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The Definition of Intermediates within REACH

Legal Opinion

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commissioned by *Verband der Chemischen Industrie e.V. (VCI)*

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The opinion analyses the definition of intermediates under the REACH Regulation from a legal standpoint. In May 2010, ECHA published the document “Definition of intermediates as agreed by Commission, Member States and ECHA on 4 May 2010” which shall contain a clarification of the definition of intermediates and shall explain the obligations under REACH in respect of intermediates¹.

The legal opinion will discuss the approach and conclusions of ECHA. After a glance at the legal background (**cf. I.**), a first analysis of Article 3(15) of the REACH Regulation which contains the definition of intermediates is provided (**cf. II.**). Then, by looking at selected cases (**cf. III.**), the interpretation of ECHA (**cf. IV.**) will be discussed in detail (**cf. V.**). Finally, the results are summarized (**cf. VI.**).

I.

The rules for intermediates within the framework of REACH

The REACH Regulation (EC) No. 1907/2006 established a new legal framework for chemical substances. The idea behind REACH is to regulate the risks resulting from chemical substances which may affect the environment and/or the health of humans if they are exposed to chemicals as consumers or workers. To fulfill those aims of REACH, i.e. the protection of the environment and human health, REACH establishes a scheme for the assessment and management of risks resulting from chemical substances, by laying down provisions on substances on their own, in mixtures or in articles. The scheme of REACH to regulate the risks resulting from substances rests on four pillars: registration, evaluation, authorization and restriction.

Yet, it is not the approach of REACH to identify, assess and manage all thinkable risks for all substances in a comprehensive way, but rather to take also other interests and considerations into account. This is already demonstrated by Article 1(1) of the REACH Regulation which lists the purposes of REACH. Besides the objective to ensure a high level of protection of human health and the environment, REACH aims at enhancing competitiveness and innovation, safeguarding the free circulation of substances on the internal market as well as promoting alternative methods for assessment of hazards of substances. On this basis, the European Legislator implemented in REACH a differentiating and focused approach of risk regulation, while taking various aspects into account: inter alia, the special nature and specific properties of substances, considerations of workability and practicality (cf. recitals 11, 61 and 77), requirements of proportionality to avoid excessive burdens for industry (cf., inter alia, recitals 61 and 25), the volume of a substance manufactured or placed on the market, or specific uses

¹ The document is the outcome from the conclusive written procedure initiated on 20 April 2010 on document CA/04/2010rev. 1 to the attention of the Competent Authorities for REACH and CLP (CARACAL).

of a substance². Those considerations are reflected in the regulatory framework of REACH which contains special provisions which are tailored to meet the above mentioned aims and concepts. In respect of the registration phase there are several examples for this differentiating approach:

- (i) Even though there may be risks associated with a substance, but to avoid excessive burdens (recital 25), the submission of a registration is not necessary for substances which are manufactured or imported in quantities of less than one tonne per year (Article 6(1) of the REACH Regulation); in addition, Article 14 of the REACH Regulation provides that a chemical safety assessment shall be performed and a chemical safety report completed only for substances in quantities of 10 tonnes or more per year per registrant³.
- (ii) Substances in articles, at least in principle, must only be registered if the particular substance is intended to be released under normal or reasonably foreseeable conditions of use (Article 7(1) of the REACH Regulation)⁴.
- (iii) Article 2(7) (a) and (b) of the REACH Regulation contains exemptions from the registration requirements for substances listed in Annex IV (because they are considered to cause minimum risks due to their intrinsic properties) and Annex V (because a registration is deemed inappropriate or unnecessary for these substances and the objectives of REACH are not prejudiced)⁵.

Also, in respect of intermediates, the European Legislator introduced special provisions with regard to registration⁶. In this context, recital 41 of the REACH Regulation states:

² Other factors which are taken into account are the specific characteristics of research, development and manufacturing of a substance, the work for authorities which implement or enforce REACH (cf. recital 42), compatibility with WTO law, animal protection by promotion alternative testing methods; consistency with other regulatory provisions of the EU.

³ Furthermore, Article 12 and Annexes VII to X of the REACH Regulation provide that the data requirements rise if specific tonnage thresholds are crossed.

⁴ In addition, also the tonnage threshold of 1 t/a applies. Further exemptions are provided by Article 7(2) of the REACH Regulation; pursuant to Article 7(5) of the REACH Regulation, ECHA may take decisions requiring producers and importers of articles to submit a registration.

⁵ Other special provisions with regard to registration exist, inter alia, for R&D substances (cf. Article 9 and recital 28 of the REACH Regulation), for polymers and monomers (cf. Article 2(9) and Article 6(2), (3) of the REACH Regulation), for the use of substances in food, feedingstuffs, medicinal products, plant protection products and biocidal products (cf. Article 2(5) and Articles 15, 16 of the REACH Regulation), or waste (cf. Article 2(2) and recital 11 of the REACH Regulation).

⁶ In addition, the requirements under REACH are also modified with regard to evaluation (cf. Article 49), restrictions (cf. Article 68(1)), authorization (cf. Article 2(8)(b)) and information (cf. Articles 118(2)(b), 119(2)(g)(iii)).

“For reasons of workability and because of their special nature, specific registration requirements should be laid down for intermediates”.

The reference to “reasons of workability” demonstrates that the European Legislator puts a special emphasis on the fact that the registration of intermediates shall take the practical impacts for industry and authorities into account. The special nature of an intermediate results from the fact that the particular substance is part of chemical processing. Due to the specific situation for intermediates (and to assess and manage the risks resulting from intermediates in an appropriate, adequate end efficient way), the European Legislator provided special rules in respect of the registration of intermediates, while taking the different types of intermediates and their possible modes of handling into account.

Article 3(15) of the REACH Regulation (after defining the term “intermediate”) distinguishes between three types of intermediates: (a) non-isolated intermediates which, during synthesis, are not intentionally removed (except for sampling) from the equipment in which the synthesis takes place⁷; (b) on-site isolated intermediates which do not meet the criteria of non-isolated intermediates, but where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site; (c) transported isolated intermediates which do not meet the criteria of a non-isolated intermediate and which are transported between or supplied to other sites.

While non-isolated intermediates are exempted from REACH at all (Article 2(1)(c) of the REACH Regulation), reduced registration requirements apply for the registration of on-site isolated intermediates and transported isolated intermediate (cf. Articles 17, 18 of the REACH Regulation), if the criterion of strictly controlled conditions is fulfilled (cf. Articles 17(3), 18(4) of the REACH Regulation). It is the condition of strictly controlled conditions which embodies the special risk regulation strategy for intermediates: The risks resulting from an intermediate are regarded as sufficiently managed if the particular intermediate is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole life cycle. If those conditions are met, reduced registration requirements are justified. If those conditions are not met, the regular registration requirements shall apply.

II.

The definition of intermediates in Article 3(15) of the REACH Regulation

Pursuant to Article 3(15) of the REACH Regulation, an intermediate

⁷ Such equipment shall include the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipe work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture.

“means 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)”.

Hence, the definition of the term „intermediate“ in Article 3(15) of the REACH Regulation contains singular elements:

(1) “substance” ...

First, the definition of an intermediate requires that the intermediate as a precursor of another substance is as well a substance itself within the meaning of Article 3(1) of the REACH Regulation. Such precursor can also be part of a mixture within the sense of Article 3(2) of the REACH Regulation.

(2) ... “that is manufactured for” ...

The precursor must be manufactured for chemical processing. The wording “for“ demonstrates that the aim of the manufacturing of the precursor must be that it is used for chemical processing⁸. The term „manufacturing“ is defined in Article 3(8) of the REACH Regulation as „production or extraction of substances in the natural state“.

(3) ... “and consumed in or used for” ...

The precursor must be either consumed in or used for chemical processing. For a classification as intermediate it is sufficient that one of the two alternatives is fulfilled. A consumption requires that the particular substance does not exist anymore after the chemical processing. The term “use” embodies any utilisation of the substance within chemical processing which includes, pursuant to Article 3(24) of the REACH Regulation, the production of an article.

(4) ... “chemical processing” ...

The term “chemical processing” is not defined by the REACH Regulation. Neither does Article 3(15) of the REACH Regulation describe the function, aim or content of a chemical processing. Article 3(15) only demonstrates that a chemical processing includes the consumption or use of the precursor and also the transformation of the precursor into another substance.

In particular, the term “chemical processing” cannot be considered as a synonym for the term “manufacturing of a substance” in the sense of Article 3(8) of the REACH Regulation. If the European Legislator had meant to use both terms synonymously, he would

⁸ ECHA (Definition of intermediates, p. 4) states correctly that the status of a substance as an intermediate is not specific to its chemical nature but to how it is used following manufacturing.

have expressed it by using the term “manufacturing” instead of “chemical processing” in the definition of Article 3(15).

Moreover, Article 3(39), (40) of the REACH Regulation indicates that the term “chemical processing” must be understood in a broad sense: Article 3(40) shows that chemical processes may even take place when the chemical structure of a substance remains unchanged, e.g. if impurities are removed. This is a clear indication that activities like the removal of impurities (or also a treatment of the surface of an article) which are not primarily directed at manufacturing a substance, may qualify as chemical processing. Also, Article 3(39) provides, in respect of substances that occur in nature, several examples for “processes”, e.g. processes which are performed by manual, mechanical means or by dissolution in water.

(5) ... “in order to be transformed” ...

The term “transformation” is not defined in the REACH Regulation either. Since the result of the transformation has to be “another substance”, it is clear that the chemical identity⁹ of the substances must change. Also, this implies that the precursor, after the transformation, does not exist anymore in its original form. Yet, it cannot be derived from the term “transformation” that the substance must be transformed permanently. From a literal interpretation it is sufficient that the precursor is transformed temporarily¹⁰.

Further, the wording does not indicate that the term “transformation” is used as a synonym for the term “manufacturing of a substance” in the sense of Article 3(8) of the REACH Regulation. If the European Legislator had meant to use both terms synonymously, he would have expressed it by using the term “manufacturing of another substance” instead of “transformed into another substance” in the definition of Article 3(15) of the REACH Regulation.

The wording “in order to” shows that an intention to transform the precursor is needed. Yet, Article 3(15) does not require that this has to be the only purpose of the activity. Rather, the person who performs the chemical processing may have more than one singular aim; i.e. he may have secondary goals to obtain the primary goal. Thus, it is sufficient (but also essential) that the transformation of a precursor into another substance is intended as a necessary step in the process.

⁹ Cf. ECHA, Guidance for identification and naming of substances in REACH, June 2007.

¹⁰ This is confirmed, if one looks at non-isolated intermediates which are, by definition, substances. This indicates that the REACH Regulation considers also transitional substances as intermediates.

(6) ... “into another substance” ...

The term “into another substance” indicates that the precursor which was manufactured for chemical processing is transformed into that substance. However, Article 3(15) does not impose specific requirements in respect of the character, form and use of the other substance¹¹. Therefore, the definition of Article 3(15) does not stipulate (i) that the other substance has to be a substance which must be registered; (ii) that the other substance cannot be a substance in an article; (iii) that the other substance cannot be a substance in a mixture; (iv) that the other substance cannot be another intermediate (such as a non-isolated intermediate in case of catalysts) as long as it qualifies as substance in the sense of Article 3(1) of the REACH Regulation.

(7) ... “(hereinafter referred to as synthesis).“

The definition of intermediates contains in brackets the concluding remark: “hereinafter referred to as synthesis”. Thus, the chemical processing which results in the transformation of the precursor into another substance is defined as “synthesis”. Since this last element of the definition is only declaratory to enable a clear wording of lit. a) to c) of Article 3(15), it does not stipulate additional requirements for the definition of intermediates.

III.**Selected Cases**

Despite the fact that the European Legislator introduced a definition of intermediates in Article 3(15) of the REACH Regulation it is not clear which situations are covered by the term „intermediate“. Against this background, various situations for which a classification as intermediate can be discussed shall be listed, before the interpretation of ECHA is analysed.

Case 1: Substances used as reactants for the manufacturing of another substance (example 1 of ECHA)

Substance A is used for the manufacturing of substance X. A chemical reaction takes place in which substance A is transformed into substance X.



Is substance A an intermediate?

¹¹ Furthermore, Article 3(15)(b) and Article 18(4) of the REACH Regulation show that also two or more substances may be the product of a transformation.

Case 2: Substances used as catalysts (example 2 of ECHA)

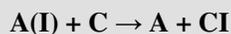
Substances A and B are used for the manufacturing of substance X, using catalyst C for the manufacturing of substance X. A chemical reaction takes place in which substances A and B are transformed into substance X, and substance C is transitionally transformed into substance AC (as non-isolated intermediate).



Is substance C an intermediate?

Case 3: Substances used to remove impurities or used as desiccants (example 7 of ECHA)

(a) Substance I consists as an impurity of substance A. To remove the impurities of substance A, substance C is used. A chemical reaction takes place in which substance C is transformed into substance CI. The substance CI needs to be disposed of.



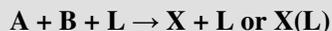
Is substance C an intermediate?

(b) The same situation arises if a substance is used as dewatering agent, e.g., to remove water from a gas, a solid or a liquid. One example for a desiccant can be found as example 7 of the ECHA-Document (page 10): Calcium hydride is used to remove water from treated organic solvents and, within this process, is transformed into calcium hydroxide.

Is calcium hydride an intermediate?

Case 4: Substances used as processing agents (example 3 of ECHA)

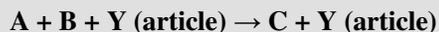
Substances A and B are used for the manufacturing of substance X, using substance L as lubricant to optimise the physico-chemical environment of the reaction medium. L remains as a substance, either isolated from the substance X or as an impurity of substance X.



Is substance L an intermediate?

Case 5: Substances used as surfacing treating agents (example 6 of ECHA)

Substances A and B are used for treating of the surface of article Y, by providing a specific physico-chemical property to that article. For this purpose, a chemical reaction takes place in which substances A and B are transformed into substance C.



Are substances A and B intermediates?

Case 6: Substances used for the production of an article

Substances A and B are used for the production of a substance C in an article Y. A chemical reaction takes place in which substances A and B are transformed into a substance C in an article Y.



Are substances A and B intermediates?

Case 7: Substances transformed into a substance covered by Annex V.3 or V.4 of the REACH Regulation

Substance A and B are used for the manufacturing of substance X, using substance C as a lubricant. A chemical reaction occurs in which substance C is transformed into substance Y, and substance Y is covered by Annex V.4.a) of the REACH Regulation.

A + B + C → X + Y (Annex V.4.a))

Is substance C an intermediate?

IV.

Interpretation of ECHA

With its document “Definition of intermediates as agreed by Commission, Member States and ECHA on 4 May 2010” ECHA published its interpretation of the definition of intermediates. The ECHA-Documents contains the following interpretation of Article 3(15) of the REACH Regulation:

“Whenever 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, either as part of the manufacturing of another substance (B) (e.g. as catalyst, processing agent, solvent), or as part of another activity (e.g. as an individual step in the production process of an article). While this other function may still involve chemical modification of the substance (A) used in the process, this type of use cannot be considered as the manufacturing of another substance (B) from the transformation of substance (A). Therefore, 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.”¹².

Thus, the essence of ECHA’s interpretation is: **For a classification as an intermediate, the main aim of the chemical processing must be that the precursor is used in the manufacturing of another substance by transforming the precursor itself into that other substance. If a precursor is used in order to achieve another function than the aforementioned, the precursor is not regarded as an intermediate.**

The concept that the transformation of the precursor into another substance must be a manufacturing of that substance is also embodied in the previous paragraph of the ECHA-Documents:

“An isolated intermediate (i.e. a substance “used [...] in order to be transformed into another substance”), is used in the manufacturing of another substance where it is itself transformed into that other substance. This other substance should be different from the intermediate used in the process. The definition of “intermediate” substance should therefore be understood to cover

¹² ECHA, Definition of intermediates, p. 5 et seq.

such transformation of this intermediate into another substance which is considered as “manufacturing” of that other substance in the sense of Article 3(8) REACH.”¹³

The last sentence demonstrates that ECHA considers as a mandatory requirement for a classification as intermediate that the transformation is a “manufacturing” in the meaning of Article 3(8) of the REACH-Regulation. The justification for this interpretation is provided by the previous paragraph of the ECHA-Dokument:

“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 reference to “site” in Article 3(15) emphasises that an intermediate is used within industrial processes. 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.”¹⁴

In addition, ECHA argues that a synthesis requires the manufacturing of another substance:

“In the case that a substance (A) is used by the manufacturer himself or by a downstream user and chemically reacts in a process other than the manufacturing of 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 another substance, but rather to achieve another function, specific property, or a chemical reaction as an integrated part of producing articles (semi-finished or finished), the substances used for this activity should not be regarded as intermediates under REACH.”¹⁵

Finally, ECHA argues that, in particular cases, when the substances originating from parent substances are not subject to registration, it shall be necessary to address the risks of those substances in the registration of the parent substances:

„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 such a substance should be addressed in the registration of the substances from which it originates (the parent substances). As these parent substances cannot be 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), since the risks associated with substances referred to in these paragraphs should be addressed in the CSR of the parent substance.”¹⁶

On this basis, ECHA reaches the following conclusions:

¹³ ECHA, Definition of intermediates, p. 5.

¹⁴ ECHA, Definition of intermediates, p. 5.

¹⁵ ECHA, Definition of intermediates, p. 8 et seq.

¹⁶ ECHA, Definition of intermediates, p. 10 et seq.

(1) Substances used as **reactants** are regarded as intermediates (substance A in case 1; example 1 of ECHA).

(2) Substances used as **catalysts** are not regarded as intermediates (substance C in case 2; example 2 of ECHA):

“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 itself converted into the manufactured substance”¹⁷.

(3) Substances used as **desiccants** are not regarded as intermediates (substance C in case 3; example 7 of ECHA):

“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”¹⁸.

(4) Substances used as **specific processing agents** are not regarded as intermediates (substance L in case 4; example 3 of ECHA):

*“As these processing agents are not used in order to be themselves converted into another substance and the manufactured 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.”¹⁹*

(5) Substances used as **surface treating agents** are not regarded as intermediates (substances A and B in case 5; example 6 of ECHA):

“As long as the process does not consist in the manufacturing of another substance on its own, the main aim of the process being to provide 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.”²⁰

(6) Substances used for the **production of an article** are not regarded as intermediates (substances A and B in case 6):

“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(8) 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.”²¹

¹⁷ ECHA, Definition of intermediates, p. 8.

¹⁸ ECHA, Definition of intermediates, p. 10.

¹⁹ ECHA, Definition of intermediates, p. 5, 8.

²⁰ ECHA, Definition of intermediates, p. 9.

²¹ ECHA, Definition of intermediates, p. 9.

(7) Substances transformed into a **substance covered by Annex V.3 or V.4 of the REACH Regulation** are not regarded as intermediates (substance C in case 7):

“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 (including end use but excluding further manufacturing).”²²

V.

Analysis of the interpretation of ECHA

(1) Does Article 3(15) of the REACH Regulation require that the main aim of the chemical processing must be that the precursor is used in the manufacturing of another substance by transforming the precursor itself into that other substance?

In respect of Article 3(15) of the REACH Regulation, ECHA demands a specific function: the main aim of the chemical processing must be that the precursor is used in the manufacturing of another substance by transforming the precursor itself into that other substance. For the reasons set out below, I do not concur with the interpretation of Article 3(15) by ECHA.

The interpretation of ECHA cannot be derived from the wording of Article 3(15) of the REACH Regulation. Article 3(15) does not stipulate that the transformation of the precursor into another substance must be a manufacturing of that substance. Neither does Article 3(15) stipulate that the chemical processing must be a manufacturing of that other substance. Article 3(15) simply does not say that, in respect of that other substance, a “manufacturing” in the sense of Article 3(8) of the REACH Regulation is required. If the European Legislator indeed intended to demand a “manufacturing” of that other substance, then he would have named it explicitly in the definition of Article 3(15) of the REACH Regulation. The wording of Article 3(15) only requires a transformation of a substance into another substance.

ECHA even goes one step further: The manufacturing of another substance shall be the main aim of the chemical processing. Even if a substance used in a chemical processing is used in the manufacturing of another substance in order to be itself transformed into that other substance, ECHA regards this as not sufficient, if the manufacturing of that other substance is not the main aim, but only the secondary aim. This becomes relevant in case 3 (example 7 of ECHA) when substances are used to remove impurities or used as desiccants. Although a new substance is formed during chemical processing and by transformation of the precursor itself (in the example of ECHA calcium hydride is transformed into calcium hydroxide), ECHA regards this forming of a new substance (which is necessary in this process, but not the main aim – the main aim is to have a substance without impurities or without water) as not relevant. However, the wording of Article 3(15) does not distinguish between main and secondary aims of chemical processing. Article 3(15) only requires that the transformation of

²² ECHA, Definition of intermediates, p. 11.

the precursor into another substance is intended – which may be the main goal or the secondary aim of the process. It is sufficient that the transformation of the precursor into another substance is intended as a necessary step in the process. In case 3, substance C must be used in chemical processing and must be transformed into substance CI; otherwise the impurities are not removed. In case 2, catalyst C is used to initiate or support a reaction of substances A and B to form substance X. In both cases, the transformation of the precursor is necessary and therefore intended to reach the overall goal (in case 3 to remove the impurities in respect of substance A; in case 2 to manufacture substance X).

The interpretation of ECHA which was cited above and which concludes that the chemical processing must constitute a manufacturing in the sense of REACH is justified by ECHA with the reasoning that the chemical processing of isolated intermediates takes place on one or more “sites” (Article 3(15)(b) or (c) of the REACH Regulation); that the definition for „site“ in Article 3(16) of the REACH Regulation suggests that a manufacturing (of the intermediate or of the other substance) takes place; and, therefore, that chemical processes involving the use of isolated intermediates shall be manufacturing activities.

However, Article 3(16) of the REACH Regulation does not indicate which activities are performed on a “site”; i.e., if a manufacturing in the meaning of Article 3(8) of the REACH Regulation takes place or not. Article 3(16) does not contain, neither directly nor indirectly, a statement on the processes which occur on the location. Of course, it is possible that sites which handle precursors are manufacturing substances from those precursors. However, also other activities can be performed on a site, e.g. the manufacturing of intermediates²³ or processes not involving a manufacturing. Article 3(16) simply does not indicate how the term “intermediate” in the sense of Article 3(15) should be interpreted. Therefore, the conclusion of ECHA that chemical processes involving the use of isolated intermediates are manufacturing activities and, therefore should be considered as manufacturing under REACH is not convincing.

Finally, the term “synthesis” used in Article 3(15) does not require that the main aim of the chemical processing must be that the precursor is used in the manufacturing of another substance by transforming the precursor itself into that other substance. As described under II., the nature of the remark “hereinafter referred to as synthesis” used in Article 3(15) is only declaratory. This means that the essential requirements for the definition of an “intermediate” are (i) that a precursor is part of a chemical processing, (ii) that the precursor is consumed in or used for this processing, and (iii) that the precursor – which is intended – is transformed into another substance. An activity which fulfils those mandatory requirements is defined as

²³ Even ECHA (Definition of intermediates, p. 5) refers to the manufacturing of intermediates.

“synthesis” within the meaning of the REACH Regulation, in particular for the provisions dealing with intermediates²⁴.

In **case 1** (example 1 of ECHA), substance A is used as reactant for the manufacturing of substance X, and substance A is transformed into substance X. It is undisputed that substance A qualifies as an intermediate.

In **case 4** (example 3 of ECHA), substance X is manufactured from substances A and B, and substance L is used as lubricant to optimise the physico-chemical environment of the reaction medium and remains as a substance (either isolated from the substance X or as an impurity of substance X). Substance L cannot be regarded an intermediate, as it is not transformed into another substance during the process.

In **case 3** (example 7 of ECHA), substances are used to remove impurities or used as desiccants. In example 7, ECHA concludes that calcium hydride which is used as dewatering agent shall not be regarded as 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. I do not concur with the conclusion of ECHA, because Article 3(15) of the REACH Regulation does not require that the main aim of chemical processing must be the manufacturing of another substance. In my opinion, it is sufficient that the transformation of the precursor into another substance is an intended and necessary step during chemical processing (while chemical processing is not limited to the manufacturing of another substance). The same reasoning applies for substances used to remove impurities if those substances are transformed into another substance (e.g. in case 3 when substance C is transformed into substance CI).

In **case 5** (example 6 of ECHA), substances A and B are used for treating of the surface of article Y, by providing a specific physico-chemical property to that article. Even if a chemical reaction takes place in which substances A and B are transformed into substance C, ECHA would not consider substances A and B as intermediates, because the main aim of the process would be to provide a specific physico-chemical characteristic to a material and not to manufacture another substance. Again, I do not concur with the conclusion of ECHA, because – in my opinion – Article 3(15) of the REACH Regulation does not require that the main aim of chemical processing must be the manufacturing of another substance; and that it is sufficient that the transformation of the precursor into another substance is an intended and necessary step during chemical processing (while chemical processing is not limited to the manufacturing of another substance).

²⁴ Especially, this understanding has to be applied when Article 3(15)(b) and Article 18(4) of the REACH Regulation refer to “synthesis”.

In **case 2** (example 2 of ECHA), substance C is used as catalyst C for the manufacturing of substance X which is manufactured by transformation of substances A and B. Substance C is transitionally transformed into substance AC. Pursuant to ECHA, substance C could not be regarded as intermediates under REACH because catalysts are not used to be itself converted into the manufactured substance. As demonstrated above, Article 3(15) does not require that the intermediate itself is converted into the manufactured substance. Article 3(15) only requires (i) that a precursor is part of a chemical processing, (ii) that the precursor is consumed in or used for this processing, and (iii) that the precursor – which is intended – is transformed into another substance. Even though catalysts are not “consumed” during chemical processing, they are “used” in this process. It is the intention to temporarily transform the catalyst C into another substance AC (in form of a non-isolated intermediate), as this is a necessary step for the manufacturing of substance X. Article 3(15) does not say that a transitional transformation is not sufficient. Neither does Article 3(15) say that the “other substance” (substance AC) cannot be an intermediate, as long as the requirements of the definition of substances in Article 3(1) of the REACH Regulation are fulfilled.

(2) Is it valid to argue that a substance used for the production of an article can not be regarded as an intermediate, because the particular substance was not used for the manufacture of another substance?

ECHA argues that a substance used for the production of an article cannot be considered an intermediate, because the substance is not used for the manufacture of another substance but used in order to achieve another function.

The line of argumentation of ECHA (The production of an article needs to be distinguished from the manufacturing of a substance) is not convincing. Although chemical processing ends with the production of an article, there still is a transformation into “another substance”. The only specialty is that this substance is part of an article: The substances – inter alia the substance which originates from the precursor – continue to exist after they are incorporated in the article. It is the concept of REACH to focus on the substance, even if it is incorporated in an article. Therefore, the REACH Regulation explicitly foresees provisions for “substances in articles”: Article 1(2) of the REACH Regulation provides that the provisions of the Regulation shall apply for substances on their own, in mixtures or in articles. The same distinction is made in Articles 5 et seq. In particular, Article 7 of the REACH Regulation provides that, in respect of articles, the registration requirement is fulfilled by the submission of a registration “for any substance contained in those articles” (cf. also Article 7(1)(a): “substance present in those articles”). This clearly demonstrates that the substance contained in the article is the main link for introducing legal obligations; i.e. that the substances contained in an article and not the article itself must be registered (in accordance with Article 7 of the REACH Regulation).

As already mentioned under I., it was the decision of the European Legislator to implement a differentiating and focused approach of risk regulation within REACH; and, in respect of substances in articles, as a general principle, to require only a registration of those substances which are intended to be released under normal or reasonably foreseeable conditions (Article 7 of the REACH Regulation). It would be a circumvention of this regulatory concept and contrary to the rationale of Article 7 of the REACH Regulation if one would suggest a standard registration of precursors (which fulfill all criteria of Article 3(15) of the REACH Regulation) and would demand that the uses of the substance in an article need to be covered.

It is not in line with those principles when ECHA suggests, by referring to the rule of Article 7 of the REACH Regulation that substances in articles are only under specific circumstances subject to registration, that the risks associated with those substances should be addressed in the registration of the parent substance (*„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 such a substance should be addressed in the registration of the substances from which it originates (the parent substances).“*). Besides the conflict with Article 7 of the REACH Regulation, the argumentation of ECHA is problematic because:

- (i) the circumstance if the „other substance“ which originates from the transformation is subject to registration is not a criteria which is mentioned in the definition of Article 3(15) of the REACH Regulation. Based on the legal text of Article 3(15), it is irrelevant for the qualification as an intermediate whether the “other substance” is subject to registration or not.
- (ii) A registration of the parent substance is not necessarily helpful because the properties of the parent substance may be completely different from that of the new substance it is transformed to.
- (iii) If one looks at the rationale of the rules on intermediates, the only condition for the European Legislator to introduce reduced registration requirements for intermediates was the fact that intermediates may be manufactured and used under strictly controlled conditions. The question whether substances originating from the parent substances are subject to registration or not doesn't make any difference in this respect.
- (iv) The irrelevance of this aspect is proven if one takes substances produced or imported under the threshold of 1 t/a into account: Based on the reasoning of ECHA, precursors of substances under the threshold of 1 t/a could never be intermediates, because the substances originating from such precursors are not subject to registration. It goes without saying that such result is not intended by the European Legislator.

It is not in line with the aforementioned principles either when ECHA argues that the risks associated with substances in articles are covered via the chemical safety report which is prepared for the parent substance („As these parent substances cannot be regarded as intermediates, REACH ensures that their registration dossiers include a CSR covering these risks, as appropriate.”). It seems that ECHA has the rules of Annex I No. 5.2.3 and 5.2.4 of the REACH Regulation in mind which deal with the exposure assessment within the chemical safety assessment and which refer to possible transformation or reaction processes and products. However, the fact that Annex I refers to transformation or reaction processes and products does not determine the scope of Article 3(15) of the REACH Regulation; it is simply not related to the definition of intermediates. Rather, Annex I and Article 14 do not apply for registrations for intermediates pursuant to Articles 17 and 18 of the REACH Regulation (cf. Article 14(1) of the REACH Regulation: ”...subject to registration in accordance with this chapter...”). Moreover, Annex I and Article 14 do not apply for substances under the threshold of 10 t/a (Article 14(1) of the REACH Regulation)²⁵.

In **case 6** the substances A and B are used for the production of substance C in an article Y (where the article may consist partially or fully of the substance C). Even though a chemical reaction takes place in which substances A and B are transformed into a substance C in an article Y, ECHA would not consider substances A and B as intermediates, because the substances are not used for the manufacture of a substance but used in order to achieve another function. I do not concur with the conclusion of ECHA. As demonstrated above, Article 3(15) of the REACH Regulation does not require that the main aim of chemical processing must be the manufacturing of another substance. Furthermore, it is the concept of REACH that the substances in an article and not the article itself are the main link for introducing legal obligations, e.g. to submit a registration pursuant to Article 7 of the REACH Regulation. Since Article 7 of the REACH Regulation, as a general principle, requires only a registration of substances in articles which are intended to be released under normal or reasonably foreseeable conditions, it would be a circumvention of this regulatory concept and contrary to the rationale of Article 7 of the REACH Regulation if one would suggest a standard registration of precursors (which fulfill all criteria of Article 3(15) of the REACH Regulation). For the qualification of a substance as intermediate it is irrelevant whether the substance which originates from the transformation is subject to registration or not. Therefore, in my opinion, substances A and B should be regarded as intermediates.

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Additionally, the statement of ECHA that the risk associated with substances in articles formed during the production of the articles are covered by the CSR of the “parent substance” is in general incorrect, as Annex I of the REACH Regulation does not require hazard assessment or risk characterization for these substances formed from the “parent substance”.

(3) Is it valid to argue that a substance used for the manufacturing of a substance listed in Annex V(3) or (4) cannot be regarded as an intermediate, because it is a substance used in order to provide a specific function / physico-chemical property?

ECHA does not regard precursors as intermediates if the substances originating from those precursors are exempted from registration pursuant to Annex V.3 or V.4 of the REACH Regulation:

“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 (including end use but excluding further manufacturing)”²⁶.

Pursuant to Article 2(7)(b) of the REACH Regulation, substances covered by Annex V are exempted from registration, because registration is deemed inappropriate or unnecessary for these substances and their exemption does not prejudice the objectives of this Regulation.

The following substances were included in Annex V.3 and V.4:

“3. Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.

4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:

(a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or

(b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.”

Article 2(7)(b) in conjunction with Annex V.4.a) covers, for example, the following situation: like in case 6, a lubricant is used for optimising the physico-chemical environment of the reaction medium. In contrast to case 6, a chemical reaction occurs, and the lubricant is transformed into another substance. In such case, the lubricant is part of a chemical processing, it is consumed in this processing, and the lubricant is transformed into another substance.

In such case, it is not the main aim of the chemical processing that the parent substance (lubricant) is used in the manufacturing of another substance by transforming the parent substance itself into that other substance. Thus, in such case ECHA would deny the status of an intermediate by arguing that the parent substance is used to provide a specific function other than manufacturing another substance. Yet, as demonstrated above, in my opinion, this is not

²⁶ ECHA, Definition of intermediates, p. 11.

an essential requirement of the definition in Article 3(15). However, it is necessary (but also sufficient) that the transformation of the parent substance (lubricant) into that another substance is an intended and necessary step in the process (intended chemical reaction). If this is not the case, the criteria “in order to”, named in Article 3(15), is not fulfilled (unintended chemical reaction).

As described in detail above, the chemical processing by transforming the precursor into another substance does not require a manufacturing process. Rather, the term chemical processing has to be understood in a broad sense. Thus, it also covers substances which result from chemical reactions described in Annex V.3 and V.4. Against this background, it is clear that the wording in Annex V.3 and V.4, referring to “themselves manufactured”, does not hinder that the parent substance is classified as intermediate.

Furthermore, like under (2), the following observations have to be made:

- (i) The circumstance that the „other substance“ which originates from the transformation is not subject to registration pursuant to Article 2(7)(b), Annex V.4., V.3 of the REACH Regulation is not a criterion which is mentioned in the definition of Article 3(15) of the REACH Regulation. Therefore, it is not relevant in this respect.
- (ii) As mentioned above, the only condition for the European Legislator to introduce reduced registration requirements for intermediates was the fact that intermediates may be manufactured and used under strictly controlled conditions. The question whether substances originating from the parent substances are subject to registration or not doesn't make any difference in this respect.
- (iii) The European Legislator decided that substances listed in Annex V of the REACH Regulation shall be exempted from registration. It would be a circumvention of this regulatory concept and contrary to the rationale of Article 2(7)(b) and Annex V of the REACH Regulation if one would suggest a standard registration of precursors (which fulfill all criteria of Article 3(15) of the REACH Regulation).

Thus, the circumstance that the substance which originates from the parent substance is exempted from registration is not related to the definition of intermediates in Article 3(15) of the REACH Regulation.

Also, ECHA states that the risks associated with the substances referred to in Annex V.3 and V.4 should be addressed in the chemical safety report of the parent substance (*“This is also consistent with the provisions under Annex V paragraphs (3) and (4), since the risks associated with substances referred to in these paragraphs should be addressed in the CSR of the*

parent substance.”). In this context, ECHA refers in a footnote to Commission Communication C(2009)2482 and to ECHA’s Guidance for Annex V:

“Both the Commission Communication C(2009)2482 and the Guidance on Annex V state that, although they are exempted from registration, the risks emanating from substances covered by Annex V paragraphs 3 and 4 should be addressed in the chemical safety assessment of the parent substance(s).”²⁷

However, the question whether a parent substance is an intermediate or not has to be decided on the legal basis of Article 3(15) of the REACH Regulation. Only if the status of an intermediate is totally denied or if an intermediate is not handled under strictly controlled conditions and the respective requirements of Article 14 and Annex I of the REACH Regulation are fulfilled, the completion of a chemical safety report is required. The fact that a substance is covered by Annex V.3 and V.4 is irrelevant with regard to a classification of the parent substance as intermediate.

Nothing else can be derived from Commission Communication C(2009)2482 and ECHA’s Guidance for Annex V²⁸. While Communication C(2009)2482 does not contain a statement concerning this matter, Guidance for Annex V states in respect of Entry 4:

“The exemption only applies to the substances generated when the substances listed in Annex V(4)(a) and (b) function as intended, but it does not apply to the substances listed in Annex V(4)(a) and (b) themselves. In other words, the registration obligations apply to the manufacture or import of the groups of substances listed in Annex V(4)(a) and (b) and where a chemical safety report is required, it should cover the intended uses and the risks of the substance(s) generated during the use.”

This clarifies that the parent substance itself (e.g. the stabilisator or lubricant mentioned in Annex V.4.a)) is not exempted from registration pursuant to Annex V. As a consequence, the regular rules of REACH on registration apply to the parent substance, and if applicable, also the rules on the chemical safety assessment (Article 14 and Annex I), and also the rules on intermediates if the parent substance fulfills the criteria of Article 3(15). Yet, the aforementioned citation stresses that a CSR must only be completed if REACH actually demands the completion of a CSR (“and where a chemical safety report is required”); only in this case, the CSR should cover the risks of the substances generated during the use.

Thus, ECHA’s statement that “the risks emanating from substances covered by Annex V paragraphs 3 and 4 should be addressed in the chemical safety assessment of the parent sub-

²⁷ The footnote referring to Guidance on Annex V and Commission Communication C(2009)2482, however, does not take into account, that Annex I of the REACH Regulation only requires a risk characterization of the substance to be registered as such (non-transformed).

²⁸ Guidance for Annex V, Exemptions from the obligation to register, Version 1, March 2010, p. 3.

stance(s)“ needs to be corrected and specified: This does not apply if REACH does not require the performance of a chemical safety assessment, e.g. for intermediates (because the criteria of Article 3(15) are fulfilled) which are manufactured and used under strictly controlled conditions.

In case 7, the substance C is used as a lubricant and, as a result of a chemical reaction is transformed into substance Y, while substance Y is covered by Annex V.4.a) of the REACH Regulation. ECHA would not regard substance C as an intermediate, because it is used in order to provide a specific function / physico-chemical property other than manufacturing another substance. In my opinion, it is sufficient (but also necessary) that the transformation of substance C is an intended and necessary step in the process. If this is the case in respect of substance C and also the other requirements of Article 3(15) are fulfilled, substance C can be regarded an intermediate even if substance Y is exempted from registration pursuant to Annex V.3 or V.4 of the REACH Regulation.

VI. Summary and Conclusions

In May 2010, ECHA published the document “Definition of intermediates as agreed by Commission, Member States and ECHA on 4 May 2010” which shall contain a clarification of the definition of intermediates. ECHA concludes that, for a classification as an intermediate, the main aim of the chemical processing must be that the precursor is used in the manufacturing of another substance by transforming the precursor itself into that other substance. If a precursor is used in order to achieve another function than the aforementioned, the precursor is not regarded as an intermediate.

I do not concur with the conclusion of ECHA. Article 3(15) of the REACH Regulation does not stipulate that the transformation of the precursor into another substance or the chemical processing must be a manufacturing of that other substance. Neither does Article 3(15) stipulate that the manufacturing of another substance shall be the main aim of chemical processing. Article 3(15) only requires that the transformation of the precursor into another substance is intended – which may be the main goal or the secondary aim of the process. It is sufficient that the transformation of the precursor into another substance is intended as a necessary step in the process.

On this basis, it is undisputed that substances which are used for the manufacturing of another substance and which itself are transformed into that other substance qualify as intermediates. On the other hand, substances used as processing agents, such as lubricants, that are not transformed into another substance during the process do not qualify as intermediates.

In respect of **substances used to remove impurities, substance used as desiccants and substances used as surface treating agents**, ECHA would deny a classification as intermediates, because the main aim of the chemical processing is not to manufacture another substance. In my opinion, those substances can be regarded as intermediates, because Article 3(15) of the REACH Regulation does not require that the main aim of chemical processing must be the manufacturing of another substance; and that it is sufficient that the transformation of the precursor into another substance is an intended and necessary step during chemical processing (while chemical processing is not limited to the manufacturing of another substance).

In my opinion and contrary to the conclusion of ECHA, also **catalysts** – as characterised by case 2 – can be considered as intermediates in the sense of Article 3(15) of the REACH Regulation. Even though catalysts are not “consumed” during chemical processing, they are “used” in this process. In this process, it is an intended and necessary step to temporarily transform the catalyst into another substance (in form of a non-isolated intermediate). Article 3(15) does not say that a transitional transformation is not sufficient. Neither does Article 3(15) say that the “other substance” can not be an intermediate.

Furthermore, I do not concur with the conclusion of ECHA that **substances used for the production of an article** cannot be considered an intermediate. ECHA’s line of argumentation that such substances are not used for the manufacture of a substance but in order to achieve another function is not convincing. It is the concept of REACH that the substances in an article and not the article itself is the main link for introducing legal obligations, e.g. to submit a registration pursuant to Article 7 of the REACH Regulation. Since Article 7 of the REACH Regulation, as a general principle, requires only a registration of substances in articles which are intended to be released under normal or reasonably foreseeable conditions, it would be a circumvention of this regulatory concept and contrary to the rationale of Article 7 of the REACH Regulation if one would suggest a standard registration of precursors (which fulfill all criteria of Article 3(15) of the REACH Regulation). For the qualification of a substance as intermediate it is irrelevant whether the substance which originates from the transformation is subject to registration or not.

Substances transformed into a substance covered by Annex V.3 or V.4 of the REACH Regulation should not be generally denied the status as intermediates. In particular, the fact that a substance is exempted from registration pursuant to Annex V.3 or V.4 is not related to the definition of intermediates in Article 3(15) of the REACH Regulation and irrelevant with regard to a classification of the parent substance as intermediate. ECHA argues that such parent substances cannot be considered intermediates, because they are used in order to provide

a specific function / physico-chemical property other than manufacturing another substance. In my opinion, it is sufficient (but also necessary) that the transformation of the parent substance is an intended and necessary step in the process. If this is the case and also the other requirements of Article 3(15) are fulfilled, the parent substance can be regarded as an intermediate even if the substance originating from the parent substance is exempted from registration pursuant to Annex V.3 or V.4 of the REACH Regulation.

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