Interim Relief in Case of Inclusion of a Substance on the REACH Candidate List

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Case T-1/10 R, SNF SAS v. European Chemicals Agency (ECHA)

The manufacturer of a substance that is used safely and, in more than 99.9 % of cases, used as an intermediate (and thereforeis exempted from the authorisation procedure) is deemed to have no legal grounds for claiming the suspension of the inclusion of that substance in the Candidate List for lack of urgency. Its mere inclusion should not automatically result in any significant damages to the manufacturer, neither should the Candidate List serve as a regulatory blacklist (official headnote).**

I. Facts

The Plaintiff, SNF SAS ("Plaintiff"), is a part of a group of companies and manufactures acrylamide. Acrylamide is a substance classified as carcinogenic and mutagenic. Without being challenged by Defendant (the European Chemicals Agency or ECHA), SNF states that in more than 99.9 % of cases acrylamide is used as an intermediate[1] – the miniscule remaining quantity would be used for grouting or electrophoresis purposes, which could also be qualified as an intermediate use. The company claims that "acrylamide-based products have been sold in the European Union for more than 50 years without ever having given rise to serious health or environmental problems."

The ECHA is responsible for managing and implementing the REACH Regulation, including its authorisation procedure. Under this procedure, the use of certain hazardous substances is subject to authorisation by the Commission. It is divided into the following steps:

- *Candidate List:*[2] At the request of one or more public authorities and after public consultation, the ECHA may shortlist substances solely based on their hazardous nature (CMR, PBT, vPvBT and substances giving rise to an "equivalent level of concern," such as endocrine disruptors). This shortlisting in some cases triggers notification to the ECHA, and communication requirements vis-à-vis customers and to consumers in respect of substances, mixtures and products containing substances in the Candidate List.
- *List of substances subject to authorisation:* On ECHA's proposal, the Commission may subject the use of substances on the Candidate List to authorisation (Annex XIV of REACH). In its decision, the Commission must provide a deadline by which companies must submit a request for authorisation and a 'sunset date' after which the use of the substance without authorisation is prohibited.
- *Authorisation procedure:* In respect of substances subject to authorisation, companies must submit a request for individual authorisation 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 authorisations are subject to a review period that could result in the ban of the substance.

Between October 2008 and February 2010, the ECHA put 29 substances on the Candidate List. In June 2009, the ECHA proposed to the Commission

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** Editorial Hint: Article 2(8) and 59 of Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), last amended by Regulation 552/2009, OJ L – 396, of 30.12.1996, pp. 1–849.

1 From the decision, it seems that acrylamide is used as isolated intermediate.

2 Candidate List available on the Internet at <http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp>.

seven of these substances for authorisation.[3] The Commission has not yet come to any decision.

On 25 August 2009, the Netherlands submitted a dossier to the ECHA for the inclusion of acrylamide in the Candidate List. After public consultation and unanimous agreement of the Member State Committee for such inclusion, the ECHA decided on 22 December 2009 to include acrylamide as of 13 January 2010.

On 5 January 2010, one day after submitting an action for annulment, Plaintiff requested the President of the Court (the "President") to suspend this decision for inclusion.[4] On 11 January 2010, the President ordered the suspension of the inclusion decision pending its ruling on the interim measures.

On 26 March 2010, the President rejected the application for interim measures for lack of urgency, hence the ECHA is including acrylamide in the Candidate List of 30 March 2010.

II. Judgment

The ECHA raised several defences against the claim, including lack of urgency, the preparatory character of the challenged decision, and the absence of direct concern. The President only addressed the lack of urgency that he deemed sufficient to reject the claim. Pursuant to settled case law, "the urgency of an application for interim measures must be assessed in relation to the need for an interlocutory order in order to prevent serious and irreparable damage to the party requesting the interim measures. "(...) purely hypothetical damage, (...), cannot justify the granting of interim measures."

The Plaintiff argued that in over 99.9 % – perhaps even 100 % – of cases, acrylamide is used as an intermediate, which exempts it from the authorisation procedure. It also argued that, as an ECHA official stated in January 2009, the result of the inclusion of acrylamide in the Candidate List would be that "its customers will stop using acrylamide, causing it to lose its market shares in the European Union." In that respect, Plaintiff observed that "it has already received letters from three of its key customers in which they state that, due to concerns arising from the identification of acrylamide as a substance of very high concern, they will cancel their orders if the situation is not swiftly resolved." Plaintiff's insurer has also "expressed serious concerns".

However, the President considered that the mere inclusion of a substance in the Candidate List "does not entail a ban on, or limitation of, the marketing and use of that substance." It only triggers an information requirement for which Plaintiff has not asserted that it "would be such as to cause it serious and irreparable damage, because of their cost or their content."

Pursuant to the President, the inclusion of a substance in the Candidate List "does not lead automatically to its progressive replacement." "[F]ar from thereby establishing an absolute and unconditional objective of replacement, that provision [Article 55 setting up the objectives of the authorisation procedure] expressly makes the replacement envisaged dependent (...) upon the technical and economic feasibility of any substitution." "[A]part from the objective of replacement, [there are] other aims pursued by the establishment of that list, such as the aim of gathering and providing information on uses of substances of very high concern."

Furthermore, "it is necessary to reject (...) the argument alleging that the candidate list of substances is to be regarded as a 'black list'. Since the inclusion of substances in the candidate list of substances does not lead automatically to their progressive replacement by suitable alternative substances or technologies, that argument cannot succeed. It is not founded on any objective factor capable of establishing its validity. In any event, the applicant refers too generally to the candidate list of substances as a whole, when the inclusion of acrylamide in that list, with which alone the present proceedings are concerned, does not appear to prevent the applicant from continuing to engage in its economic activities relating to acrylamide and polyacrylamides, at least 99.9 % of which seem to comprise intermediate uses, so that the progressive replacement of acrylamide by suitable alternative substances or technologies cannot be regarded as proven (...)."

"[T]he identification of acrylamide as a 'substance of very high concern', simply by reference to its car-

3 See <http://echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_subst_inclusion.pdf>.

4 "Suspend the operation of the contested decision pursuant to Article 105(2) of the Rules of Procedure of the Court, pending the ruling on the application for interim measures; in any event, suspend the operation of the contested decision with effect from the date on which it was adopted; grant any other interim measures as appropriate."

cinogenic and mutagenic nature, essentially does no more than confirm that it is potentially 'hazardous'. It follows that the negative reactions of the customers of the applicant, banks, investors, insurers or other economic operators cannot be regarded as conclusions that an economic operator could reasonably have drawn from the mere identification of acrylamide as a substance of very high concern, since its identification does not provide any new information regarding the intrinsically hazardous properties of that substance. Assuming that those negative reactions are explained by a policy change on the part of the economic operators in question, based on increased awareness in relation to carcinogenic and mutagenic substances (see the eco-labels mentioned by the applicant) or on a misunderstanding of the objectives pursued by ECHA in identifying acrylamide as a substance of very high concern, that would be an independent choice made by those economic operators, which would constitute the decisive cause of the damage pleaded."

III. Comment

The inclusion of acrylamide in the Candidate List and the decision of the President raises several concerns.

First, it reveals what seems to be a blurred line arising under the REACH Regulation between "substances" and and uses of a substance. All chemicals regulated under the REACH Regulation, including intermediates, are substances. An intermediate is merely a specific use of a substance, which may also have other non-intermediate uses. One example of this confusion is the lack of coordination between the mandatory joint registration by several registrants of a substance that is used both as intermediate and for other uses. It is subject to two different legal provisions, both of which requiring the submission of one registration dossier for all registrants by one lead registrant, while the information requirements in each case are different (intermediate registrations benefit from reduced data requirements). It is unclear how these two sets of provisions may simultaneously apply to the same substance used both as intermediate and for other purposes. ECHA's REACH IT may not accommodate two lead registrants or two joint registration dossiers for the same substance.

Another example of blurred line between substance and use is the list of exclusions from the authorisation procedure. The first two steps of the authorisation procedure are (i) the shortlisting of substances based on their hazardous nature followed by (ii) the authorisation requirement for the use of several of these substances. The use of such a substance – intermediate, biocide, fuel, etc. – is only relevant to the second step. Certain uses (such as uses in biocidal and plant protection products) are only excluded from the second step,[5] i.e. the authorisation requirement, while other uses (such as for intermediates and in medicinal products) are exempted from the whole authorisation procedure. In the case of the second category of exclusions, it is not entirely clear whether and to what extent a substance having other, non-excluded, uses or even having only excluded uses may be included in the Candidate List.

The ECHA takes the position that it may include any hazardous substance in the Candidate List, whatever its use and whether or not they have already been excluded ("This stage in the authorisation procedure therefore involves only an assessment of the intrinsic properties of the substance, without consideration of its actual uses.") The REACH Regulation, however, provides exclusions from the whole authorisation procedure, including the Candidate List, such as the exclusion of intermediates. On a closer reading, the REACH Regulation suggests that the ECHA must first determine whether an exclusion applies, and then determine whether it is hazardous and should be included in the Candidate List. This is reinforced by the distinction between exclusion from the mere authorisation requirement (such as for pesticide use) and the exclusion from the whole authorisation procedure.

Second, the President's argument with regard to the incentive for substitution arising from inclusion in the Candidate List is not entirely convincing. The Candidate List is not just a confirmation of the hazardous nature of a substance (if this were so, there was no need for the list) or does not have, for certain substances, as its sole objective the gathering of information. The REACH Regulation expressly provides that the purpose is to establish "a candidate list *for eventual inclusion* in Annex XIV [List of substances subject to authorisation]" (emphasis added). This

5 There are also exemptions available from the authorisation requirement.

is reinforced by the fact that it is provided under the heading of authorisation, not under the heading of information. The consequences of authorisation for companies can be dramatic: the administrative burden and the costs of the authorisation procedure are expected to be very heavy. There is also the threat of a regulatory ban of any authorised substance, a factor that would result in significant uncertainties regarding the mid- and long-term availability of such a substance.

Thus, the implication for a whole industry of the inclusion of a substance in the Candidate List goes far beyond the mere confirmation of the hazardous nature of that substance. If this were the real intent, the REACH Regulation could have referred to an existing list of hazardous substances, possibly with a "grace period", rather than specifying a strict procedure for compiling a Candidate List. Under these conditions, it is no wonder that the Candidate List is being viewed as a "blacklist" by the industry. One may reasonably assume that the disadvantages associated with being on the list (administrative burden, cost, uncertain mid- and long-term supply and bad publicity) may well result in a decrease in demand for the substance. Thus, at least in cases where substitutes exist, the inclusion of a substance in the Candidate List tends to lead to a phasing out of the substance and its progressive replacement.

Further, it is not obvious that one of the purposes of the inclusion in the Candidate List is to enhance the gathering of information on the uses of hazardous substances. This is not a stated purpose of the authorisation procedure nor of the procedure for the Candidate List itself.

Third, at the policy level, there is no justification for the inclusion of acrylamide in the Candidate List under the conditions described by Plaintiff, which were not challenged by the ECHA. As indicated above, the Candidate List is intended to be used as a shortlist of substances that may eventually be subject to a procedure of authorisation. Acrylamide, a CMR, is used in more than 99.9 % (possibly 100 %) of cases as an intermediate. This implies, first of all, that its inclusion in the Candidate List does not trigger any additional information requirement: as a CMR, acrylamide and mixtures containing acrylamide are already subject to an information requirement; as an intermediate, acrylamide is transformed into another substance and is thus not present in the final substance, mixture or product. This means that it does not trigger either any information requirement for products. Further, in more than 99.9 % (possibly 100 %) of cases acrylamide will ultimately not be subject to authorisation, which is the sole purpose of the Candidate List.

This analysis and the fact that acrylamide is a substance that has been used in products in the European Union "for more than 50 years without having given rise to serious significant health or environmental problems", suggest that acrylamide is not a substance that should be listed on the Candidate List. There does not appear to be a justification for imposing burdensome inventory requirements and supply uncertainty on the industry in respect of this substance. Thus, the inclusion of acrylamide in the Candidate List is also problematic in light of the recent agreement between the Environment Commissioner and the Industry Commissioner on a roadmap for the inclusion of 106 additional substances in the Candidate List by 2012 without any clarification on the prioritisation of the substances that will be included.

Finally, this ruling raises the issue of the effectiveness of the right to challenge unlawful decisions. The Treaty of Lisbon makes it easier for people to challenge generally binding decisions made by the European authorities. However, an action for annulment takes several months, at best, and the current case law of the European Union's Court of Justice makes it difficult to obtain any interim measures (obligation to prove likelihood of serious and irreparable harm). Shouldn't the current very high threshold be lowered in light of the interests at stake? It is no longer a case of the interest of the European Union against one person, but potentially a case against a group of persons, a sector of industry or even a larger group. When a substance is included in the Candidate List, in each and every case, this places an inventory burden on a majority of the industry concerned – most companies, including SMEs, must at least check that their substances, mixtures and products do not contain acrylamide. It also entails a risk of forced substitutions for companies that depend on that substance. In some cases, it might also mean the additional burden of the information requirements and more or less significant real loss of market share. The total damage caused by an unfounded or even unlawful decision, when compared to the interests of the authorities, should be considered when determining whether there is urgency to suspend such a decision.