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CLIENT ALERT

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In Europe, regulatory burdens for hazardous substances increase, but legal remedies for companies decrease

By Lucas Bergkamp and Nicolas Herbatschek

In March 2010, two decisions were made that will significantly impact both chemical companies and companies using chemicals in production processes. The combined effect of these two decisions is that more chemical substances will likely be subjected to the onerous REACH authorization program, and companies will have more limited rights to challenge these kinds of decisions.

On Thursday, March 25, 2010, the two European Commissioners responsible for the European Chemicals Regulation known as "REACH"[1] settled their differences of opinion and agreed to speed up the procedure for phasing out hazardous substances, after criticisms from NGOs and the European Parliament.

In an unrelated development, on Friday, March 26, 2010, the President of the General Court of the European Union (the "President") rejected a request for suspension of the inclusion of a chemical, acrylamide, in the list of hazardous substances prioritized to be considered for REACH authorization, the so-called "Candidate List."[2] The Court of Justice found that there was no urgency and the issue is now being reviewed in regular judicial proceedings, which will take at least several months. Consequently, the European Chemicals Agency, "ECHA," has included acrylamide in the Candidate List in 2010.[3]

These two decisions are briefly discussed in turn below. We then review the consequences for chemical companies and producers.

REACH Authorization and Phaseout

The REACH Regulation is based on the principle of "no data, no market," which means that companies, not the authorities, must demonstrate that their chemicals are safe before they are manufactured or placed on the market. REACH is not one regulation but a

[1] Regulation (EC) 1907/2006 of the European Parliament and of the Council of December 18, 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, J.O., L 396, 30.12.2006, p. 1.

[2] The President's order was made publically available immediately after it was pronounced, but was subsequently pulled off the court's website for unknown reasons. The court registry has indicated that the decision "will be made available in due course."

[3] ECHA's press release: http://echa.europa.eu/doc/press/pr_10_05_acrylamide_20100330.pdf

series of regulatory programs that complement each other and often overlap. In addition to registration of virtually all chemicals above a one-ton threshold, individual authorization for uses of chemicals may apply.

The authorization procedure is intended to cause the phaseout of the hazardous substances that are subject to it. The procedure for subjecting chemicals to the authorization procedure involves the following steps:

- **Candidate List**[4]: At the request of one or more Member States and after public consultation, the ECHA may shortlist substances based on their hazardousness (CMR, PBT, vPvBT and substances giving rise to an "equivalent level of concern," such as endocrine disruptors). This listing may trigger reporting to the ECHA, and communication requirements vis-à-vis customers and to consumers in respect to products containing substances on the Candidate List. REACH requires also that, as of June 1, 2011, suppliers of products containing substances on the Candidate List notify the ECHA and provide information necessary for "safe use" in some situations.

- **List of substances subject to authorization**: At ECHA's proposal, the Commission may subject the use of the substances on the Candidate List to authorization (Annex XIV of REACH). In its decision, the Commission must provide a deadline by which companies must submit a request for authorization and a sunset date by which the use of the substance without authorization is prohibited.

- **Authorization procedure**: In respect to substances subject to authorization, companies must submit a request for individual authorization for use of the substance concerned. This procedure is onerous, and could include an obligation to prepare a socio-economic analysis of the use of the substance. All authorizations will be subject to a review period that could result in a complete ban of the substance.

Since October 2009, the ECHA has included 30 substances in the Candidate List. In June 2009, the ECHA proposed that seven of these substances be subjected to authorization,[5] but the Commission has not yet made a decision.

NGOs, who have developed their own black list,[6] and the European Parliament have criticized the sluggish pace of the authorization procedure. The main reason for the delay was a difference of opinion between the two responsible Commissioners.

This difference of opinion has now been resolved. During a visit to the ECHA on March 25, 2010, the European Commissioner for the Environment, Mr. Potočnik, and the European Commissioner for the Industry, Mr. Tajani, announced that they agreed on a roadmap to triple the number of substances on the Candidate List from 30 to 106 by 2012. To effectuate this expansion, action by the Member States will also be necessary. The two Commissioners announced also the forthcoming release of the guidance on authorization for the industry. Under this guidance, an applicant will be required to provide a timeline showing when substitutes for substances subject to authorization might become available. Further, the two Commissioners decided to update criteria for the identification of PBT and vPvBT substances.

Legal Remedies

The Lisbon Treaty, which entered into force in December 2009, significantly eased the rules regarding standing for private parties. Companies and natural persons may now challenge the lawfulness of a generally binding regulatory decision if they have a "direct concern." An annulment procedure before the European courts, however, takes at least several months, but a procedure for interim relief is available to address urgent situations. A recent European Court case addressed the issue as to whether the procedure for interim relief is available in respect to a decision to include a substance on the Candidate List.

In the case at issue, the plaintiff challenged the inclusion of acrylamide on the Candidate List. Acrylamide is classified as carcinogenic and mutagenic, and thus meets the requirements for listing. The plaintiff argued, however, that acrylamide is almost exclusively used as an intermediate, which is exempted from authorization, and therefore there is no basis for listing it. The President rejected the request for interim relief based on the lack of urgency.[7] In doing so, the President

[4] List available at: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

[5] Musk xylene, MDA, SCCPs, HBCDD and related substances, DEHP, BBP and DBP. List available at: http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_subst_inclusion.pdf

[6] See, for example, the Substitute It Now List, available at: www.chemsec.org/list/

[7] Case T-1/10 R.

confirmed settled case law requiring that the plaintiff prove that the interim relief is "urgent in so far as, in order to avoid serious and irreparable harm to the applicants' interests, it must be made and produce its effects before a decision is reached in the main action [for annulment]." The President concluded that no such harm had been demonstrated. Specifically, according to the President, the Candidate List cannot be viewed as a "black list" of substances that customers will phase out, causing the plaintiff to lose its market share and its European production plant. "Since the inclusion of substances in the candidate list does not lead automatically to their progressive replacement by suitable alternative substances or technologies, that argument [blacklisting] cannot succeed. It is not founded on any objective factor capable of establishing its validity." Even if it were, the inclusion of a substance in the Candidate List does not automatically lead to its inclusion in the list of substances subject to authorization. If economic operators would press for the phaseout of such substances, this decision, rather than the inclusion in the Candidate List, should be viewed as the decisive cause of the damage alleged by the plaintiff, the President found.

Even though this decision appeared to be based on settled criteria for construing "serious and irreparable harm," the ruling's result raises concerns. Notably, the inclusion of acrylamide in the Candidate List is questionable, considering that it is almost exclusively used as an intermediate, which is exempted from authorization, and in practice its use does not appear to have given rise to any significant health or environmental problems. The ruling also raises the question as to whether companies will have appropriate and effective rights to challenge decisions made in connection with the REACH authorization procedure.

Impact for the Industry

The combined effect of these two developments should be a concern for both chemical companies and industrial and commercial users of chemicals. The number of substances on the Candidate List will likely increase, which will trigger information and notification requirements. Through demand stigmatization, users of listed chemicals may start looking for substitutes. They may seek information on the composition of imported mixtures and products from EU importers and non-EU manufacturers. Information on safe use may well trigger further queries and concerns. Consequently, the phasing out of substances may start well before they are formally subjected to authorization.

To stay on top of these processes, companies should monitor the developments at the European Union. Companies need a regularly updated list of the substances that they market and use, in bulk, in mixtures and in products. Companies should consider participating actively and early in the authorization procedure and submitting comments on proposed decisions in public consultations. Finally, they should understand their legal remedies and when a legal claim could successfully be brought against a decision of the authorities.

The Regulatory Team of Hunton & Williams has extensive experience in assisting clients with all REACH-related matters, including compliance management, liability assessment, product stewardship audits, product defense, specific compliance issues, consortium and SIEF management, data rights, REACH-related contracts, inspections and enforcement, and legal remedies. We work closely with our clients and with regulatory and technical experts so that clients' interests are protected effectively by professionals best placed to assist.

Hunton & Williams is a global law firm with a strong focus in regulatory law and with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels, Raleigh and Washington D.C., and also in its Asian offices, including Beijing.

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