Intermediate concept within the framework of the European Chemicals Legislation – applicable rulings by the European Court of Justice (ECJ) have to implemented

Background:

According to the REACh Regulation, the obligation for authorisation does not apply to intermediates. In this context, a clear definition is provided under which conditions a substance is to be classified as an intermediate.[1] The European Chemicals Agency (ECHA) in 2010 presented a *Guidance on Intermediates*, which, according to an ECJ ruling in 2017, does not correspond with the aforementioned definition and does not reflect the intention of REACh. Despite this judgement, the enforcement of the concept of intermediates has not been changed. Therefore, the surface treatment sector has for several years been advocating for the correct interpretation and implementation of the intermediates concept.

In the context of the upcoming revision of REACh, the European Commission (COM) aims to make adaptions to the existing definition. For the 45th meeting of Competent Authorities for REACh and CLP (CARACAL) on 06 July 2022, a proposal[2] was presented regarding possible clarifications and changes to the REACh provisions on intermediates. The European Committee for Surface Treatment (CETS) would like to provide comments on some of the key aspects of the proposal.

Comments:

- The main purpose of the proposal is to provide some clarifications to the existing definition. On the one hand, this is not necessary since the definition within REACh as well as the ECJ ruling already provide for a clear and concise concept. On the other hand, this would not be sufficient as long as the ECHA Guidance has not been adapted in order to comply with the judgement of the ECJ. The only applicable options therefore are (a) changing the ECHA Guidance or (b) changing (and not just clarifying) the intermediate concept in the course of the revision of REACh. Option (b) would have retroactive effects, as it would then have to be examined whether the previous application was possibly incorrect and thus whether the authorisation of certain substances would not have been obligatory so far.
- Furthermore, the proposal says that the transformation described in article 3(15) of REACh must take place in the context of a chemical process known as synthesis, which the COM describes as "*a chemical process that results into the manufacturing of a new substance 'on its own'*". As of now, the same article 3(15) defines synthesis is as intended transformation into another substance without any further reference or criterion. Neither the REACh text nor the ECJ's ruling prescribe a manufacturing process or even the production of the substance "on its own" as a mandatory condition. In fact, this misinterpretation of the proposal results in an additional requirement although this was unequivocally rejected by the ECJ. There is no indication in REACh for the indivisibility of synthesis and manufacturing. Such an idea clearly runs counter the common chemical understanding.
- Additionally, the proposal claims that "*it is the lack of exposure (as the substance is not removed from the equipment) that justifies that REACH does not apply*". This is not justifiable for two main reasons:
  1. REACh always applies! In particular when it comes to distinguishing between substances or uses that shall/shall not be further evaluated, registered and/or authorised.
  2. In REACh article 3(15), three different kinds of intermediates are defined. Although there is no reference to a lack of exposure in these definitions, it is obvious that all three must be recognised as intermediaries. Following article 2(8b), they have to be excluded from Title VII in general.
- The proposal foresees that *"(…) the SCC referred to in Articles 17 and 18 of REACH should also be considered as eligibility criteria for intermediate uses to benefit from exemptions from authorisations and restrictions*." (SCC = strictly controlled conditions). While this conviction has to be decided in the course of the REACh revision process, it is not given by the current version of REACh Regulation, because article 2(8b) makes no distinction between the different types of intermediates defined.

Conclusion:

With the presented proposal, the European Commission makes it clear that it has a different understanding of the term "intermediate" than the one given in the current REACh Regulation – the latter of which has been affirmed by the court. The new approach, once it has officially been presented by the COM, has to be discussed by the deciding legislative bodies (EP and Council). However, it must not be included in the revised version of ECHA Guidance, as this would obviously run against the judgement of the ECJ. CETS once again calls on ECHA and the European Commission to implement the necessary changes in the ECHA Guidance as per the judicial ruling. This should be done without any further delay and without additions or amendments to its content. The adjusted version would be applied at least for the next couple of years until a revised REACh Regulation is in place.

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[1] REACh-Regulation, Chapter 2, Article 3 (15): "intermediate: 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)"

[2] Doc. CA/39/2022, 22.06.2022