

In that regard, a correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the substances or foods concerned, and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research (see, to that effect, judgments of 9 September 2003, *Monsanto Agricoltura Italia and Others*, C-236/01, EU:C:2003:431, paragraph 113, and of 28 January 2010, *Commission v France*, C-333/08, EU:C:2010:44, paragraph 92). Thus, where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the

insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective (judgment of 28 January 2010, *Commission v France*, C-333/08, EU:C:2010:44, paragraph 93 and the case-law cited). Moreover, in accordance with Article 7(2) of Regulation No 178/2002, measures adopted on the basis of Article 7(1) are to be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Union, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. Furthermore, those measures are to be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Such uncertainty, which is inseparable from the concept of precaution, influences the extent of the discretion of the Member State and thus has an impact on the means of applying the proportionality principle. In such circumstances, it must be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated. However, the assessment of the risk cannot be based on purely hypothetical considerations (judgment of 28 January 2010, *Commission v France*, C-333/08, EU:C:2010:44, paragraph 91 and the case-law cited).

(see paras 56, 57, 59, 60, 68, operative part)