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Some clarification regarding challenges to REACH candidate listing

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In a series of recent judgments[1] the EU General Court has given some guidance to companies considering challenging the inclusion of their substances in the REACH Candidate List. In summary, it is now clear that the listing of a PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative) substance is of direct concern to registrants of that substance. There is therefore no formal bar to manufacturers and importers of such stances challenging their inclusion in the Candidate List, in contrast to manufacturers and importers of substances listed on the grounds that they are carcinogenic, mutagenic or reprotoxic (see our alert on earlier case-law). However, the Court continues to be reluctant to interfere with ECHA's decisions in this technical area and it remains difficult to argue successfully that such decisions are legally flawed.

Background

The Candidate List lists substances that have been identified in accordance with REACH as Substances of Very High Concern ("SVHC") and are therefore candidates for inclusion in Annex XIV to REACH, substances requiring authorisation. On 13 January 2010 ECHA published its decision to include a series of substances in the Candidate List. A number of manufacturers of pitch, coal tar, high temperature (CTPHT); anthracene oil; anthracene oil, anthracene low; and anthracene oil (anthracene paste) brought actions before the General Court seeking annulment of that decision with regard to those substances.

Procedural hurdles

A decision of an EU agency such as ECHA may be challenged only if it (i) was intended to have legal effects, (ii) is of direct concern to the applicants and (iii) either is a regulatory act not entailing implementing measures or is of individual concern to the applicants. It is very difficult to show that a decision is of individual concern to persons affected by it.

The General Court ruled that (i) including a substance on the Candidate List is intended to produce binding legal effects since it can give rise to information requirements under Articles 7(2), 31(1)(c), 31(3)(b), 33(1) and 33(2) of REACH; (ii) the identification of a substance as an SVHC on the ground that it had PBT or vPvB properties contained new information (a) capable of affecting the risk management measures, or new information on hazards, within the meaning of Article 31(9)(a) of REACH, and therefore the applicants were obliged to update the safety data sheets concerned, and (b) as regards its hazardous properties and therefore triggered the obligation to communicate information under Article 34(a) of REACH, and consequently was of direct concern to the applicants; (iii) a decision to include a substance on the Candidate List is a regulatory act not entailing implementing measures.

The formal requirements for challenging ECHA's decision were therefore met.

[1] Case T-93/10 *Bilbaína de Alquitranes and Others v ECHA*, Case T-94/10 *Rütgers Germany and Others v ECHA*, Case T-95/10 *Cindu Chemicals and Others v ECHA* and Case T-96/10 *Rütgers Germany and Others v ECHA*.

Some clarification regarding challenges to REACH candidate listing

Legal arguments

The applicants put forward a number of arguments as to why the decision was contrary to EU law and should be annulled. All arguments were rejected by the General Court. A very brief summary follows.

Principle of equal treatment

The applicants argued that identification of each substance as an SVHC breached the principle of equal treatment since the listed substance was comparable, in terms of its content of chemical substances and of competition on the market, to other substances with similar constituents which had not been identified as SVHCs. The Court ruled that under Article 59 of REACH it was for the Commission or the Member State which had prepared the Annex XV dossier to decide whether a substance met the criteria for being identified as an SVHC. Since ECHA had no discretion as regards the choice of the substance to be identified, and since no other Annex XV dossiers had been prepared for the allegedly comparable substances, in identifying each listed substance and not identifying allegedly comparable substances as an SVHC ECHA did not breach the principle of equal treatment.

Principle of proportionality

The applicants argued that the decision did not respect the principle of proportionality on a number of grounds. That principle requires that measures adopted by EU institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.

The Court started by stressing that ECHA has a broad discretion in a sphere which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. A measure adopted in that sphere will be unlawful only if it is manifestly inappropriate having regard to the objective of the legislation in question.

First, the applicants had argued that the decision was not suitable for the attainment of the objective of REACH, which was to ensure a high level of protection of human health and the environment, since the substances which could be used to replace each listed substance also had PBT or vPvB properties. The Court ruled that identification of a substance as being of very high concern improved information for the public and professionals as to the risks and dangers incurred and, consequently, was a means of enhancing that protection.

Second, the applicants had argued that the contested decision exceeded the limits of what was necessary to achieve those objectives, given that the application of risk management measures on the basis of the chemical safety assessment in the registration dossier or the presentation of an Annex XV dossier for restrictions would also meet those objectives but would be less onerous. The Court ruled that the objective of the authorisation procedure, of which candidate listing was part, was, inter alia, progressively to replace SVHCs with other appropriate and economically or technically viable substances or technologies. Consequently, risk management measures were not appropriate for the achievement of those objectives. Even if restriction measures were also appropriate for the achievement of such objectives, they were not, as such, less onerous measures than candidate listing.

The following, more technical, arguments were also dismissed by the Court, illustrating the difficulties of successfully challenging ECHA's decision to include a substance on the Candidate List:

Some clarification regarding challenges to REACH candidate listing

- The Annex XV dossier for each substance did not observe the requirements set out in Article 59(2) and (3) and in Annexes XIII and XV to REACH because it was not based on an assessment of the substance itself but on an assessment of the properties of its constituents.
- The rule that a substance may be identified as having PBT or vPvB properties provided that it contains a constituent which has PBT or vPvB properties and is present in a concentration of 0.1% or more is not provided for in Annex XIII to REACH and therefore has no legal basis.
- The assessment of the constituents of a substance is not a sufficient basis for its identification as having PBT or vPvB properties since those constituents have not been individually identified as having PBT or vPvB properties in a separate ECHA decision based on a thorough assessment for that purpose.
- The rule of the 0.1% threshold was not respected given that the listed substance contained the only constituent officially identified as a PBT substance, at levels of less than 0.1%.
- Contrary to REACH, some Annex XV dossiers did not include information on alternative substances even though Germany (which submitted the dossier) had been informed by the applicants of the existence of such substances. Without that irregularity and if the fact that the alternative substances also contained PBT constituents had been known, the decision might not have been adopted and a different procedure might have been triggered.
- ECHA had no authority to amend the proposal made by Germany concerning the inclusion of certain substances in the Candidate List, which was based solely on the fact that that substance had PBT and vPvB properties. Following that amendment, the substance concerned was identified as an SVHC on the basis not only of its PBT and vPvB properties as alleged, but also of its carcinogenic properties.
- The assessment of the constituents of the substance at issue did not furnish a sufficient basis to identify it as having PBT or vPvB properties since those constituents were not individually identified as having PBT or vPvB properties.

Time-limits for Candidate List challenges

Even more recently, an Advocate General (AG) at the Court of Justice (the senior EU court) has delivered his Opinion in appeals against two judgments of the General Court[2] in which that Court ruled that (i) the date of publication of the updated Candidate List on the ECHA website was the start of the period within which challenges must be brought and (ii) the provision in its Rules of Procedure that the time-limit started from the end of the 14th day following publication did not apply to acts published not in the *Official Journal of the European Union* but exclusively on the Internet.

The AG considers that the Court of Justice should rule that:

- The decision of the Executive Director of ECHA to include a substance on the Candidate List is the final act bringing to an end the procedure laid down in Article 59 of REACH and accordingly starts time running from the date of publication of that decision.
- The 14-day provision applies to the calculation of the time-limits for bringing proceedings against any published acts of EU institutions, bodies, offices and agencies, whatever method of publication is used.

The AG's Opinion is not binding on the judges of the Court of Justice but in the majority of cases the judgment comes to the same conclusion. The judgments in these cases should be delivered in the course of this year.

[2] Cases C-625/11 and C-626/11 *Polyelectrolyte Producers Group and SNF v ECHA*; see our alert on earlier case-law for a summary of the judgments of the General Court appealed against.

Some clarification regarding challenges to REACH candidate listing

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