



*EU Environmental Policy Briefing**

Court of First Instance Quashes Commission Directive on Paraquat Due to Inadequate Assessment of Health and Environmental Risks

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The European Commission and the agrochemical industry suffered a severe setback as the EU Court of First Instance, in a 33-page judgment issued on 11 July,¹ criticised the flaws of the risk assessment procedure for the herbicide paraquat, conducted within the framework of Directive 91/414/EEC on plant protection products,² and decided to annul the resulting Commission Directive adding this substance to the positive list of active substances whose use is authorised in pesticides placed on the market in the EU.

The action for annulment had been brought by Sweden, with the support of Denmark, Austria and Finland, after the Commission, following a comitology procedure in which those Member States had voted against its proposal, adopted Directive 2003/112/EC,³ by which paraquat was added to Annex I of Directive 91/414/EEC, thus making possible its use in plant protection products throughout the EU. The use of this highly toxic herbicide is banned under national law in these four Member States as well as in many non-Member States.

In accordance with the regulatory procedure established by the 1991 Directive, several pesticide producers, including Zeneca, which later became Syngenta, had submitted an application for the listing of paraquat in Annex I in 1993. The UK was designated as the Member State in charge of examining the toxicological and ecotoxicological dossier submitted by the applicants. It sent a preliminary assessment report to the Commission in 1996, followed by an addendum in 2000, after the applicants had supplied additional information. Based on the British report and observations made by other Member States, the applicants and an EU scientific committee (the Standing Committee on Plant Health) completed the comitology procedure, leading to the adoption of the contested measure by the Commission in December 2003. Directive 2003/112/EC authorised the use of paraquat as a herbicide, subject to certain conditions and restrictions designed to reduce the health and environmental risks associated with the substance.

In its judgment, the Court of First Instance assesses the decision-making procedure leading to the adoption of the contested Directive against the background of the relevant provisions of Directive 91/414/EEC and of the EC Treaty itself, including the

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precautionary principle. Most of the grounds on which Sweden has based its action for annulment are found to be well-founded.

With respect to the assessment of risks to human health, in particular to agricultural workers and other users of paraquat, the Court concludes that the Commission has wrongfully disregarded certain scientific evidence concerning a possible link between exposure to paraquat and Parkinson's disease, as well as other evidence showing that, even when the substance is used according to the producer's instructions, with all necessary precautions and safety equipment, the actual exposure of users to paraquat may in certain circumstances exceed the level considered as safe. The assumptions on which the majority of the members of the Standing Committee and the Commission have based their conclusion that the use of paraquat-containing herbicides entails no adverse effects on human health are found to be insufficiently substantiated by the scientific dossier.

As regards effects on human health, the Court states that the provisions of Directive 91/414/EEC, interpreted in conjunction with the precautionary principle as laid down in Article 174(2) of the Treaty, imply that whenever there is serious evidence justifying reasonable doubt as to the innocuity of an active substance, even in the absence of scientific certainty, this substance should, in principle, not be listed in Annex I and allowed for use in plant protection products.

The environmental impacts of paraquat at issue in the case concern suspected effects on non-target species, especially hares and ground-nesting birds. In the context of the 1991 Directive, effects on non-target species are regarded as risks to animal health, to which the same basic principles apply as to human health risks. The Court examines the evidence on which the Commission's conclusions as to the lack of significant risks for non-target species are based and again finds it flawed. In particular, it holds that the studies invoked to substantiate this conclusion are insufficient, since these studies only considered exposure scenarios associated with two out of fourteen authorised uses of paraquat as a herbicide. There is also insufficient evidence that a number of specific risk reduction measures recommended by the producers to minimise potential impacts on hares and ground-nesting bird species are in fact effective.

On these multiple grounds, the Court of First Instance finds that the Commission has exceeded the limits of its discretion in deciding to add paraquat to the positive list and declares Directive 2003/112/EC null and void. However, its judgment is not yet final, since the Commission has a right of appeal to the Court of Justice on points of law.

References

1. Case T-229/04, *Sweden v Commission*; not yet published in English, but available in other official languages at <http://curia.europa.eu>
2. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0414:EN:HTML>
3. Commission Directive 2003/112/EC of 1 December 2003 amending Council Directive 91/414/EEC to include paraquat as an active substance; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0112:EN:HTML>

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