

E-ALERT | Environment

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EU COURT REQUIRES EU AUTHORITIES TO DISCLOSE INFORMATION ON IMPURITIES AND COMPOSITION OF SUBSTANCES SUBMITTED BY COMPANIES

Very recently, the General Court of the European Union [held](#) that European institutions and agencies (e.g., European Commission, ECHA, EFSA, EMA) must disclose to the public, upon their request, information on the impurities and composition of substances emitted into the environment even if this may affect the commercial interests and intellectual property rights of the companies that developed the products.

The Court ruled against a European Commission decision that denied two NGOs access to several documents relating to the approval of the active substance glyphosate in plant protection products. The refusal was based on the need to protect the commercial interests of the manufacturers of the substance. The Court held that [Regulation 1367/2006](#) on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community Institutions and Bodies (“Aarhus Regulation”) requires EU institutions and bodies to disclose information if it “relates to emissions into the environment” even if it can undermine the commercial interests of companies. This applies to any information that “relates in a sufficiently direct manner to emissions into the environment.” The Court found that information concerning the identification and quantity of impurities contained in the substances meets that definition.

The Court’s decision may have significant consequences for chemical companies and downstream users (e.g., manufacturers of pharmaceuticals, cosmetic products, detergents, biocidal products, and medicinal products). Unless the Court’s decision is reversed, companies should not assume that EU authorities will keep confidential any information on the substances of their products that they submit to them.

Facts

The NGOs Stichting Greenpeace Nederland and Pesticide Action Network Europe requested from the European Commission access to several documents that companies had submitted to obtain the inclusion of glyphosate in the list of active substances authorized for use in plant protection products under [Directive 91/414](#) on the Placing of Plant Protection Products on the Market.¹ In particular, the NGOs requested information relating to the degree of purity of the active substance, the identity and quantities of the impurities present in the technical material, the analytical profile of the batches used for the dossier, and the exact composition of the plant protection product.

The Commission refused to disclose this information on the basis of one of the exceptions included in Article 4(2) of [Regulation 1049/2001](#) on Public Access to European parliament, Council and Commission Documents, namely that for the protection of the

¹ The Directive is now replaced by Regulation (EC) No 1107/2009 on the Placing of Plant Protection Products on the Market OJ (2009) L 309/1.

commercial interests (including intellectual property rights) of a natural and legal person. The Commission considered that the need to protect the intellectual property rights of the manufacturers that sought the approval of glyphosate outweighed the public interest in disclosure of the information requested.

Overriding Public Interest to Access Information Relating to Emissions into the Environment

The General Court disagreed with the Commission and held that when an EU institution or body receives an application for access to a document “it must disclose it where the information requested relates to emissions into the environment, even if such disclosure is liable to undermine the protection of the commercial interests of a particular natural or legal person, including that person’s intellectual property, within the meaning of Article 4(2), first indent, of Regulation 1049/2001.” This is because Article 6(1) of the Aarhus Regulation imposes a legal presumption that an overriding public interest in disclosure exists where the information requested relates to emissions into the environment. That public interest automatically trumps the protection of commercial interests.

The Court also held that the Aarhus Regulation is very clear and cannot be interpreted restrictively to reflect fundamental rights, such as the right of property, protected by the Charter of Fundamental Rights of the European Union or Article 39 of the Agreement on the Trade Related Aspects of Intellectual Property Rights (“TRIPs”) of the WTO.

The Concept of Emissions into the Environment Includes Information on the Composition of Substances

Importantly, the General Court also interpreted broadly the concept of information relating to emissions into the environment so as to include any information that “relates in a sufficiently direct manner to emissions into the environment.” As the impurities contained in glyphosate are released into the environment together with the plant protection product itself, the Court held that the information concerning the identification and the quantity of such impurities is related in a sufficiently direct manner to emissions into the environment. The Court also held that information on the impurities present in the batches used for testing in the approval process of glyphosate should be disclosed because that information would allow to “verify any differences between the analytical profiles of the batches tested [...] and those placed on the market, and to determine whether the tests carried out were relevant as regards the actual emission of glyphosate into the environment.”

Broader Ramifications

The Court’s decision may have a significant impact on companies required to disclose information to EU institutions and agencies under different regulatory frameworks, such as the REACH Regulation, Biocidal Products Regulation, GMO Food and Feed Regulation, Cosmetics Regulation, and even medicines rules. If this decision is not reversed by the Court of Justice of the European Union, an important issue will be whether EU authorities and courts interpret the standard of relation “in a sufficiently direct manner to emissions into the environment” as covering only direct emissions into the environment (such as spraying on the fields) or also any possible release into the environment even if it occurs solely through the consumer’s use of the substance (in household waste water, or possibly even through excretion after metabolization by humans or animals) or in small quantities

during manufacturing or in discarded containers. The exact scope of the “sufficiently direct” relation with emission into the environment will be crucial.

Companies should take these developments into account when preparing regulatory filings for submission to EU authorities.

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