Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fourth Chamber)

11 February 2015 *

(Consumer protection — Regulation (EU) No 15/2011 — Lipophilic toxin detection methods in bivalve molluscs — Replacement of the mouse bioassay with a liquid chromatography-mass spectrometry (LC-MS/MS) method — Article 168 TFEU — Proportionality — Legitimate expectations)

In Case T-204/11,

Kingdom of Spain, represented initially by M. Muñoz Pérez, and subsequently by S. Martínez-Lage Sobredo and finally by A. Rubio González, abogados del Estado,

applicant,

v

European Commission, represented by F. Jimeno Fernández and A. Marcoulli, acting as Agents,

defendant,

ACTION for annulment of Commission Regulation (EU) No 15/2011 of 10 January 2011 amending Regulation (EC) No 2074/2005 concerning recognised testing methods for detecting marine biotoxins in live bivalve molluscs (OJ 2011 L 6, p. 3),

THE GENERAL COURT (Fourth Chamber),

composed of M. Prek, President, I. Labucka and V. Kreuschitz (Rapporteur), Judges,

Registrar: J. Palacio González, Principal Administrator,

having regard to the written procedure and further to the hearing on 19 March 2014,

gives the following

* Language of the case: Spanish.

Judgment[1]

Legal context

General provisions …

Contested regulation …

Facts …

Procedure and forms of order sought …

Law

Preliminary considerations …

30 Furthermore, on the matter of assessment of the pleas relied on, it should be recalled that the institutions of the European Union possess a wide discretion in the implementation of measures to be taken for the protection of public health. In addition, it has already been held that, where the Common Agricultural Policy is concerned, they have a broad discretion regarding definition of the objectives to be pursued and choice of the appropriate means of action (see judgment of 11 September 2002 in *Pfizer Animal Health* v *Council*, T-13/99, ECR, EU:T:2002:209, paragraph 166 and the case-law cited).

31 That broad discretion implies a limited power of review on the part of the Courts of the European Union. The effect of this discretion is that review by the Courts as to the substance is limited to verifying whether the institutions' exercise of their powers is vitiated by a manifest error of assessment, whether there has been a misuse of powers, or whether the institutions have manifestly exceeded the limits of their discretion (judgments of 9 September 2003 in *Monsanto Agricoltura Italia and Others*, C-236/01, ECR, EU:C:2003:431, paragraph 135, 15 October 2009 in *Enviro Tech (Europe)*, C-425/08, ECR, EU:C:2009:635, paragraph 47; and 9 September 2011 in *France* v *Commission*, T-257/07, ECR, EU:T:2011:444, paragraph 85).

32 Concerning the assessment of the Courts of the European Union as to whether an act of an institution is vitiated by a manifest error of assessment, it must be stated that, in order to establish that that institution committed a manifest error in assessing complex facts so as to justify the annulment of that act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible (see, to that effect, judgments of 12 December 1996 in *AIUFFASS and AKT* v *Commission*, T-380/94, ECR, EU:T:1996:195, paragraph 59, and 28 February 2012 in *Grazer Wechselseitige Versicherung* v *Commission*, T-282/08, EU:T:2012:91, paragraph 158). Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the decision (judgments in *Enviro Tech (Europe)*, cited in paragraph 31 above, EU:C:2009:635, paragraph 47, and of 12 February 2008 in *BUPA and Others* v *Commission*, T-289/03, ECR, EU:T:2008:29, paragraph 221).

33 The abovementioned limits to the review by the Courts of the European Union do not, however, affect their duty to establish whether the evidence relied on is factually accurate, reliable and consistent, whether that evidence contains all the information which must be taken into account in order to

1 — Only the paragraphs of the present judgment which the Court considers it appropriate to publish are reproduced here.

assess a complex situation, and whether it is capable of substantiating the conclusions drawn from it (judgments of 22 November 2007 in *Spain* v *Lenzing*, C-525/04 P, ECR, EU:C:2007:698, paragraph 57, and 6 November 2008 in *Netherlands* v *Commission*, C-405/07 P, ECR, EU:C:2008:613, paragraph 55).

34 Moreover, it must be remembered that, where an institution has a wide discretion, monitoring the observance of guarantees conferred by the European Union legal order in administrative procedures is of fundamental importance. The Court has made it clear that those guarantees include, particularly for the competent institution, the obligations to examine carefully and impartially all the relevant elements of the case and to give an adequate statement of the reasons for its decision (judgments of 21 November 1991 in *Technische Universität München*, C-269/90, ECR, EU:C:1991:438, paragraph 14; 7 May 1992 in *Pesquerias de Bermeo and Naviera Laida* v *Commission*, C-258/90 and C-259/90, ECR, EU:C:1992:199, paragraph 26; *Netherlands* v *Commission*, cited in paragraph 33 above, EU:C:2008:613; paragraph 56, *France* v *Commission*, cited in paragraph 31 above, EU:T:2011:444, paragraph 88).

Infringement of Article 168 TFEU

Introduction …

41 Given the EFSA Panel's scientific assessments, the biological method is to be considered inappropriate for the detection of known lipophilic toxins. Particularly for OA toxins, this method is likely to result in false negative results (see paragraph 38 above). Retaining the biological method for the detection of lipophilic toxins therefore creates a risk to public health. The Commission, in its capacity as the body responsible for adopting measures to maintain a high standard of public health, was required to take immediate measures to that end.

…

Analysis time of the LC-MS/MS method …

Costs of the LC-MS/MS method …

Matrix effect of the LC-MS/MS method …

Detection of new or unknown toxins …

Availability of the necessary specified material for the use of the LC-MS/MS method …

121 It follows that the Kingdom of Spain does not satisfactorily prove the LC-MS/MS method's unreliability on the basis of substantive testing, thus creating a public health risk. Nor does the Kingdom of Spain show that the choice of the LC-MS/MS method creates a higher risk than retaining the biological method as the reference method.

…

123 As has been acknowledged by case-law, the legality of a Community measure must be assessed on the basis of the elements of fact and of law existing at the time when the measure was adopted (judgments of 7 February 1979 in *France* v *Commission*, 15/76 and 16/76, ECR, EU:C:1979:29, paragraphs 7 and 8, and 12 December 1996 in *Altmann and Others* v *Commission*, T-177/94 and T-377/94, ECR,

EU:T:1996:193, paragraph 119). It follows that elements post-dating the adoption of the European Union measure cannot be taken into account in assessing the legality of that measure (judgment of 27 September 2006 in *Roquette Frères* v *Commission*, T-322/01, ECR, EU:T:2006:267, paragraph 325).

…

129 Finally, the Kingdom of Spain fails to compare the reliability of the LC-MS/MS method with the biological method. It does not show on the basis of Villar's article that the LC-MS/MS method is less reliable than the biological method.

130 Regarding Ortero's article, it is necessary to note that the observations therein have been widely criticised by other authors in commentaries subsequently published in the journal *Analytical Chemistry*. These authors have especially criticised the scientific quality of Otero's assessments, and those of other authors of the article in question. In particular, they considered the following:

'The experiments and observations described in this document do not justify calling into question the merits or the reliability of the LC-MS/MS method as an assessment method with the aim of protecting consumers … We conclude that, since the authors have referred to the wrong method, the entire publication is rendered irrelevant with regard to "concerns" and "proposed assessment methods". Unfortunately, that also means that the publication is based on a mistaken premiss … This document reveals a misunderstanding of the factors crucial for successful general use of the LC-MS/MS method, and some problems with specific competences in work on the three toxins. We show the existence of problems in the carrying-out of and briefing on the experiments, including an eventual cross contamination due to the injector and the lack of quality assurance/quality control. As a result, the specific conclusions drawn are not considered to be valid.'

131 The criticisms made thus cast doubt over the scientific quality of the research carried out by Otero and his colleagues in the article in question. Therefore, just as what has been decided in the context of the precautionary principle, scientific assessment must be made on the basis of scientific opinion which is itself supported by the principles of excellence, transparency and independence. These demands constitute an important procedural safeguard with a view to assuring the scientific impartiality of measures and avoiding the use of those that are arbitrary (see, to that effect, judgment in *Pfizer Animal Health* v *Council*, cited in paragraph 30 above, EU:T:2002:209, paragraph 172).

132 Taking into account these criticisms and the fact that the LC-MS/MS method has been validated by research undertaken by Member State laboratories and coordinated by the European Union Reference Laboratory for Marine Biotoxins (EURLMB) for the 13 substances involved on the basis of reference materials available at the time of undertaking, the Kingdom of Spain fails satisfactorily to show that the choice of the LC-MS/MS method as the assessment method carries with it a risk to human health.

Conclusion

133 For the reasons given above, it must be concluded, first that the Kingdom of Spain is mistaken in considering that the decision to replace the biological method with the LC-MS/MS method as reference method was taken precipitously and, secondly, that it has not been satisfactorily proved that this decision led to a risk to public health infringing Article 168 TFEU. Consequently, the Kingdom of Spain's first claim must be rejected in so far as it alleges an infringement of Article 168 TFEU.

Infringement of the principle of proportionality

Introduction …

The aim, appropriateness and necessity of the contested regulation …

The non-disproportionality of the disadvantages …

141 Protection of public health takes precedence over economic considerations and may therefore justify adverse economic consequences, even those which are substantial, for certain traders (see, to that effect, order of 12 July 1996 in *United Kingdom* v *Commission*, C-180/96 R, ECR, EU:C:1996:308, paragraph 93, and judgment of 28 June 2005 in *Industrias Químicas del Vallés* v *Commission*, T-158/03, ECR, EU:T:2005:253, paragraph 134.

142 In the present case, it is established that the LC-MS/MS method is more reliable than the biological method in detecting known lipophilic toxins. Unlike the LC-MS/MS method, which has been validated by a number of laboratories under the control of the EURLMB, the biological method has been considered inappropriate for the detection of recognised lipophilic toxins, and likely to give false negative results when testing OA toxins (see paragraph 40 above).

143 Taking these facts into account, even if the Kingdom of Spain's allegation is well founded, that the LC-MS/MS method's cost per sample is at least 60% greater than the biological method, that additional cost cannot be regarded as disproportionate in relation to the objective of protecting the health of bivalve mollusc consumers.

144 Regarding the additional cost, it must be noted that the alleged supplementary cost of the LC-MS/MS method, as opposed to the biological method, was calculated precisely. As indicated in paragraph 73 above, the Kingdom of Spain has not shown with sufficient precision the methodology followed in order to determine the supplementary cost.

145 Moreover, when determining the supplementary cost of the LC-MS/MS method, the Kingdom of Spain has not demonstrated that it also took into consideration the cost reduction that this method could bring for business operators in that sector due to its increased reliability for known toxins. According to the Commission, the closing of production zones due to a number of false positive results, the most significant of which resulted from a test carried out by the biological method, must also be taken into account in such an assessment. In the same way, the fact that the LC-MS/MS method is more reliable will reduce the number of false negative results that also represent a cost for those who trade in live bivalve molluscs. The Kingdom of Spain acknowledges this when it indicates that each health problem linked to a product of Galician origin could damage the general reputation of such goods.

146 Given all the preceding factors, the Kingdom of Spain is mistaken in alleging that the costs of the LC-MS/MS method are disproportionate in relation to the objective of protecting public health that was in mind when designating that method as the method of reference.

147 The Kingdom of Spain's arguments based on infringement of the principle of proportionality must therefore be dismissed.

Infringement of the principle of legitimate expectations …

Costs …

On those grounds,

THE GENERAL COURT (Fourth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders the Kingdom of Spain to bear its own costs and pay those incurred by the European Commission.**

Prek Labucka Kreuschitz

Delivered in open court in Luxembourg on 11 February 2015.

[Signatures]