General Court of the European Union
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Press and Information

Judgment in Case T-204/11
Spain v Commission

The General Court confirms that the biological method of detection of marine biotoxins in live bivalve molluscs may be replaced by a chemical method

The chemical method better protects the health of consumers and also allows the number of tests on animals to be reduced

The Treaty on the Functioning of the EU (TFEU) ensures a high level of human health protection in the definition and implementation of all EU policies and activities. To that effect, the EU is to adopt measures in the veterinary and phytosanitary fields in order to protect public health. One of those measures consists in limiting the total amount of marine biotoxins which may be contained in live bivalve molluscs sold for human consumption (in particular, clams, oysters, mussels, scallops and other shellfish).[1]

Bivalve molluscs may be contaminated by marine toxins which are often due to high concentrations of toxic phytoplankton in the sea, also called 'red tides'. In order to protect public health, the production areas for live bivalve molluscs for human consumption must be subject to periodic controls intended to ensure the absence of marine toxins. Lipophilic toxins are a specific group of marine toxins.

Pursuant to EU law,[2] between 2005 and 2011 the official method of detection of lipophilic biotoxins was the biological method. That method involved, inter alia, using mice in order to carry out the analyses.[3]

In 2009, at the Commission's request, the European Food Safety Authority (EFSA) adopted a scientific opinion on marine biotoxins in shellfish. In that opinion, EFSA took the view, in particular, that the biological method has shortcomings and was not an appropriate method of control on account of the high variability in results, its insufficient detection capability and its limited specificity.[4]

In 2010, the EU adopted a directive to protect animals used for scientific purposes.[5] That directive requires the Member States, as far as possible, to use scientifically satisfactory testing strategies which do not entail the use of live animals.

In 2011, the Commission changed the methods of analysis for the detection of marine biotoxins.[6] Henceforward, the official method is the chemical method LC-MS/MS.[7] It is a new method judged

[1] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004).
[2] Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 for the organisation of official controls under Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ2005 L 338, p. 27).
[3] That method consisted essentially in injecting mice with extracts obtained from the flesh of molluscs. The death of the mice within 24 hours of the injection enabled the presence of substances toxic for humans to be detected.
[4] In its opinion, the EFSA also considered that certain limit values for marine biotoxins imposed by EU legislation did not provide sufficient protection for consumers.
[5] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ 2010 L 276, p. 33).
[6] Commission Regulation (EU) No 15/2011 of 10 January 2011 amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs (OJ 2011 L 6, p. 3).

to be more reliable and which does not entail the use of animals. The new reference method for the detection of known lipophilic toxins must be used as matter of routine, both for the purposes of official controls at any stage of the food chain and own-checks by food business operators. However, to enable Member States to adapt their methods to the chemical method, the Commission authorised the application of various biological dosing procedures on mice until 31 December 2014.

The Autonomous Community of Galicia (Spain) is one of the main regions of bivalve mollusc production in Europe and worldwide. Spain takes the view that the Commission has infringed the Treaties because, in its opinion, the replacement of the biological method by the chemical method as the reference method seriously undermines the protection of public health and severely affects producers in Galicia. Thus, it alleges an infringement of Article 168 TFEU and the principles of proportionality and the protection of legitimate expectations. Spain therefore asks the General Court to annul the regulation by which the Commission imposed that method.

By today's judgment, the General Court rejects Spain's action.

The Court emphasises that, taking account of the scientific assessments by EFSA, maintaining the biological method would have created a risk for public health. The Commission was therefore required to take measures to protect public health without delay. However, **the Commission has not acted too hastily** since the chemical method was validated as a result of a study by the Member States coordinated by the EU Reference Laboratory for Marine Biotoxins.

The Court also observes that Spain has not established that the decision to replace the biological method by the chemical method as the reference method for known biotoxins entails a risk to public health contrary to the TFEU. Spain has not proved that the chemical method is less reliable than the biological method. In particular, it has failed to prove: (i) that there is a difference between the time required for analysis of the chemical method and that of the biological method which is the cause of a risk to public health; (ii) that the higher cost of the chemical method will lead to a lesser degree of protection for public health,[8] and (iii) that the available reference materials do not permit a proper control.

The Court considers that the principle of proportionality has not been infringed, since the additional costs alleged by Spain by reason of the use of the chemical method cannot be regarded as excessive as compared with the objective of protecting the health of consumers of bivalve molluscs. First, the biological method does not enable certain types of toxins to be detected in a sufficiently reliable manner. Secondly, Spain has failed to establish that it has taken into consideration the reduction in costs which may arise from the use of the chemical method for operators in the sector on account of its increased reliability with regard to known toxins.[9]

According to the Court, there is also no infringement of the principle of the protection of legitimate expectations. Although, at the time that the regulation was adopted, the reference materials necessary for the use of the chemical method were not available for certain toxins, it was possible none the less to have satisfactory recourse to an indirect assessment on the basis of existing reference materials intended for substances which are part of the same group.

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[7] The liquid chromatography coupled with tandem mass spectrometry method ('LC-MS/MS method') is a method of chemical analysis based on an extraction and analysis of toxins in tissue. It has been validated under the coordination of the European Union Reference Laboratory on marine biotoxins (EU-RL) in an inter-laboratory validation study.

[8] Spain argues that it is the demand from undertakings in the canning sector which determines the price in Galicia, so that operators cannot pass on the additional costs of own-checks onto end consumers. Spain fears that the increase in costs linked to the chemical methods will encourage undertakings to reduce the number of own-checks.

[9] The Commission notes, in that regard, that the closures of the production areas on account of a greater number of false positive results produced by a control carried out with the biological method must also be taken into consideration. Likewise, the greater reliability of the chemical method will reduce the number of false negative results which also represent a cost for the operators cultivating live bivalve molluscs. Spain itself recognises that any health problem linked to a production originating in Galicia might give rise to situations in which such products are generally discredited.

NOTE: An appeal, limited to points of law only, may be brought before the Court of Justice against the decision of the General Court within two months of notification of the decision.

NOTE: An action for annulment seeks the annulment of acts of the institutions of the European Union that are contrary to European Union law. The Member States, the European institutions and individuals may, under certain conditions, bring an action for annulment before the Court of Justice or the General Court. If the action is well founded, the act is annulled. The institution concerned must fill any legal vacuum created by the annulment of the act.

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