Court of Justice of the European Union
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Press and Information

Judgment in Case C-616/17
Procureur de la République v Blaise and Others

There are no grounds to question the validity of the regulation on the placing of plant protection products on the market

The procedural rules applicable to the authorisation of plant protection products, in particular products containing glyphosate, are therefore valid

A number of environmental activists, members of the group 'Voluntary Reapers of GMOs, Ariège', have been prosecuted for damaging cans of weed-killer containing glyphosate (and more specifically 'Roundup') in shops in the towns of Pamiers, Saint-Jean du Falga and Foix (France). The activists have been accused of defacing and damaging the property of another.

Since the tribunal correctionnel de Foix (criminal court of Foix, France) considers that if the regulation in question (the regulation on plant protection products;[1] 'the PPP Regulation' were invalid, that might nullify the legal element that is a constituent of the offence the accused persons are alleged to have committed, that court asks the Court of Justice to give a ruling on the compatibility of that regulation with the precautionary principle. More specifically, the referring court has doubts as to the compatibility with that principle of the rules of the PPP Regulation that it interprets as (i) conferring on the manufacturer of the product which is to be placed on the market too much discretion as regards the identification of the substance that it describes as the 'active substance' in its product ; (ii) providing that the analyses and assessments contained in the dossier are to be submitted by that manufacturer, with no independent counter-analysis or adequate publicity; (iii) not ensuring that account is taken of the presence of a number of active substances in the same product and of the possible 'cocktail effect' which may thereby arise, and (iv) not ensuring that sufficient tests are carried out with respect to long-term toxicity.

In today's judgment, the Court states, first, that it the duty of the EU legislature, when it adopts rules on placing plant protection products on the market, to comply with the precautionary principle in order, in particular, to ensure a high level of protection of human health. Those rules must therefore establish a normative framework that ensures that the competent authorities have available to them sufficient information in order adequately to assess the risks to health resulting from the use of such products.

The Court then states that an applicant is bound to identify, when submitting his application for authorisation of a plant protection product, any substance forming part of the composition of that product that corresponds to the criteria set out in the PPP Regulation, so that, contrary to what is envisaged by the referring court, an applicant does not have the option of choosing at his discretion which constituent of that product is to be considered to be an active substance for the purposes of the examination of that application. The Court adds that **it is not clearly evident that the criteria set out in that provision are insufficient to permit an objective determination of the substances concerned and to ensure that substances that actually play a role in the action of the plant protection products are actually taken into account in the assessment of the risks arising from the use of those products**.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1).

The Court concludes therefore that the choices made by the EU legislature with respect to the obligations imposed on the applicant in relation to the identification of the active substances that form part of the composition of the plant protection product which is the subject of his application for authorisation are not vitiated by a manifest error of assessment.

The Court then examines the question whether the alleged failure to take into account and specifically analyse the effects of a combination of a number of active substances contained in a plant protection product ('cocktail effect') is compatible with the precautionary principle. The Court states that in the procedure for the authorisation of a plant protection product, taking into account the known cumulative and synergistic effects of the constituents of that product is required.

Consequently, the Court continues, **the procedures leading to the authorisation of a plant protection product must necessarily include an assessment not only of the specific effects of the active substances contained in that product, but also of the cumulative effects of those substances and their effects combined with other constituents of that product**. The PPP Regulation is therefore again not vitiated by a manifest error of assessment in that respect.

The Court then states that, first, the EU legislature sought to control the quality of the tests, studies and analyses submitted in support of an application based on the PPP Regulation and, second, the Member State to which an application is submitted must undertake an independent, objective and transparent assessment of that application in the light of current scientific and technical knowledge, while the European Food Safety Authority must adopt a decision in the light of current scientific and technical knowledge. For that reason, it is the duty of the competent authorities, in particular, to take account of the most reliable scientific data available and the most recent results of international research and not to give in all cases preponderant weight to the studies provided by the applicant.

The Court observes also that the rapporteur Member State is to prepare a draft assessment report which is to be sent to the other Member States and to the European Food Safety Authority. In addition, in order to determine its conclusions, that authority has the option of organising a consultation of experts and of asking the Commission to consult a Community reference laboratory, to which the applicant may be required to submit samples and analytical standards. Those conclusions are, moreover, communicated to the Member States. Last, the Commission may review the approval of an active substance at any time, including where, in the light of new scientific and technical knowledge, there are indications that the substance no longer satisfies the approval criteria laid down in PPP Regulation.

The Court concludes therefore that **the PPP Regulation is again not vitiated by a manifest error of assessment in that it provides that the tests, studies and analyses necessary in the procedures for approval of an active substance and for authorisation of a plant protection product are to be submitted by the applicant, but does not systematically require that an independent counter-analysis be carried out.**

As regards access to the information contained in applications, the Court states that the PPP Regulation expressly refers to the provisions of the directive on access to environmental information.[2] That directive states that Member States may not provide that a request for access which concerns information on emissions into the environment should be refused on grounds based on protection of the confidentiality of commercial or industrial information. That specific rule is applicable, in particular, to studies designed to assess the harm that may be caused by the use of a plant protection product or the presence in the environment of residues after the application of that product.

The Court concludes therefore that **the rules put in place by the EU legislature to ensure public access to information in application dossiers that is relevant to an assessment of the**

[2] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ 2003 L 41, p. 26).

risks arising from the use of a plant protection product are not vitiated by a manifest error of assessment.

Last, the Court states that a plant protection product can be authorised only if it is established that it has no immediate or delayed harmful effect on human health, the burden of adducing proof of that lying on the applicant. As the Court emphasises, a plant protection product cannot be considered to satisfy that condition where it exhibits any long-term carcinogenicity or toxicity.

The Court concludes that **it is the task of the competent authorities, when examining an application for the authorisation of a plant protection product, to verify that the material submitted by the applicant**, and primarily the tests, analyses and studies of the product, **is sufficient to exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity.**

The Court concludes that an examination of the questions referred by the national court has revealed nothing capable of affecting the validity of the PPP Regulation.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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