EU court makes it harder to fight candidate list inclusion

The European Court's recent rulings on challenges to the inclusion of substances on the REACH candidate list make it hard for chemical companies to fight these decisions even if they have strong arguments. Professor Lucas Bergkamp and Nicolas Herbatschek of Hunton & Williams explain why.

The European Court recently ruled in four cases related to the REACH Regulation's candidate list. These cases were brought by companies involved with chemical substances included on the candidate list – borates (T-346/10 and T-343/10) and acrylamide (T-1/10 and T-268/10). They dealt with standing requirements for plaintiffs and the deadline for bringing actions seeking annulment of a decision to include a chemical on the candidate list. Two of the four cases were dismissed for lack of standing, while two others were dismissed for having been filed out of time. The inclusion of a chemical on the candidate list does not merely imply that the substance will be considered for listing on Annex XIV, the list of substances subject to authorisation; it also triggers informational obligations for industry, as further discussed below. The candidate list currently includes 53 chemicals and the European Commission has committed to expanding it to 136 by the end of 2012.

Candidate list inclusion and information requirements

The REACH authorisation provisions empower the European authorities to require prior authorisation for the use of a chemical on its own or in a mixture, or for its incorporation into a product. The chemicals that are subject to authorisation are listed in Annex XIV of REACH. Before a chemical is listed in this annex it must first be included on the candidate list. Article 57 of REACH provides that a substance that is classified as carcinogenic, mutagenic or reprotoxic (CMR), as persistent, bioaccumulative and toxic (PBT), as very toxic and very bioaccumulative (vPvB), or as a substance of "equivalent concern" may be placed on the candidate list.The listing procedure starts with a dossier (an "Annex XV dossier") prepared by ECHA or a member state. This is sent for comment to all member states and is issued for public consultation. If no member state or ECHA makes any comments the chemical must be included on the candidate list. If one or more of them do submit comments, ECHA's Member State Committee may decide by unanimous vote to include the chemical, but if there is no consensus the Commission must prepare a proposal for a decision that is subject to approval under the comitology procedure. ECHA must publish "without delay" the inclusion of a chemical on the candidate list on its website.Under Articles 7(2), 31(1)(c), 31(3(b) and 33 of REACH, the listing of a chemical on the candidate list triggers information requirements for both suppliers of chemicals and producers and importers of products:

* suppliers of chemicals must supply a safety data sheet (SDS) to their customers if they were not already required to do so. However, in most cases chemicals added to the candidate list were already classified as dangerous and thus suppliers were already subject to the obligation to supply an SDS before the inclusion of the chemical on the candidate list.
* producers and importers of products: if the chemical's concentration in a product exceeds 0.1% w/w, information on safe use must be provided to customers and, upon request, to consumers. This information must, at a minimum, include the name of the chemical. In addition, ECHA must be notified if the annual volume exceeds one tonne.

Acrylamide was included on the candidate list even though its main, if not exclusive, use is an an intermediate

Recent cases

The recent court cases focused on the candidate listing of certain borates and acrylamide. The classification of the borates concerned was harmonised in August 2008. They were classified as category 2 reprotoxic substances even though, according to the plaintiffs, unrealistically high levels of exposure would be required for a person to receive a dose liable to cause adverse effects on reproduction. This harmonised classification was challenged without success before the European Court (cases T-539/08 (and C-15/10) These borates were added to the candidate list in June 2010 on the basis of this hazard. The inclusion was challenged before the Court. The plaintiffs arguments included: (i) that the Annex XV dossier inaccurately indicate as justification that borates are currently classified in Part 3 of Annex VI to the CLP Regulation; (ii) ECHA did not perform an "on the merits" assessment of whether borates are category 2 reprotoxic substances; (iii) the borates do not meet the criteria for such hazard; and (iv) the harmonised classification infringes the EU law principle of proportionality.

Acrylamide was included on the candidate list in March 2010 as a carcinogenic and mutagenic substance even though, according to the plaintiffs, its main, if not exclusive, use is as an intermediate and under REACH intermediates are exempt from authorisation. A suspension of the listing decision was first granted by the President of the European Court pending a decision on the request for interim relief, which was dismissed in March 2010 for lack of urgency. The plaintiff's arguments in the main case were, among others, that: (i) there was a manifest error of appraisal because the decision was based on unreliable evidence; and (ii) there had been infringement of general principles of EU law, such as the principle of proportionality and of non-discrimination, because the inclusion discriminated against acrylamide in relation to other comparable substances without any objective justification.

Standing requirements for challenging candidate listing

The inclusion of a chemical on the candidate list is in the form of a decision that is generally binding and not addressed to any particular individual or legal entity. The standing rules for private parties were somewhat relaxed by

the Lisbon Treaty, with effect from December 2009. A regulatory act of general application may now be challenged by an individual or a legal entity but only if the decision is of "direct concern" to that individual or entity and the decision does not entail implementing measures. Under settled case law, this requires that the challenged decision directly affects the legal situation of the applicant; and that it leaves no discretion to the addressees of that measure who are to implement it without application of further rules.

The four cases concerning the candidate list were launched by suppliers of the chemicals concerned, not by producers or importers of products incorporating these chemicals, and this, as discussed below, had a decisive effect on the outcome. The applicants argued that inclusion of the chemicals on the candidate list was of direct concern to them because it would trigger: the obligation to either supply or update an SDS and obligations to provide information for them and their customers; and possibly cause their customers to stop using the chemicals concerned.

However the European Court rejected all of these arguments on the basis of the following reasoning:

* SDS supply: the chemicals concerned were treated as dangerous prior to their inclusion, and thus the applicants were already required to supply an SDS to their customers. Inclusion on the candidate list did not add any requirement.
* updating an SDS: the inclusion of a chemical on the candidate list does not trigger any requirement to update an SDS because such inclusion is neither new information on hazard nor new regulatory information. The court found that the regulatory requirements triggered by inclusion on the candidate list do not have to be reported under the SDS heading of regulatory information.
* informational requirements: the applicant misinterpreted the legal provisions, which do not impose obligations on them as suppliers. In any event, these obligations are limited to communicating new hazard information, and in this case no new hazard information was implied in the contested decision. Further, the requirements imposed on customers are irrelevant to determining whether suppliers have standing;
* risk of losing business: the alleged risk of losing business does not amount to "specific circumstances" resulting in direct concern.

An action in annulment must be instituted within two months from publication of the decision. The European Court's rules of procedure provide that, in the case of publication, this time limit is extended by ten days on account of distance and it only begins to run from the end of the 14th day following the date of publication in the EU Official Journal. The Court dismissed the two acrylamide cases because they were not submitted in timely fashion. The first case challenged the unanimous agreement of ECHA's Member State Committee to include acrylamide on the candidate list, which was made following the ECHA executive director's positive opinion. The publication of the listing itself was certain, although due later in time. The European Court ruled that the time starts to run as of the effective inclusion of a chemical on the candidate list, which takes place upon publication on ECHA's website. In this case the time limit was exceeded. The second case was brought against the effective inclusion of acrylamide on the candidate list, and was filed more than two months and ten days after the relevant date. The European Court ruled that the applicant inappropriately relied on the 14-day extension of the time limit, which applies only in the case of publication in the EU Official Journal. In this case, the inclusion of a chemical on the candidate list was published on ECHA's website and the time limit to challenge such a decision starts to run immediately upon publication.

Implications

The rules regarding the listing of chemicals on the candidate list and the standing requirements before the European Court are relatively new. The candidate list is an increasingly important concern for companies as more and more chemicals are added to the list and the serious business impact of listing is becoming clear. The European Commission, the member states and ECHA have not always been sensitive to these concerns, and companies had to bring law suits. Under EU law, however, standing requirements and time limitations have proved to be significant obstacles, as the four cases concerning the candidate list cases confirm.

What lessons can be learned from these cases? The most important lesson is that producers and importers of products have a better chance of success in challenging candidate listing, and so they should be added as parties before the court. Although suppliers of chemicals may have more expertise and resources, as these cases illustrate, they will have a hard time establishing standing. Producers and importers of articles containing chemicals on the candidate list, on the other hand, should be able to show that their legal situation changes because they will incur obligations directly as a result of candidate listing and thus may be able to establish standing based on the "direct concern" requirement. There is a further standing condition, however. Even if producers and importers of articles have a direct concern, they must also establish that the contested decision is a "regulatory act" and "does not entail implementing measures". In practice, this can also be a significant hurdle. So far, with the exception of some preliminary rulings and an interim injunction against the inclusion of acrylamide on the candidate list that was lifted later on, no annulment action related to REACH has resulted in a judgment on the merits. There are two pending cases on the inclusion of chemicals on the candidate list that may shed further light on these issues.

Further, as these cases illustrate, the time limit for bringing legal action is short, and shorter than some expected. An annulment action must be brought within two months from the inclusion of a chemical on the candidate list as published on ECHA's website. This means that a company must proceed diligently and keep its eye on the clock, if it wants to launch a law suit. Finally, these four cases provide some clarification on the information requirements within the supply chain, assuming the European Court maintains its position if it were to judge on the merits. If the recent judgements can be extrapolated, suppliers of chemicals have no obligation to update their SDSs and do not need to inform their own suppliers of the inclusion of a chemical on the candidate list. At least this would be one less thing for chemical companies to worry about.

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