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Rapid Removal Workshop

ECHA - Helsinki, June 11th 2019**Summary Report**

BACKGROUND

With entry into force of the CLP Regulation (EC) No 1272/2008, the Globally Harmonised System (GHS) of Classification and Labelling of chemicals was implemented in the EU. The 3rd revised edition of the UN GHS (2009) introduced new criteria for long-term hazards (chronic toxicity) to the aquatic environment and the 2nd ATP to the CLP Regulation implemented the criteria in the CLP Regulation. In general, the classification criteria apply to all substances i.e. organic substances as well as inorganic substances and metals or metal compounds. In this respect, degradability is one of the important properties of organic substances that determine their potential long-term environmental hazards. However, the concept of degradability as applied to organic compounds has limited or no meaning when it comes to the classification of metals and inorganic metal compounds (Section 4.1.2.10.1 of Annex I to CLP). In contrast it is rather environmental transformation processes which could influence (increase or decrease) the bioavailability of the species causing toxicity to the aquatic organisms. The aspect of bioavailability is reflected in the *Guidance on the application of the CLP criteria* with the application of the existing Transformation/Dissolution protocol (T/Dp). Thus, the rate and extent to which a metal ion will dissolve and transform to water soluble forms is taken into account in the decision on the environmental classification.

Furthermore, with reference to the assessment of environmental transformation (also known as the rapid removal concept), the guidance document states the conditions under which such an assessment may be taken into account. However, due to a lack of scientific consensus on the interpretation of rapid removal in the context of classification and the impact of the concept as a result of the agreed definition, a workshop was organised in February 2012.

Overall, no consensus on the validity of the use of the concept governing the removal of metals from the water column could be reached at that workshop. Nonetheless, it was recognised that a categorisation of different types of metals into three groups is possible in respect of the assessment of environmental transformation:

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Group 1 - Metals that methylate such as Hg

It was agreed that volatilisation cannot be considered a removal route for metals, as is the case for organics.

Group 2 - Metals that quickly hydrolyse and form different species that precipitate in the water column (Fe, Al, Sb, Sn, Mo, Cr, ...).

Group 3 - Metals for which the key question is 'irreversibility' (i.e. binding-of metals to oxides or sulphides and natural organic matter forming a non-bioavailable form under a range of environmental conditions). This group would cover, for example: Cu, Ni, Zn and Pb.

At that workshop it was furthermore concluded for group 2 metals that *hydrolysis and precipitation to form different species is a very significant removal process for their removal from the aquatic system. When this process occurs very quickly it can be taken into account for hazard classification, noting that the hazard assessment should consider the properties of the newly produced species.* For group 3, however, the nature of binding, the intrinsic properties of the metal, and defining irreversibility under different conditions were subject to various views and no consensus was reached. Industry presented at the workshop a predictive model (TICKET Unit World Model) allowing to predict the speciation and fate behaviour of type 3 metals under relevant environmental conditions. While member states experts felt this model relevant for fate assessment, it was considered as too much risk based for use in hazard assessment schemes. Industry was consequently called to provide further arguments including a more empirical approach supported by examples, if in future they wish to justify the application of the concept of 'rapid removal' to groups of metals other than group 2.

The summary report, background documents and presentations from the 2012 workshop can be found [on the ECHA website](#).

Following the workshop in 2012 industry followed-up on the concerns and questions raised. In particular, over the past 4 years industry developed a test-based approach building on the existing Transformation/Dissolution protocol (T/Dp) which resulted in a so-called "Extended T/D protocol" (T/Dp-E) including a removal and resuspension phase, aiming to address the assessment of environmental transformation under the conditions of the CLP Guidance. With the progress made by industry on the development of the T/Dp-E, the discussion on the method was relaunched in February 2019 with an information session

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organised by Industry back-to-back with a MISA¹ workshop and MSC-63. A preparatory WebEx between ECHA and some Member States took place in January 2019. A report from the February 2019 information session was circulated to Member States and presented to RAC.

This June 2019 workshop was organised back-to-back with RAC-49 at ECHA in Helsinki to review the work that has been done by industry, to discuss whether agreement can be reached to use the concept of rapid removal for environmental hazard classification purposes and if so, whether the extended T/Dp is a suitable method.

In preparation for this workshop and following up on aspects raised at the informal session in February 2019, industry had submitted three technical papers to address requests for additional clarification on the rapid removal concept and T/Dp-E:

- Partitioning and Removal of Metals and Organic Substances in the Environment
- Methodological Aspects of the Extended Transformation-Dissolution Protocol
- Fate, Speciation and long-term Toxicity of metals in Sediments

In addition to the technical papers provided by industry, DK submitted a written comment on the Rapid Removal concept from the metal industry as of February 2019. All four documents were shared with the workshop participants in advance to the workshop.

INTRODUCTION

The chair opened the meeting and welcomed the participants from Commission (COM representative, via WebEx), Member States (MS representatives), RAC members, ECHA, and Industry. The chair stated that the purpose of the workshop was to follow-up the initial workshop held in 2012 (as well as an information session in February 2019 in the context of MISA) by giving Member States and regulators an opportunity to evaluate work done by industry to address concerns raised at the workshop in 2012. That is, to evaluate the scientific work conducted on the rapid removal concept and a proposed test system, and to continue the discussion whether further guidance on the assessment of Rapid Removal could be introduced in CLP without introducing contradictions as regards the assessment of rapid degradability of organic substances.

To begin the workshop, ECHA presented the background to rapid removal and the discussions around the concept, including a recap of the workshop in 2012 and its

¹ MISA... Metal and Inorganics Sectoral Approach (see also [ECHA website](#) and [Metals Gateway](#) for further information on the programme)

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conclusions. This was followed by a presentation by Eurometaux describing the advances that have been made since 2012 with regards to purely scientific aspects of metal binding in aqueous solution and also as regards the development of the extended T/D protocol to examine removal under environmentally realistic circumstances. In particular, industry focussed its work on the following aspects:

- Measuring removal rate over time under standard conditions;
- Demonstration of speciation to non-soluble chemical forms ; and
- Demonstration of lack of resuspension under normal conditions.

This was followed by a brief Q&A session for participants to ask any questions regarding the presentations and clarify any points before the breakout groups began. During this brief discussion MS representatives questioned the differences between groups 2 and 3 metals, the scope of the rapid removal concept, and whether it was needed as aspects accounted for under the approach presented are already accounted for under current guidance. Industry responded by saying that groups 2 and 3 were different and that group 2 metals do not need particles to act. Iron and aluminium will remove in the boundary of pH. Some will remove others not. Furthermore, it was emphasised that the scope was limited to CLP only and that the proposed approach for determining rapid removal was needed in order to provide a reasonable equivalent for metals as is in place for organic substances. The COM representative asked about the cut-off criteria to demonstrate rapid removal and whether this was still 70% (similar to the cut-off for rapid degradation of organic substances). Industry replied that it is although in practice observed removal rates were either far below or far above this value. The COM representative also asked about possible uptake of metals by organisms ingesting sediment, after removal from the water column. Industry answered by explaining that although dietary uptake is indeed a (minor) route of uptake for which proper detoxification mechanisms are developed by most of the benthic organisms, pore water is the major route of exposure from sediment.

An MS representative asked whether rapid removal is considered an analogy for rapid degradation. Industry clarified that rapid removal can only be considered where there is T/Dp data and is therefore limited in its applicability to the metals classification scheme. Another MS representative expressed confusion on the distinction made by industry on rapid degradability and persistency and stressed that the rapid removal concept should not be considered similar to the latter as this causes a friction with the system in place for organic substances. In response industry referred to legal boundaries on the applicability of the concept by clarifying that the rapid removal assessment is exclusively performed when T/Dp data is available. For this reason it is limited in its applicability for classification

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purposes of metals and inorganic metal compounds. Other points raised regarding the grain size of the substrate and the representativeness of the sediment types used in the T/Dp-E were more appropriate for discussion in breakout group 2.

In the following, the WS participants were split in breakout groups, to discuss (i) general aspects on the consideration of rapid removal in the hazard classification scheme (Breakout group 1) and (ii) the pros and cons of the extended Transformation/Dissolution protocol (Breakout group 2). The main discussion points of the breakout groups are summarised hereunder.

BREAKOUT GROUP DISCUSSION

Breakout group 1 – Rapid removal in the classification context

The discussion focussed mainly on the scope of the concept, the conditions to prove its applicability specifically to metals and not to organics and how this could work in the regulatory context.

One MS representative expressed concerns as to a ***potential conflict with the degradation scheme applied to organic substances*** as well as reluctance to see this concept being implemented for classification purposes and that the ***limited scope*** as explained by industry in the introduction could hold. These concerns were supported by several MSs and the COM representative sharing the view that sorption processes and transfer to another compartment into a decision scheme for the removal of metals as an equivalent for degradation of organic substances should not be permitted. Moreover it was stressed that acceptance of such a concept for metals could result in manufacturers of organic substances wanting to incorporate the same principles into the classification scheme for substances other than metals. It was reminded by one MS representative that such approaches had already been rejected in the past for hazard assessment of organic substances as they were considered to be risk assessment.

Industry in response emphasised that there has never been an intention to move near a persistency assessment and stressed again the importance of a limited scope of the proposed concept as being only applicable to the chronic hazard classification of metals and inorganic compounds. Industry recognised that while it cannot be guaranteed that this approach is not used for other purposes, it is our responsibility to clearly outline the limited scope in the regulatory context of environmental hazard classification for metals and inorganic metal compounds. In addition to the limited scope also the question on irreversibility has to be seen in the classification context and in doing so a pH range of 5.5

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to 8.5 (representing normal environmental conditions).

One RAC member reminded of the UN GHS and the CLP referring to **bioavailability** rather than degradation *per se*. Thus, the key issue would be to demonstrate that these metals become significantly less bioavailable over relatively short timeframes. The current test methods available already allow drawing a conclusion on this for regulatory purposes. However, the question of bioavailability then turns into whether the metals are irreversibly removed and how this can be demonstrated. In essence, industry would need to demonstrate that removed metals cannot be remobilised and are not bioavailable as a result of removal as it is outlined in the CLP criteria. It was stressed that any attempt to do so in a test scenario must be suitably representative of real world conditions. Industry pointed out that the binding of metals to oxides and natural organic matter is a covalent bond, which is functionally irreversible, whereas the binding of organics is of different nature. Furthermore, the fundamental difference between metals and organic molecules is the change in speciation for metals when binding to organic matter and subsequently putting them in a form that is no longer bioavailable. Finally, industry offered to provide further proof on irreversibility by including milder extraction techniques into the testing regime, if this was requested by the WS participants.

One RAC member suggested to provide further evidence with regard to the proof of lack of bioavailability. For example, to incorporate an extraction method of the sediment layer as part of the test to demonstrate that the metals are quickly bound and as a consequence not available any more.

The COM representative stressed that the overall approach of rapid removal could be linked with CLP, Article 12(b) rather than an analogy to degradation as referred to in CLP, Annex 1, Part 4. In this regard the notion of irreversibility is the key issue to be discussed which is so far missing.

Breakout group 2 – Discussion of the extended T/Dp

Does the extended T/Dp sufficiently address environmental variability (i.e. standardisation based on realistic worst-case conditions), allowing regulators to agree on standardised realistic worst-case conditions?

The breakout group participants questioned various aspects of the proposed extended T/Dp, such as pH, temperature, the duration, sediment loading, and sediment type. Industry responded by indicating that pH 6 was the worst case scenario used in the metals classification scheme and is the pH where most metals are most available in pore water and that the temperature used was consistent with that in the standard T/Dp. The 28-day

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duration is used as this is the duration of most chronic toxicity test as well as the rapid degradation assessment for organics, so the test duration would provide information in the context of long-term tests. However, a MS representative felt that this was somewhat arbitrary and would require further validation. The loading of 10 g/L sediment was stated to be rounded up from 7.4 g/L for simplicity, a value that represents natural systems. Industry indicated that they felt it was quite conservative, as far higher levels have been tested. Comparisons are often made between rapid removal and ready biodegradability testing, particularly the amount of inoculum introduced. However, the chair pointed out the amount of inoculum used is around 30 mg/L and that it would be useful to test the extended T/Dp at lower loadings. In conclusion, the chair of the breakout group felt that the 10 g/L loading rate would require further justification. It was also felt by a MS representative that a number of different sediment types would be needed in order to represent real world circumstances. Finally on this question, some RAC members felt that expressing the binding of metals only in terms of covalent binding was somewhat narrow and did not represent the range of sorption mechanisms available or known to occur to dissolved metals. Industry indicated that several of these aspects were explained in the technical papers provided in preparation of the workshop. Most importantly, the objective was to simplify the system under reasonable worst case conditions and that covalent binding was the end result.

How to interpret "bioavailability" (transformation to non-available forms, in particular irreversibility via strong bonds) in this context?

Industry asserted that as a result of the covalent binding, metals would not be remobilised from the sediment. However, a MS representative and some RAC members felt that further evidence was needed to demonstrate that this was the case and that bound metals were indeed not bioavailable. It was questioned whether the remobilisation methods employed were sufficient and represented real world conditions. Industry's view was that test results represent what was seen in field studies and that the conditions of the test were reasonable worst case. However, a MS representative felt that further methods, such as harsher extraction techniques, would need to be used to demonstrate that there is no remobilisation and that the removed metals are not bioavailable. Industry accepted that further work on the demonstration of the irreversibility would be required.

Can the T/Dp-E be further adapted for use?

On this question from the chair to sum up the discussion, one RAC member expressed the view that the test employed suitable worst-case, albeit unrepresentative conditions. Despite this, there was the potential for adaptation to make it suitable for use under CLP

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and this was supported by industry. However, the remaining MS representatives and RAC members were sceptical as to whether the T/Dp could be adapted for use under CLP, as further binding concepts need to be included in the overall rapid removal model and extended T/Dp. All agreed that the stated “irreversibility” requires more robust demonstration.

CLOSED SESSION

Following the summary from the breakout groups, a discussion among workshop participants involving Member States, RAC members, Commission and ECHA took place.

Overall, MS and COM representatives as well as RAC members acknowledged the amount of work done by industry over the years. However, it was felt that a number of key issues remained unresolved. In particular, the following aspects were discussed:

- Processes governing rapid removal have already been discounted for classification of substances other than metals and inorganic metal compounds. In this respect it has not been convincingly proven that metals should be treated differently by applying the extended T/Dp and rapid removal, given the T/Dp as currently applied allows for addressing rapid environmental transformation.
- With regards to the use of the extended T/Dp, the view was expressed that there was not enough convincing evidence that removed metals could not be remobilised and that it therefore could not be demonstrated that they were no longer bioavailable.
- It was further questioned whether the extension of the existing protocol was needed at all, as the current T/Dp already allows to demonstrate whether a metal is transformed to non-bioavailable forms and rapidly removed in aquatic toxicity testing media. In this context it was mentioned that the notion of irreversibility (lack of bioavailability) is in line with Article 12(b) of CLP, but the approach developed by industry so far is more understood as a surrogate to degradability and it was suggested that the legal basis for the concept needs to be clarified.
- It was furthermore argued that the extended T/Dp appears to only be valid under limited circumstances and environmental conditions, and it seems to be more risk based than hazard assessment.

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SUMMARY, CONCLUSIONS AND FOLLOW-UP

The chair summarised the workshop discussions and the main conclusions. Overall, the Workshop participants (except those representing industry) agreed that based on the scientific and technical aspects discussed at the workshop, the extended T/Dp is not suitable for hazard classification and appears to be more suitable for risk assessment.

To date it is felt that the fundamental issue of irreversibility has not yet been demonstrated with the method developed so far. Moreover, and following the highlighted regulatory issues as regards the possible interference and risk of inconsistency with the system currently applied for organic substances, the WS participants (except industry) cannot recommend the concept of rapid removal being applied for chronic environmental hazard classification purposes. The main arguments that form the basis for this conclusion are summarised as follows:

- MSs, RAC members and the COM representative concluded that limiting the scope of the concept strictly to classification of metals and inorganic metal compounds might be difficult to maintain. It was furthermore argued that this cannot guarantee that a similar approach is taken up for other substances. In doing so the current system as applied for organic substances would be put at risk. At a scientific level the processes are comparable for both metals and organic substances, so the difference is in the policy decision that has been taken in the past for organic substances.
- Processes governing the rapid removal, such as binding to and settling of particles and binding of particles in the sediment, were discussed for organics but dismissed as being risk assessment and for this reason not taken into account in the hazard classification system which is based on intrinsic properties. The relevance of the exact nature of the binding of metals to particles is questioned and therefore the proposed concept of rapid removal is considered inconsistent with the approach currently applied for organic substances.
- The UN GHS (and CLP) refer to bioavailability and not degradation *per se*. So the key question is whether or not these metals become significantly less bioavailable over relatively short timeframes. How to demonstrate irreversibility remains the key issue in this regard. At present no convincing evidence could be provided that metals are irreversibly removed and thus no longer bioavailable.

Industry responded that they appreciated the opportunity to present the work they have done although they were disappointed with the outcome. They then questioned whether

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there had been a breach between REACH and CLP (as REACH refers to persistence and the classification for chronic environmental hazards is covered by CLP) and called on the Commission to conduct a legal assessment on the correctness as to whether an assessment of rapid removal for metals and inorganic metal compounds can be performed with or without influencing the existing scheme for organic substances. Commission reacted on this intervention from industry by asking for the legal basis for the concept (degradability as referred to in Annex 1 to CLP or bioavailability as referred to in Article 12(b) of CLP). In this context the COM representative re-iterated the need to agree in what way Article 12(b) should be implemented as at present the issue of bioavailability and irreversibility still needs to be solved.

The chair thanked all participants for their valuable contributions to the discussion and informed that the outcome of the workshop will be communicated to CARACAL for discussion in November 2019. It is also planned to communicate the issue to the UNGHS/SCE (UN GHS Sub-Committee of Experts on the GHS) to emphasise the importance of following a harmonised approach in classifying metals.