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4TH MEETING OF COMPETENT AUTHORITIES FOR REACH AND CLP (CARACAL)

2-4 February 2010

Centre A. Borschette, Room 1D, Rue Froissart 36, BE-1040 Brussels, Belgium

Concerns:	**Clarification on the concept of intermediates under REACH**
Agenda Point:	**6.1**
Action requested:	**The REACH Competent Authorities are invited to take note of this document and to provide comments where appropriate.**

Clarification on the concept of Intermediates under REACH[1]

1. Introduction

Intermediates are a class of substances for which specific provisions have been laid down under REACH for reasons of workability and because of their special nature (recital 41). REACH distinguishes between non-isolated and isolated intermediates. While the REACH Regulation does not apply to non-isolated intermediates, isolated intermediates are ruled under REACH but the general requirements are significantly reduced. In particular, isolated intermediates benefit from reduced registration requirements, provided their manufacture and use take place under the conditions set in Article 17 and 18. For on-site isolated intermediates used under strictly controlled conditions, neither dossier nor substance evaluation apply (Article 49).[2]

For on-site isolated intermediates, the provisions on introducing new and amending current restrictions (Article 68(1)) do not apply. Isolated intermediates are also exempt from authorisation (Article 2(8)).

For the proper implementation of the REACH Regulation, the status of a substance as to whether it is an isolated intermediate or not should be unequivocal. From the experience on the enquiries submitted to the ECHA Helpdesk and on the public consultation for the prioritisation of substances of very high concern to be included in Annex XIV of REACH (the "*authorisation list*"), it appears that further clarification on the concept of isolated intermediate is necessary.

The objective of this note is therefore to clarify the circumstances under which a substance may or may not be regarded as an isolated intermediate under REACH. Considerations on non-isolated intermediates are not relevant since these substances are outside the scope of REACH and the intention of this document is not to explain when an intermediate should be regarded as a non-isolated or isolated intermediate.

2. Analysis of the definition of intermediate (Article 3(15))

In accordance with Article 3(15) of the REACH Regulation, an intermediate is "*a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance*." The status of a substance as an intermediate is in fact not specific to its chemical nature but to how it is used following manufacturing.

The definition of an intermediate is therefore the definition of an intermediate use of a substance. If the whole quantity of a registered substance is consumed in or used for chemical processing in order to be transformed into another substance, then the substance is called an intermediate *for that registrant*. If this is not the case, then the substance is not called an intermediate, but is a substance which may have an intermediate use, among other uses.

This definition includes non-isolated intermediates, on-site isolated intermediates and transported isolated intermediates.

Article 3(15)(a) of REACH defines non-isolated intermediates as an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. This type of intermediates will not be further discussed in this note.

Article 3(15)(b) of REACH defines on-site isolated intermediates as intermediates not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the

[1] This note has been prepared jointly by the Commission and ECHA

[2] Further guidance on the concept of (strictly) controlled conditions under REACH is being developed as part of a service request (Framework Contract No ECHA/2008/02/SR19).

synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities. Therefore, these substances are by definition first isolated before being used for chemical processing to be transformed into another substance. In 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. It is a condition that such a use is a certainty rather than a mere possibility. In the case of on-site isolated intermediates, Article 3(15)(b) specifies that this subsequent step should take place on the same site as the manufacturing of the intermediate.

A transported isolated intermediate is defined in Article 3(15)(c) of REACH as an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites. Clearly, if the substance is transported between sites, it fails the criteria of a non-isolated intermediate, so the essential elements of the definition is that the substance is an intermediate (i.e. is used as an intermediate) and is transported between or supplied to other sites.

It is clear from Article 3(15)(b) that on-site isolated intermediates are substances used for chemical processing to be transformed into another substance on one specific "site", i.e. a single location with infrastructure and facilities of one or more manufacturers (Article 3(16)). Similarly, it is clear from Article 3(15)(c) that transported isolated intermediates are used for chemical processing to be transformed into another substance on one or more "sites". The definition of "site" in Article 3(16) suggests that it is a location, in which "manufacturing" (of the intermediate or of the other substance) takes place. Hence, chemical processes involving the use of isolated intermediates are manufacturing activities where the synthesis or transformation is carried out and should therefore be considered as "manufacturing" under REACH.

The new substance formed should be different from any of the substances used in that process.

On the other hand, as soon as the main aim of the chemical process is not to transform a substance into another one or the substance is not used for this main aim but rather to achieve another function, the substances used for this activity should not be regarded as intermediates 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 a new substance using the intermediate for chemical processing into that new substance.

Examples of circumstances under which substances that may be considered as intermediates can be chemically transformed in industrial activities are provided in next Section 3.

3. Examples of Industrial activities involving chemical transformation of substances considered as intermediates

Having in mind the definition of intermediate and following the analysis developed in the previous section, the following manufacturing activities leading to the chemical modification of a substance may be distinguished under REACH (the provided examples are illustrative of cases for which a common understanding is necessary):

3.1. Manufacturing of another substance on its own

A substance (A) may be used as a reactant in the manufacturing of another substance (B) (also referred to as "new substance" in this note). For this new substance (B) any use may be conceived. The reactant (A) used in the manufacturing process to manufacture the new substance (B) can therefore be defined as a substance used "in order to be transformed into another substance". Such a type of use of the reactant (A) is therefore considered as a use as an intermediate under REACH and therefore the reactant (A) is called an intermediate as far as this particular application or use goes.

It is important to note that in this particular case the use of the intermediate is exclusively that of the use as reactant in the manufacturing of other substances. Any other use of the reactant (A) would disqualify the reactant (A) from being an intermediate.

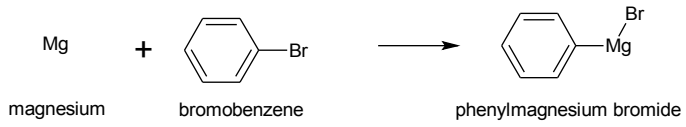
Due to the practical nature of manufacturing processes and to the fiscal attributes of manufacturing sites, one or more steps between the manufacturing of the reactant (A) and its use in the manufacturing of the new substance (B) may be necessary to facilitate/ensure proper chemical processing in the manufacturing of a new substance.

However these steps do not alter the fact that the substance was manufactured and used in synthesis and do therefore not discredit the substance from being an intermediate. An example of such a steps is set out in example 4 below.

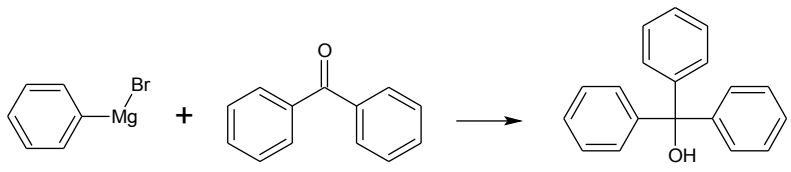
Any substance used in the manufacturing process of another substance but which is not a reactant, for instance a solvent, cannot be an intermediate.

Example 1: Substances used as reactants

Triphenylmethanol may be manufactured in accordance with a Grignard reaction using magnesium, bromobenzene and benzophenone as reactants. In this example, magnesium is first reacted with bromobenzene and the phenylmagnesium bromide (Grignard reactant) thus formed is not isolated from the reactor but is further reacted *in-situ* with benzophenone.



magnesium bromobenzene phenylmagnesium bromide



benzophenone triphenylmethanol

In this specific process, both magnesium and bromobenzene are regarded as isolated intermediates used for the manufacturing of phenylmagnesium bromide. **Phenylmagnesium bromide is a non-isolated intermediate** used for the manufacturing of triphenylmethanol. Finally, **benzophenone is an isolated intermediate** used for the manufacturing of triphenylmethanol.

Example 2: Substances used as catalysts

Catalysts are substances used to change the rate of chemical reactions. A substance used as catalyst in the manufacturing of another substance on its own can not be regarded as an intermediate under REACH because the catalyst is not used to be converted into another substance and because the new substance formed does not originate from the catalyst.

For instance p-toluenesulfonic acid is commonly used as catalyst in the manufacturing of esters from carboxylic acids and alcohols. For these uses, **p-toluenesulfonic acid cannot be regarded as an intermediate**. This applies regardless of whether it is recovered at the end of the process or not.

Example 3: Substances used as processing agent

Substances may be added at any stage in the manufacturing process of a substance in order to optimise the physico-chemical environment of the reaction medium. Examples include dispersing agents, viscosity modifiers, lubricants, antistatic agents, etc. As these processing agents are not used in order to be themselves converted into another substance and the new substance is not formed from the processing agent, **they are not regarded as intermediates**. This applies regardless of whether such agents are isolated from the manufactured substance or end up as impurities of that substance.

Example 4: Intermediates and substances in mixtures

Company X manufactures sodium hydroxide and sells this substance to company Y in order for that company to manufacture sodium acetate. The chemical processing used by company Y requires water to be added to the sodium hydroxide prior to both the reaction to manufacture sodium acetate. For technical reasons, company Y adds water to sodium hydroxide at one location on the manufacturing site and then uses this at another location on the same site to manufacture sodium acetate. Sodium hydroxide may still be regarded as an intermediate although the production process of sodium acetate entails several steps isolated in location on the manufacturing site. This is based on the fact this step is ancillary to the aim of synthesising sodium acetate from sodium hydroxide.

3.2. Industrial end use other than in manufacturing of another substance on its own

In the case that a substance (A) is used by the manufacturer himself or by a downstream user in a process where it chemically reacts but it is not transformed on a site into another substance (there is no 'synthesis'), then substance (A) cannot be an intermediate. As soon as the main aim of the chemical process is not to manufacture a new substance but rather to achieve another function or specific property, the substances used for this activity should not be regarded as intermediates under REACH.

An example is the production of articles. Article 3(15) of the REACH Regulation requires that the intermediate is transformed into another substance. Hence by virtue of Article 3(1) and 3(9) an intermediate must be used for the manufacture of a substance. The intermediate can therefore not be used for the production of an article. Indeed, as mentioned above a substance, which is used for chemical processing with the main aim not being to transform it into another substance but rather to achieve another function, should not be regarded as an intermediate under REACH. This is further clarified through the consistent use of the words ‘production’ and ‘producer’ when referring to articles and ‘manufacture’ and ‘manufacturing’ when referring to substances.

Further examples not limited to the production of articles are given below:

Example 5: Substance used as curing agent

Curing agents are normally used to convert a resin into a solid mass which cannot be alone further processed as such but is given a shape as part of a more complex product (in general an article). Substances used as curing agents are normally not intermediates under REACH because they are not transformed into another substance as such but used to provide a specific physical property to a resin.

As an example, the adhesive properties of epoxy-based adhesives essentially originate from the *in-situ* curing of epoxy resins with a curing agent. Hence, even though the curing agent chemically reacts with the epoxy resin the substance used as curing agent in **these two-component adhesives is not an intermediate** under REACH.

Example 6: Substance used as surface treating agent

A surface treatment is generally carried out to provide a specific physico-chemical property to a macroscopic substance, either on its own or in a mixture, or in an article. Surface treatment may involve chemical reactions at the surface of the material to be treated. As long as the main aim of the process results in providing a specific physico-chemical characteristic to a material (irrespective of whether the surface treating agent is consumed in a chemical reaction and which results in another substance), surface treating agents are not regarded as intermediates.[3]

For instance, silver cyanide may be used as treating agent to provide a protective layer of silver metal for decorative purposes. Although the technique consists in the electrochemical modification of the treating agent into silver metal, **the treating agent cannot be regarded as an intermediate**, because the process aims at providing a physico-chemical property to the material by modifying the visual appearance of a surface of an article.

Example 7: Substances used as desiccant

Calcium hydride (CaH_2) may be industrially used as dewatering agent. The mode of action of this drying agent is based on the chemical reaction taking place between calcium hydride and water (e.g. as form of humidity in certain gases, as impurity in an organic solvent), which results in the formation of calcium hydroxide ($Ca(OH)_2$). This way, for example, the gas or the organic solvent are free of water. For this application, **calcium hydride is not an intermediate**, since the main aim of the use of this substance is to remove water from treated organic solvent and not to be transformed into calcium hydroxide.[4]

4. Intermediates and registration provisions under REACH

One of the key-objectives of REACH is to ensure a high level of protection of human health and the environment. For this purpose, the REACH Regulation includes mechanisms for industry to address the risks associated with any substance formed, regardless of whether it is in the context of the manufacturing of a substance on its own or other (professional) activities.

In this respect, registration constitutes the basic mechanism to be used by industry for the reporting of data on the substances they manufacture or import, the assessment of the risks related to them and the recommended appropriate risk management measures.

While specific registration requirements have been laid down for intermediates, REACH still ensures that the risks associated with the manufacturing and use of any registered substance is adequately assessed, as explained below.

An intermediate being a substance used as reactant in the manufacturing of another substance on its own, the standard registration requirements should normally apply to the new substance formed. Where relevant, the risks associated with the new substance formed should be addressed in its registration. On the other hand, the registration of the intermediate is to cover the risks from its manufacture and use until it is reacted. REACH requires that the reduced registration information requirements specified in Article 17 and 18 only apply to intermediates manufactured and handled under the conditions set in these Articles. REACH therefore ensures the complete coverage of the risks throughout the supply chain.

[3] Please note that in some of these instances the substance resulting from the chemical reaction of the surface treating agent and the material does not need to be registered as per Annex V point 4.

[4] Indeed, in this example, calcium hydroxide ($Ca(OH)_2$) is exempted from Titles II, V and VI of REACH as it benefits from Annex V point 4 (see Communication from the Commission (C(2009)2482 on the reviews of Annexes I, IV and V of REACH). The reason why $Ca(OH)_2$ is exempted is that the registration provisions apply to the manufacture or import calcium hydride (CaH_2), but the information on $Ca(OH)_2$ should be included in the Chemical Safety Report (CSR) of CaH_2.

This same logic is taken in the exemptions contained in Annex V: if a substance (A) is transformed into another substance (B), and substance (B) benefits from Annex V exemptions, as it is not considered to be itself manufactured, imported or placed on the market, then substance (A) must be registered with the full information requirements and the CSR, if required, should take account of the exposures to substance (B). It is therefore not possible under REACH to have a situation where both substance (B) benefits from the Annex V exemptions and substance (A) is an intermediate as this will hinder the protection of human health and the environment which are chief objectives of REACH.

Any 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 the new substance formed should however be addressed in the registration of the substances from which it originates. Because these parent substances are not regarded as intermediates, REACH ensures that their registration dossiers include a CSR covering these risks, as appropriate. This is also consistent with the provisions under Annex V paragraphs (3) and (4) which clarify that substances formed either upon end use of another substance or in order to ensure that a specific function / physico-chemical property is provided are exempted from the registration provisions if they are not themselves manufactured, imported or placed on the market. Both the Commission Communication C(2009)2482 and the draft Guidance on Annex V state that, although they are exempted from registration, the risks emanating from them should be reflected in the chemical safety assessment of the parent substance(s).

5. Conclusions

A substance is an intermediate if all following conditions are met:

- The substance is manufactured to be converted into another substance on a(n) (industrial) site,
- The outcome of the process is another manufactured substance on its own but not another substance in an article.