General Court of the European Union
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Press and Information

Judgment in Case T-521/14
Sweden v Commission

By failing to adopt measures concerning the specification of scientific criteria for the determination of endocrine-disrupting properties, the Commission has breached EU law

Biocidal products are necessary to combat organisms harmful to human or animal health and organisms which harm natural or manufactured materials. However, those products can present various risks to humans, animals and the environment, because of their intrinsic properties and the associated uses.

In order to improve the free movement of biocidal products in the EU, while ensuring a high level of protection of human and animal health and the environment, the EU legislature adopted Regulation No 528/2012 concerning the making available on the market and use of biocidal products.[1]

That regulation sets out the active substances which, in principle, cannot be approved. They include active substances which, on the basis of criteria to be established, are regarded as having endocrine-disrupting properties which may be harmful to humans, or which have been designated as having those properties.

The regulation provides in that regard that, by 13 December 2013 at the latest, the Commission was to adopt the delegated acts as regards the specification of the scientific criteria for the determination of endocrine-disrupting properties.

By an application lodged on 4 July 2014 before the General Court, Sweden brought an action for failure to act seeking a declaration that, by failing to adopt the acts provided for in the regulation, the Commission had infringed that regulation. The purpose of actions for failure to act, provided for in Article 265 TFEU, is to have a declaration from an EU Court that an institution unlawfully refrained from laying down rules. They are comparatively rare.

In today's judgment, the General Court finds, firstly, that it is explicit in the regulation that the **Commission had a clear, precise and unconditional obligation to adopt delegated acts as regards the specification of the scientific criteria for the determination of the endocrine-disrupting properties and that that was to be done by 13 December 2013**. Nevertheless, the Commission did not adopt such acts. Given that the wording of the regulation is perfectly clear and does not give rise to any ambiguity, there is no reason to interpret the obligation in the light of its context or its purpose.

In that regard, the General Court adds that, following the adoption of the regulation, the legislature neither amended nor repealed, by any binding text, the deadline for adoption of the delegated acts. Nor has the Commission proposed that the legislature amend that regulation in order to defer that date.

Next, the General Court notes that the Commission cannot rely on the fact that the scientific criteria which it had proposed were the subject of criticism, in summer 2013, on the ground that they had

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ 2012 L 167, p. 1).

no basis in science and that their implementation would affect the internal market. The existence of that criticism is irrelevant to the fact that the Commission had an obligation to act before 13 December 2013 by adopting the delegated acts referred to in the regulation.

The regulation reflects the balance desired by the legislature between an improvement in the functioning of the internal market by the harmonisation of the rules concerning the placing on the market and use of biocidal products, on the one hand, and the preservation of a high level of protection of human and animal health and the environment, on the other. In the exercise of the powers delegated to it by the legislature, the Commission cannot call that balance into question. In those circumstances, the fact that the regulation also seeks to improve the functioning of the internal market cannot, on any bases, alone, call into question the clear, precise and unconditional obligation on the Commission to adopt the delegated acts, nor allow the Commission to abstain from their adoption.

With regard to the alleged necessity, referred to by the Commission, of carrying out an impact analysis with a view to evaluating the effects of the various possible solutions, the General Court finds that that there is no provision of the regulation which requires such an impact analysis. What is more, even if the Commission ought to have carried out such an impact analysis, that does not in any way exonerate it, in the absence of provisions to that effect, from complying with the deadline set for the adoption of those delegated acts.

The General Court therefore concludes that, **by failing to adopt delegated acts as regards the specification of the scientific criteria for the determination of endocrine-disrupting properties, the Commission has failed to fulfil its obligations under Regulation No 528/2012**.

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.

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