

**Recommendation of the ECHA on REACH double pre-registration–  
Position of the chemical industry**

22 October 2008

The ECHA recommends a double pre-registration in the following cases:

- re-imported substances, Article 2 (7) c)
- recovered substances, Article 2(7) d)
- monomers in polymers, Article 6 (3)
- substances intended to be released from articles, Article 7 (6)

According to the ECHA

“...companies should pre-register if they are not sure that the substance(s) concerned will be registered by 1st December 2008...” (ECHA/PR/08/32, 06.10.08)

**The interpretation that a “double preregistration” is necessary for such phase-in substances is not correct and only based on the pure wording and disregards the additional legal methods of interpretation. In our opinion, an analogy, as legal principle accepted in the established ruling of the European courts (ECJ cases 165/85; T-108/94), is the right legal method to estimate the legal consequences of such requirements, as developed under the following reasoning:**

- **Legal gap to be filled in:**

Even though Article 2 or Article 6 have been finalized after pre-registration had been introduced by the Commission proposal, the question of the transitional period for phase-in substances has never been addressed in the subsequent negotiations. In particular, there is no evidence in the preparatory discussion documents related to the introduction of art 2.7 in the text of REACH (amendment by the Council), in the recitals or elsewhere in REACH to prove that the omission of pre-registration exemption has been made purposely. This has to lead to the assumption that the question of pre-registration has simply not been taken into account and it cannot be concluded that the case of merely pre-registered substances has purposely not been regulated. Therefore, the spirit of Article 2(7)(c) for example should in analogy be transferable to pre-registration. Pre-registration is an alternative first step to a registration and, thus, should not be assessed differently from registration as such.

- **preregistration is covered by Title II:**

Some of the pre-registration requirements of the REACH Regulation come under the same section – Title II – as the registration requirements. Hence it could be argued that the terms of art 2 (7) “*registered in accordance with Title II*” also include pre-registered substances.



- **Contradiction with article 28:**

Article 28 states that each potential registrant shall submit a pre-registration. The term “potential registrant” implies an intention to register. A re-importer or a downstream user of monomers for example being covered by a pre-registration of his suppliers would be forced to do a formal pre-registration although he does not intend to be registrant – in fact he will not be a potential registrant. Although there is no intention for the re-importer or the downstream user of the monomer to register the substances, there would be no concern as the pre-registration and registration will be done by the original manufacturer of the (later) re-imported substance or by the manufacturer or importer of the monomers, and thus the substances will be covered and in line with REACH.

- **Contradiction with article 3. 13:**

Article 3.13 provides that “*A re-importer exempted pursuant to Article 2 (7)(c) shall be regarded as a downstream user.*” Article 3.13 places the re-importer in the position of downstream user because it is recognized that the re-importer does not have the legal obligations of the registrant in that it will not be responsible for updating the registration per Article 22 or fulfilling the other obligations of registrant. In the same fashion, a re-importer should be considered a downstream user during the phase-in period because it has no intention to fulfill the role of potential registrant.

In analogy, in case of monomers that are purchased from a supplier for example, these monomers need not to be registered, because of the basic rule that a downstream User is not obliged to (pre-)register. This basic rule is violated in case the buyer uses these monomers for polymerization, because he would be obliged still to register pursuant article 6.

- **Articles 5, 6 and 23:**

According to Articles 28 and 23, in case of a valid pre-registration, the articles 5 and 6 do not apply for the transitional period. Potential registrants are released from the registration obligations for that period. Consequently, according to the systematics of the REACH Regulation, the pre-registration substitutes the registration for the respective transitional regime. In the law making process the instrument of pre-registration was not explicitly added to articles referring to the registration. Nevertheless the pre-registration must be considered as being a kind of temporary registration with lower requirements.

A systematical interpretation of the above mentioned articles leads to the result that the exceptions in question must be applied to pre-registered substances as well.

- **Principle of proportionality and better regulation**

That ECHA recommendation is in contradiction to the European legal principle of proportionality (Article 5, third paragraph, of the Treaty establishing the European Community), under which the extent of the action must be in keeping with the aim pursued.

Reach is supposed to contribute to a European regulatory framework of the highest standard of law-making respecting the principle of proportionality. The aim of REACH is to assure a better health and environmental safety but to require for a double pre-registration

will not serve better that purpose and at the same time, would clearly add a useless burden for industry (breach of the principle of proportionality)

The purpose of pre-registration is to ensure that the potential registrant will participate in the development of the joint registration dossier in order to fulfill its obligation to register within the phase-in deadlines set out in Article 23. An actor that will have no obligation to register because it will take advantage of the exemption under Article 2(7)c for example has no legal obligation to participate in the development of the joint dossier. Accordingly, the participation of the re-importer of an EU-manufactured substance (or the producer/importer of a polymer) in the Substance Information Exchange Forum (SIEF) serves no useful purpose as the re-importer will ultimately not register.

At the same time, the ECHA recommendation is also in contradiction to the European principles of better regulation, that request the simplification as much as possible in order to make legislation less burdensome, easier to apply and thereby more effective in achieving its goals.

Although no fee is associated with pre-registration, there are administrative costs associated with the pre-registration filing and SIEF participation. In addition, compliance problems are created where the supplier refuses to disclose the identity of the substance that needs to be pre-registered. These costs and problems are imposed without any justification as the re-importer pre-registration is made solely as a formality.

### **Conclusion:**

The above mentioned provisions of the REACH-regulation should be extended to pre-registrations by means of analogy. The strict interpretation (double pre-registrations) would lead to a **disproportionate** result. When drafting the provisions pre-registration was **accidentally** not taken into account. There is **no benefit** resulting from double pre-registration and there is no hint in the recitals why the four exceptions (Articles 2 (7) c), 2(7) d) 6 (3), 7 (6)) should not be applicable to pre-registered substances. A pre-registered phase-in substance is marketable and there is no reason to exclude such substances from the scope of the four exceptions. Consequently, one must assume that there is an **accidental gap** with regard to pre-registered substances, which must be closed by **analogy in order to achieve proportionate results**.

For further analysis, please find enclosed for example the legal developments under the particular perspective of substances re-imported that have been recently submitted by the company Arcade Europe to the ECHA and that are fully endorsed by CEFIC:



Arcade Europe SARL  
- White Paper- double

### **Practical consequences of double pre-registration:**

The strict interpretation prescribing double pre-registration leads to the destruction of a large number of running businesses and business relations. In many cases pre-registration by the re-importer is impossible, because the re-importer does not know the ingredients of re-imported preparations. Consequently, the obligation of double pre-registration is not simply additional bureaucracy, but -in many cases- setting an end to the possibility of (legal) re-import. The strict interpretation could also be subject to WTO-Law: A substance is legally traded in the EC, then exported and (if one is following the strict

interpretation) becomes illegal when re-imported to the EC (without additional pre-registration). This might constitute a trade barrier.

In the case of a preparation exported from the EU (for which the components have been pre-registered), formulated into another preparation and re-imported, it is impossible to pre-register the components again without having access to the composition of the EU manufactured preparation.

The same concept is applicable to re-imports of EU manufactured polymers - in this case it is practically impossible for the importer to pre-register the monomers and additives in the polymer which was exported.

**Typical example:**

Manufacturer M within the EC supplies large quantities of polymer dispersion to Formulator F outside the EC. These dispersions contain additives like defoaming, emulsifying and preservative agents etc., whose chemistry and compositions are the basis of M's know-how. This is why M will not disclose the formulation to third parties. M will (directly as manufacturer or indirectly via his raw material suppliers) register the substances in his polymer dispersion. In order to benefit from the respective transitional regime, M will also pre-register the substances.

Out of the raw materials supplied by M, F (outside the EU) formulates dispersion adhesives, which are mainly re-imported into the EU through affiliated companies of F.

If only registered substances were exempted from being registered again in case of re-import, the re-importing companies would be required to pre-register substances, which have already been pre-registered, but not yet been registered because of the transitional regime. The re-importers are not able to pre-register, since M guards his know-how and therefore is not willing to disclose the formulations.

Hence, during the transitional regime (until the registration has been carried out) it is impossible for the re-importing companies to place these products on the European market, which leads to the destruction of that business.