Court of Justice of the European Union
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Press and Information

Advocate General's Opinion in Case C-616/17
Procureur de la République v Blaise and others

Advocate General Sharpston: there is no factor affecting the validity of the Regulation concerning the placing of plant protection products on the market

The active substance glyphosate is not a relevant example of alleged failures in the overall system of plant protection product governance

A number of environmental activists, members of 'Voluntary Reapers of GMOs, Ariège department', are charged with causing criminal damage to containers of herbicidal products (specifically 'Roundup') containing the chemical glyphosate in premises in the towns of Pamiers, Saint-Jean du Falga and Foix (France).

The activists were charged with degrading or deteriorating the property of another. At the hearing before the Tribunal correctionnel de Foix (Regional court, France), their request that questions be referred to the Court of Justice was not opposed by the public prosecutor on the basis that if it were found that the glyphosate-containing products potentially posed risks to human health and the environment, he could have chosen not to prosecute the activists and that such a finding might remove the legal foundation on which the prosecution was based. It might also, were they to be convicted, have a bearing on the sentences imposed.

The referring court expressed doubts, with regards to the relevant Regulation[1] (the plant protection products Regulation, the 'PPP Regulation') and the precautionary principle[2], as to (i) whether too much discretion is left, in the approval process, to the industry applicant that manufactures the product to be placed on the market to define the active substance it designates as the active substance in its product and to focus its whole application dossier on a single substance, while its end product placed on the market is made up of several substances, (ii) whether the PPP Regulation rules permit industry applicants to conduct the tests, analyses and evaluations contained in the dossier on their own and to use confidentiality rules to prevent independent counter-analysis of that dossier or publication of the application reports, (iii) whether the PPP Regulations rules take into account the presence of several active substances within a single product and (iv) whether sufficient testing is required of the actual plant protection product containing glyphosate which is placed on the market (both as regards the so-called 'cocktail effect' and in terms of long-term toxicity).

As to the use of the active substance glyphosate as an example of alleged failures in the overall system of plant protection product governance, Advocate General Eleanor Sharpston explains that the essential issue before the Court is simply whether any generic, systemic provisions of the PPP Regulation are flawed in such a manner as to render that Regulation invalid.

Advocate General Sharpston then points out that, whilst all of the questions referred to the Court enquire as to the conformity of the PPP Regulation with the precautionary principle, the referring

[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)..

[2] Article 191(2) TFEU requires that 'EU policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the EU and that it 'shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay'.

court does not, however, explain what it understands to be the components of that principle. Nor does it indicate to what extent that principle is to be applied by the Court when considering whether an EU measure such as the PPP Regulation is invalid. Therefore, she notes that an understanding of both those elements is necessary to establish the scope of the present review.

The Advocate General observes that the correct application of the precautionary principle requires, first, identification of the potentially negative consequences for health (or the environment) of the proposed use of the substance at issue, and, secondly, a comprehensive risk assessment of the risk to health (or the environment) based on the most reliable scientific data available and the most recent results of international research. Annulment actions may therefore be brought on the basis of the precautionary principle to challenge an act that is deemed too restrictive, as opposed to an act that is deemed not to be restrictive enough. The PPP Regulation is itself a precautionary measure because it establishes a system of prior approval affecting a generic product category (plant protection products). The text of the Regulation indicates very clearly that it is based on the precautionary principle and that measures adopted under it are to be based on the precautionary principle.

The Advocate General then indicates that the area of law covered by the PPP Regulation is technically and scientifically complex. The EU institutions accordingly enjoy a particularly wide discretion in framing the measures they adopt. Such measures are susceptible to be annulled only where they are manifestly inappropriate or where the institutions have committed manifest errors in the light of the objective sought to be achieved.

The first and third questions referred to the Court both raise doubts as to whether the 'cocktail effect' of an active substance (i.e. the effect of exposure to different plant protection products containing the same active substance or to different active substances contained in a single plant protection product) is fully assessed by the PPP Regulation. The Advocate General observes that, should an individual approval process fail adequately to take into account the cocktail effect, safety nets exist permitting restrictive measures to be taken on the basis of the precautionary principle. Precautionary measures can be taken independently of any risk assessment undertaken as part of the PPP Regulation approval and authorisation processes. The PPP Regulation thus specifically permits relevant authorities at EU and Member State levels to invoke other assessments to justify precautionary measures where necessary. The Advocate General concludes that no material has been adduced showing that the PPP Regulation is vitiated by a manifest error such that assessments conducted under that Regulation do not take account of the 'cocktail effect' or that an industry applicant is able to manipulate its data submission such that that effect is not assessed. **The system put in place by the Regulation is sound and permits errors of assessment in individual cases to be caught and corrected.**

The Advocate General notes that the fact that all assessments conducted under the PPP Regulation, whether at EU or Member State level, depend upon the submission of complete dossiers of data precludes an industry applicant from itself conducting the necessary studies against its own (biased) protocols and (partial) standards and choosing which data it prefers to submit in its dossier. Rather, it is clear that the PPP Regulation directly mandates the opposite by imposing objective requirements on the quality of data to be submitted. The confidentiality rules in the PPP Regulation operate by way of exception to the general principle of access to information and documents and are interpreted and applied restrictively. Therefore, according to the Advocate General, **the provisions adopted by the EU institutions in the PPP Regulation regarding the public's access to data submitted by the industry applicant are consistent with the general principles of access to information and documents and with the Court's case-law. They are, accordingly, appropriate and not vitiated by manifest errors.**

She then finds that, should an assessment show that there is a risk to human health due (for example) to long-term toxicity but it is not clear how serious that risk is, nothing in the PPP Regulation inhibits the relevant authorities from rejecting the application for authorisation of that plant protection product, in application of the precautionary principle. It is always possible in principle to impose more stringent data requirements. However, requiring a long-term toxicity analysis before a plant protection product is authorised to be placed on the market involves both

incurring additional costs and delaying the moment at which farmers have access to that product to protect their crops. A balance should be struck between two competing goals: an appropriately high level of protection for humans, animals and the environment and enabling products that can enhance agricultural productivity to be placed on the market. **No material has been adduced to support the conclusion that the EU legislator has committed a manifest error in striking that balance in the PPP Regulation.**

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

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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The full text of the Opinion is published on the CURIA website on the day of delivery.

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