Concept of intermediates under REACH

Legal opinion

9 July 2010

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I. Introduction

The purpose of this legal opinion is to provide an independent opinion on the concept of intermediate substances as defined in Regulation (EC) 1907/2006 (REACH).[1] The following analysis follows the approach that is typically taken by the European Courts: it thus places an emphasis on a literal interpretation, and supports that with a systematic and teleological interpretation, of the definition of intermediates in REACH.

In addition, this paper provides some specific comments on the European Chemicals Agency (ECHA)'s note on the definition of intermediates of May 2010.

A. Legislative framework concerning the concept of intermediates under REACH

Intermediates are defined in Article 3(15) of REACH as "*a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis)*". REACH distinguishes between three categories of intermediates: non-isolated; on-site isolated and transported isolated. These are defined in more detail below in this Section. To each category, REACH grants specific exemptions to the general requirements applying to ordinary (non-intermediate) chemical substances. The justification for such exemptions is given in Recital 41 of REACH and refers to "*reasons of workability*" and to the "*special nature*" of intermediates. An analysis of the rationale of Recital 41 is given below (Section II.B.1).

Non-isolated intermediates are outside of the scope of REACH pursuant to Article 2(1)(c) of REACH.

On-site isolated intermediates are both manufactured and consumed/used in a chemical process taking place in one and the same site. The on-site isolated intermediates are "isolated" between their creation and use in chemical processing. The exemptions covering the isolated intermediates concern each of the four Titles of REACH (Registration, Authorisation, Evaluation and Restriction), namely:

- exemption from Chapter 1 of Title II (registration), except Articles 8 and 9, per Article 2(8) of REACH;
- reduced registration requirements, provided the so-called strictly controlled conditions (SCC) of Article 17 of REACH are fulfilled;
- exempted from Title VII (authorisation), per Article 2 (8) of REACH;
- exemption from substance/dossier evaluation, per Article 49 of REACH;
- exemption from new/amended restrictions (included in Annex XVII), per Article 68 of REACH.

Transported isolated intermediates are substances manufactured at one site, and consumed/used at another site. They are, therefore, "isolated" between their creation at the first site and their use at the other site. The exemptions for transported intermediates cover registration and authorisation but not evaluation and restriction. Particularly, transported intermediates are:

- exempted from Chapter 1 of Title II (registration), except Articles 8 and 9, per Article 2(8) of REACH;
- subject to reduced registration requirements, provided the SCC of Article 18 of REACH are fulfilled;
- exempted from Title VII (authorisation), under Article 2(8) of REACH.

B. Recent developments concerning the concept of intermediates: ECHA's paper

The Member States Competent Authorities for REACH and CLP (CARACAL) have recently provided an interpretation of the concept of intermediates, which was also agreed upon with the European Commission and ECHA. This interpretation was published in May 2010 (the ECHA paper).[2] The ECHA paper is presented in the form of unofficial "draft guidance" to facilitate the implementation of REACH, and it will be officially incorporated into the ECHA Guidance on intermediates after 30 November 2010.

1. Regulation (EC) No 1907/2006, of the European Parliament and of the Council, of 18 December 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, OJ L 396, 30.12.2006, p. 1-849.

2. This document represents the consolidated version of two previous ECHA notes (published in January and April 2010) on the "*Clarification of the concept of intermediates under REACH*". The final version of the document did not reflect, or otherwise appear to take on board, most of the critical comments expressed by many stakeholders (e.g. Cefic, Orgalime and Eurometaux), and Member States (e.g. France and Austria).

Once adopted, the forthcoming ECHA Guidance on intermediates, while not being legally binding, will likely be instrumental in ECHA's interpretation of the rules that apply to intermediates. This stems from the express reference to such guidance in the text of REACH itself. Recital 24, for example, provides that ECHA shall make available "*appropriate technical guidance*"; while Article 77(2)(h) of REACH provides that the Secretariat (of ECHA) shall undertake the task of "*providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities*…". The ECHA Guidance on intermediates is one of the "*appropriate technical guidance*" documents mentioned above.

In addition, the European Courts have held that such guidance may "*form rules of practice from which the administration may not depart in an individual case without giving reasons that are compatible with the principle of equal treatment*"; so that it is reasonable to assume that, after adoption of the Guidance on intermediates, ECHA will have limited its discretion to take different views "*under pain of being found, where appropriate, to be in breach of the general principles of law, such as equal treatment or the protection of legitimate expectations*".[3] Therefore, it must be assumed that, while conducting the evaluation (under Title VII of REACH) of registration dossiers concerning intermediates, ECHA will apply its Guidance on intermediates. In turn, the EU Member State authorities may decide to follow the indications included in such paper to justify their enforcement actions.

In this respect, it is noteworthy that ECHA has already informed the CARACAL authorities and the EU Member State enforcement authorities about its first findings in the evaluation of some intermediate registration dossiers.[4] These included a number of dossiers (9) which were deemed to be incomplete because the claimed intermediate status was not correctly justified. The registrants of those dossiers have been requested to provide further information in response to ECHA's quality observation letters.

The most notable and innovative conclusions discussed in the ECHA paper can be summarised as follows:

the transformation of an isolated intermediate into another substances must occur in **a subsequent step** following the manufacture of the intermediate (page 5);

the **main aim** of the chemical process must be to transform one substance into another substance, not to achieve any other function (page 6); and

the parent substance of the substances exempted from the obligation to register under **Annex V,** paragraphs 3 and 4, cannot be an intermediate as it is a substance used in order to provide a specific function / physico-chemical property (page 11).

II. Legal analysis - the concept of intermediates under REACH

In their efforts to clarify the meaning of EU law provisions, the EU Courts typically adopt a *literal* interpretation by referring to the actual wording used in a provision. Where such actual wording proves not clear enough, the Courts usually resort to a *systematic* and *teleological* interpretation.[5] This is conducted by placing the single legal provision into the context of the entire act, and by focusing on the purpose of the legislative act in which the provision to be interpreted is contained.

The same approach can be used here to identify the exact meaning of the concept of intermediates in REACH.

3. In this respect, see, by analogy, Joined Cases C-189/02 P, C-202/02 P, C□205/02 P to C□208/02 P and C□213/02 P, *Dansk Rørindustri A/S et al. v Commission* [2005], paras 209/211: "*The Court has already held in a judgment concerning internal measures adopted by the administration, that although those measures may not be regarded as rules of law which the administration is always bound to observe, they nevertheless form rules of practice from which the administration may not depart in an individual case without giving reasons that are compatible with the principle of equal treatment.(see Case C-171/00 P Libéros v Commission [2002] ECR I-451, paragraph 35). (…) That case-law applies a fortiori to rules of conduct designed to produce external effects, as is the case of the Guidelines, which are aimed at traders. (…) In adopting such rules of conduct and announcing by publishing them that they will henceforth apply to the cases to which they relate, the institution in question imposes a limit on the exercise of its discretion and cannot depart from those rules under pain of being found, where appropriate, to be in breach of the general principles of law, such as equal treatment or the protection of legitimate expectations. It cannot therefore be precluded that, on certain conditions and depending on their content, such rules of conduct, which are of general application, may produce legal effects.*"

4. This information is provided in document Doc.CA/50/10 adopted following the 5th CARACAL meeting.

5. See, for example, joined Cases C-283/94, C-291/94 and C-292/94, *Denkavit International BV, VITIC Amsterdam BV and Voormeer BV v Bundesamt für Finanzen* [1996], para 26, where the Court looked first at the actual wording of Article 3(2) of Directive 90/435/EEC, then at the purpose of that directive.

II.A. Literal interpretation of the concept of intermediates

Article 3(15) of REACH defines an intermediate as "*a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis)*". Based on a purely literal interpretation of this definition, three conclusions can be drawn:

1. First, an intermediate is a "***substance***", within the meaning of Article 3(1) of REACH.
2. Second, for such a substance to qualify as an intermediate, the key element is the **intention to transform** ("*in order to be transformed*") it into another substance through chemical processing. While it is not entirely clear whether such transformation should be the *only* purpose of the creation and consumption/use of the substance, it is clear that it *must* – at a minimum – be possible to envisage the chemical transformation as the determining factor for the definition of an intermediate.
3. Third, it must be certain that both the manufacture ***and*** use of that substance are followed by its transformation into another substance through chemical processing.

The third conclusion warrants additional (literal) interpretation. Particularly, the use of the coordinative conjunction "*and*" (as opposed to "or") between the action of manufacturing and that of consuming/using a substance, suggests a connection between those two actions (i.e. manufacture and consumption/use).[6] There is nothing from a literal interpretation that prevents the actors responsible for the two connected events (that is the manufacture *and* the consumption/use) to be two, or more, separate entities. These will inevitably be the manufacturer and the user(s) (or "downstream users" as are defined in Article 3(13) of REACH) of the intermediates, **both** of which are under an obligation to make sure that the intermediate substance will be transformed into another substance.

As a conclusion, with regard to Article 3(15) of REACH, both a literal interpretation and clear meaning appear to be synonymous. Specifically, they lead to the conclusion that a substance is an intermediate if it is transformed into another substance during chemical processing:

- irrespective of the purpose of the process during which it is transformed;
- irrespective of whether the transformation is the immediate step after manufacturing, or a subsequent step in the intermediate's life cycle;
- irrespective of whether the resulting substance is used further in the same process (e.g. to react further or to perform a function in a mixture or in an article) and is placed on the market in a mixture or in an article, or is placed on the market as such;
- irrespective of whether, in some cases, the substance can be used as an intermediate and would qualify as such and, in other cases, the same substance would not be used as an intermediate and would not benefit from the special regime granted to intermediates under REACH; and
- irrespective of whether the substance into which the intermediate is transformed may be covered by specific provisions or exemptions of REACH.

The definition also warrants a case-by-case analysis of each circumstance where a substance is claimed to be an intermediate; the need for a case-by-case analysis can be inferred from the fact that the definition takes into account the intention of the manufacturing and the use. General conclusions – such as a conclusion that, for example, catalysts (as a group of substances) cannot be intermediates – are not supported by the definition of intermediates under REACH.

Based on the above conclusion, we believe that it is unlikely that the EU Courts would have recourse to a systematic/teleological interpretation of the REACH text.[7] Therefore, such analysis is conducted below only for the sake of completeness.

6. This is reinforced by other language versions of REACH. For example, in the French version of REACH Article 3(15) provides that an intermediate is a substance "*fabriquée en vue d'une transformation chimique et consommée ou utilisée dans le cadre de cette transformation en vue de faire l'objet d'une opération de transformation en une autre substance*".
7. See Opinion of Advocat General Jääskinen in Case C□582/08, European Commission v United Kingdom of Great Britain and Northern Ireland [2010], paras 26 and 27: "*(…) the literal interpretation and the clear meaning may not be synonymous as the literal meaning of a provision may be ambiguous. (…) Where the express wording of the provision is ambiguous or contradictory, the Court may reject a literal interpretation in favour of another which is more compatible with the objectives of the legislation in question.*"

II.B. Systematic and teleological interpretation of the concept of intermediates

To determine the intention of the EU legislator when it introduced the definition of intermediates it must be first considered (i) what is the general purpose of REACH and, second, (ii) what was the rationale behind the exemption (and, therefore, definition) of intermediates.

II.B.1 General purpose of REACH

The main aim of REACH, as expressed in Recital 1, is to "*ensure a high level of protection of human health and the environment as well as the free movement of substances*". To do so, Article 1(3) of REACH imposes on manufacturers, importers and downstream users an obligation to manufacture, place on the market or use chemical substances in a way that does not adversely affect human health or the environment. This is implemented by laying down specific duties and obligations assigning to manufacturers and importers the responsibility to assess the risks and hazards of substances.

However, REACH recognises that manufacturers and importers on the one hand, and EU and national competent authorities on the other hand, may encounter a number of practical difficulties in complying with the long list of requirements it imposes. For that reason, REACH includes certain exceptions to the general requirements applying to substances and mixtures, for "***reasons of workability***". These include, amongst others, an exception for waste (Recital 11) which is not considered as a substance or mixture; an exception from the obligation to report information to ECHA for downstream users using low quantities of a substance (Recital 61); and reduced registration requirements for intermediates (Recital 41, which also refers to the intermediates' special nature).

It goes without saying that these exceptions apply provided that the main aim of REACH, i.e. the high level of protection of human and the environment, can be guaranteed. Therefore, "*reasons of workability*" are only used to counterbalance duties and obligations imposed under REACH where minimal risks to human health and the environment are involved.

II.B.2The rationale behind the specific status of intermediates in REACH and the relevance of the specific status for the definition

As stated above, **Recital 41** of REACH confirms that intermediates are subject to specific (reduced) registration requirements on two grounds: (i) for reasons of ***workability*** and (ii) by virtue of their ***special nature***.

The **first reason** does not bring any additional element in terms of interpretation of the definition: intermediates are subject to fewer requirements (compared to those applying to the other substances) for practical reasons, i.e. to ensure workability and to avoid overloading the authorities with an excessively high number of intermediates registration dossiers, which would come in addition to the significant number of dossiers for all other chemicals for which registration is required.

The **second reason** justifying the reduced registration requirements can be understood by reference to the definition of intermediates and to the main aim of REACH. As stated above (Section II.A), intermediates are only manufactured with the purpose of being transformed into another substance. Therefore, any risk to human health and the environment deriving from the exposure to the intermediate is limited to the period between the manufacture and the consumption of the intermediate during chemical processing, at the end of which the intermediate is transformed into another substance. Provided the SCC required by REACH are fulfilled, those risks are deemed to be adequately controlled Therefore, reduced registration requirements are deemed sufficient to guarantee the safe use of such intermediate.

Nothing in the definition of intermediates, interpreted as described above under section II.A, would be at odds with the general purpose of REACH or the rationale behind the specific status granted to intermediates under REACH. Further, the fact that the clear interpretation of the definition of intermediates (as described above) may result in a large number of substances benefitting from the specific status granted to them under REACH is entirely consistent with the general purpose of REACH and the rationale behind the specific status: the "*special nature*", and related specific status, of intermediates under REACH are intrinsically related to the low risk to human health and the environment deriving from their use under SCC. When the SCC are not observed, intermediates must undergo full REACH registration.

II.B.3 The rationale behind the definition of intermediates in the travaux préparatoires of REACH

The review of the preparatory documents (or "*travaux préparatoires*") is an interpretative technique used by the EU Courts to ascertain the legislator's intention.[8] With the aim of identifying the exact scope of the concept of intermediates, we have reviewed the evolution of the definition of intermediates in the preparatory documents of REACH.

From the outset it is noteworthy that, since the Commission's first REACH proposal[9] in October 2003, until the adoption of the final version in December 2006, the provisions concerning intermediates in both the recitals and the text of REACH were almost entirely unchanged.

In the introductory part of the first proposal, the Commission clarifies the scope of the articles of REACH dealing with intermediates. The Commission states: "*for reasons of **workability** and to focus resources on **substances of more concern**, these articles introduce limited registration requirements for certain isolated intermediates. Non-isolated intermediates are excluded from Reach*". Recital 28 of the same Commission proposal mirrors the final Recital 41: "*For reasons of **workability** and because of their **special nature**, specific registration requirements should be laid down for intermediates*".

A small, but important, amendment to the definition of intermediates (originally included in Article 3(14)) was introduced by the European Parliament in its first reading.[10] In its 36th amendment, the Parliament suggested to remove the work "solely" from the definition of intermediates as "*a substance that is **solely** manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called synthesis)*".[11] The Parliament's justification was that "*the derogation should also apply to substances which are **not only** used as intermediates*".

In other words, the Parliament pointed out that, regardless of its chemical nature, the same substance may be used in certain instances for its inherent capability of transforming into another substance – i.e. it is used as an intermediate – or, conversely, to be used as such without further chemical transformation, for other of its intrinsic properties.

Hence, the review of the background documents leading to the final version of the intermediates' definition supports the interpretation described under Section II.A above, i.e., that a substance can be used as an intermediate in some cases and as a non-intermediate in other cases, depending on the process applied and the intention of use, and that a case-by-case analysis must apply.

II.C Conclusion

The systematic/teleological interpretation of the concept of intermediates is consistent with, and supports the conclusions drawn from, a literal reading of Article 3(15) of REACH.

III. Comments on the ECHA paper

As stated above, while ECHA's guidance documents are not technically binding, they are persuasive and may produce legal effects. It would therefore be imprudent not to consider them in this analysis and opinion as to whether the main conclusions included therein are consistent with the interpretation presented under Section II above.

8. See, *inter alia*, Case C-336/03, *easyCar (UK) Ltd v Office of Fair Trading* [2004] para 20, where the *travaux préparatoires* were considered as documents relevant for the interpretation of a directive. Opinion of Advocate General Sharpston in case Case C-173/07, *Emirates Airlines - Direktion für Deutschland v Diether Schenkel* [2008], para 43.
9. Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} {SEC(2003 1171} /* COM/2003/0644 final - COD 2003/0256 */.
10. Final act A6-0315/2005, adopted on 24.10.2005.
11. This definition was previously contained in Commission Directive 2001/59/EC, of 6 August 2001, adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 225 , 21/08/2001, p. 1 - 0333.

III.A The transformation of an isolated intermediate in a subsequent step

At page 5 of its paper ECHA states that "*[i]n accordance with the definition, an isolated intermediate is a substance that is manufactured for the purpose of being transformed into another substance* ***in a subsequent step****. The definition also specifies that the substance should effectively be used (i.e. transformed into another substance) in* ***such a subsequent step*** *in order to be regarded as an intermediate.*"

However, the text of REACH does not specify that the transformation of a substance must take place in a "subsequent step". To the contrary, the transformation can take place during the same process as the manufacture (assuming, of course, that the substance is isolated at one point during the process, otherwise it would qualify as a non-isolated intermediate).

Therefore, the subsequent step, if there is one, does not have to be the immediate step after manufacturing: transformation of the substance can take place any time during its life-cycle.

III.B The main aim of the chemical process

Pages 5 and 6 of the ECHA paper deal with the main aim of a chemical process. Here ECHA assumes that: "*as soon as the main* ***aim of the chemical process*** *is not to transform a substance (A) into another substance (B), or when substance (A) is not used for this main aim but to achieve another function, substance (A) used for this activity should not be regarded as an intermediate under REACH. It is therefore key in the definition of an intermediate that the manufacturer of the intermediate is certain that a customer of the intermediate is a manufacturer of another substance using the intermediate for chemical processing (synthesis) into that other substance.*" In addition, ECHA provides that "*[i]n case the customer is* ***using the substance*** *for other processes than for synthesising another substance, the substance is not considered to be an isolated intermediate*."

While the ECHA paper discusses the aim of the *chemical process*, this is not dealt with by REACH. As discussed above (Section II.A), Article 3(15) of REACH is concerned with the aim of the *manufacturing* and *consumption/use* of the substance (to be transformed into another substance) as such, but not with the aim of the chemical process during which the substance is transformed. This is an essential difference. Although it cannot be excluded that such aim is the transformation of one substance into another, it cannot be considered a certainty.

For example, substance (A) may react with substance (B) *in order to be transformed* into substance (C) on the surface of an article. The purpose of the chemical process in this instance is to provide specific physico-chemical properties to that article. Based on the reasoning set out in the ECHA paper, substance (A) could not qualify as an intermediate because the main aim of the chemical process would not be to produce substance (C), rather to modify an article. However, it has been seen (Section II.A) that for a substance to qualify as an intermediate the key element is the **intention to transform** it into another substance, and not how to use the substance resulting from that transformation.

A chemical process involving an intermediate can be aimed at creating a new substance, modifying an article, etc. but this is irrelevant for the definition of intermediate under REACH.

In particular, ECHA is right to say that *[i]n case the customer is* ***using the substance*** *for other processes than for synthesising another substance, the substance is not considered to be an isolated intermediate*." The purpose of the manufacture is indeed relevant to qualify a substance as intermediate, and it should be to transform one substance into another. However, ECHA is wrong to state that "*as soon as the main* ***aim of the chemical process*** *is not to transform a substance (A) into another substance (B) (...) substance (A) (...) should not be regarded as an intermediate*". In addition, since these two sentences deal with two different matters (i.e. the aim of the use of a substance and the aim of a chemical process), they cannot be used to draw the same conclusion (i.e. that substance (A) cannot be an intermediate).

On the same page, ECHA introduces a further assumption: "*[w]henever a substance (A) used in a chemical processing is not used in the manufacturing of another substance (B) in order* ***to be itself transformed*** *into that other substance (B), it is necessarily used in*

order to achieve another function than transformation". According to ECHA, this proves that such a substance cannot be an intermediate.

However, as is clear from the literal reading of Article 3(15), REACH only deals with the need for transformation ("*in order to be transformed*"), and not with how such transformation should be done, e.g. through how many steps or in what order. Again, here ECHA appears to introduce a novel element to the definition of intermediates, which is not justified by either a literal or a systematic/ teleological interpretation.

III.C Substances exempted under Annex V, Paragraphs 3 and 4

At page 11, Paragraph 5, the ECHA paper includes some final considerations on substances that are exempted from the obligation to register pursuant to Article 2(7)(b) of REACH and are included in Annex V of REACH. Here ECHA appears to apply a teleological interpretation of REACH (focusing on the key objective of REACH, i.e. to protect human health and the environment) to support a complex reasoning leading to the conclusion that substances included in Annex V, Paragraphs 3 and 4, cannot be the result of chemical processing involving intermediates.

Particularly, ECHA considers that: "*[a]ny substance formed either during the production of an article and not intended to be released or in any activity other than the manufacturing of a substance on its own is not subject to registration. The* ***risks associated*** *with such a substance should be addressed in the registration of the substances from which it originates (the parent substances).*" Based on this consideration, ECHA concludes that "*these* ***parent substances cannot be regarded as intermediates****, (...)* ***The parent substance of the substances exempted from the obligation to register under Annex V paragraphs 3 and 4 cannot be an intermediate as it is a substance used in order to provide a specific function / physico-chemical property***".

Once again, ECHA introduces confusion and adds to the legal definition of an intermediate. The definition does not exclude the possibility of the chemical process, during which the intermediate is transformed, to have another function such as providing a stabilising function. The definition simply requires that, during this process that may have multiple purposes, the intermediate is transformed. Hence, substances covered by Annex V.4, can result from an intermediate as long as the initial (parent) substance has been transformed, even if that initial (parent) substance also performed a function such as a colorant, stabilising or physiochemical function.

Similarly, substances covered by Annex V.3 can result from an intermediate, since an intermediate can have as an end use the transformation into another substance which is not itself manufactured, imported or placed on the market.

The fact that, in these situations, the substance into which the intermediate is transformed is exempt from registration is entirely and utterly irrelevant to the classification of the intermediate as such.

IV. Final considerations

Our analysis of the relevant provisions in REACH concerning the definition of intermediates appears to arrive at different conclusions to those reached by ECHA in its paper. In Section III above we have highlighted such differences by providing some comments on some of the aspects of the ECHA paper.

More generally, we have noted that the ECHA paper narrows the concept of intermediates with the consequence that many substances run the risk of not falling within its scope and will, as a result, not benefit from the special regime granted to intermediates (e.g. reduced registration requirements; exemption from Title VII on authorisation).

In its first note on the concept of intermediates,[12] ECHA explains that the reason for a clarification on this concept emerged through the enquiries submitted to the ECHA Helpdesk, and also following "*the public consultation for the prioritisation of substances of very high concern to be included in Annex XIV of REACH (the "authorisation list")*". It may be deduced from that statement that the ultimate goal of ECHA was not actually to clarify the definition of intermediates – which, as seen above

12. Doc.: CA/04/2010, of 21 January 2010.

(Section II.A), is clear enough – but, rather, to limit the number of intermediate substances that could be exempted from the authorisation under REACH.

By doing so, ECHA has stepped outside its competence which is granted to it under REACH. At most, by virtue of Article 77(2)(h) of REACH, it can give "*technical and scientific guidance on the operation*" of REACH. With its paper, however, ECHA has brought out new reading of the text of REACH, which does not appear to be consistent with the clear provisions of REACH, as discussed in Section II. That new reading is based on, amongst other things, the introduction of new criteria which have been read into the definition by ECHA. That introduction (and the resulting far-reaching change in definition) is not within the legal competence of ECHA to do. It has no legislative competence either to narrow or widen the definition given in Article 3(15) of REACH and by ascribing itself such competence, it is both acting *ultra vires* and, given its probable intention, misusing its power.[13]

In addition, the practical result of the application of ECHA's interpretation may be that fewer substances would be considered as intermediates and registered as such. This, in turn, may in fact lower the protection of human health and environment. This is so because, under the system provided by REACH and devised by the legislator, intermediates are only subject to reduced registration requirements if they are used under Strictly Controlled Conditions. The SCC are, in turn, controlled and enforced by Member State authorities.

Hence, REACH puts into place the control by Member States (within their enforcement duties under Article 126 of REACH) in order to ensure a high level of protection of human health and the environment. The application of the strict definition of intermediates by ECHA eliminates such control, since Member States will no longer exercise formal control of the use conditions of intermediates

Moreover, on a practical point of view, it would be extremely difficult for registrants of intermediates to transform their dossiers in full registration dossiers, so as to take into account the new ECHA's guidance. As known, the amount of data and the costs involved in the development of a full registration dossier are tremendously higher if compared to those required for an intermediate dossier. Furthermore, it may be realistically impossible to meet the REACH registration deadlines, particularly for substances to be registered by December 2010. Ultimately, the number of intermediate registration dossiers to be submitted to ECHA may be so high as to affect the workability of the entire registration system. As noted by some national authorities,[14] the number of intermediates eligible for registration has been estimated to outnumber all other (non-intermediate) substances by a factor larger than two.

Therefore, considering that "*reasons of workability*" are the primary factor (as mentioned in Rectal 41 of REACH) to justify the special requirements for intermediates, ECHA's guidance goes against such general scope of REACH.

13. See, *inter alia*, joined Cases 33, 44, 110, 226 and 285/86, *Stahlwerke Peine-Salzgitter AG and Hoogovens Groep BV v Commission* [1988], para 27; and Case C-210/03 *Swedish Match AB v Secretary of State for Health* [2004], para 75.
14. See comments of the Swedish competent authorities (KEMI), of 5 March 2010, on the first ECHA's paper on the clarification of the concept of intermediates.

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