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baua:
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RCOM for document CACS/MS/19/2019 - possible risk management options for persistent, mobile and toxic substances and very persistent and very mobile substances

On 1st July 2019 the DE CA presented to CARACAL-30 a short discussion paper on how to implement Risk Management Options for PMT/vPvM substances under EU REACH Regulation (EC) No 1907/2006 (Doc. CACS/MS/19/2019). The DE CA had asked for comments until 30th August 2019. The 9 CAs from AT, ES, FI, FR, IE, NL, NO, SE and UK commented. In total 18 comments were received also from the NGO EEB, the EurEau, the JRC and the OECD. From industry interest groups CEFIC, CONCAWE, the German VCI, FuelsEurope and the Japan Chemical Industry Association commented. The DE CA would like to express their gratitude for the comments received.

The discussion paper asked whether and, if so how, the CAs support the need for risk management of PMT/vPvM substances and the implementation of the PMT/vPvM criteria.

Do you support the need for risk management measures for PMT/vPvM substances?

Concerning the need for risk management measures for PMT/vPvM substances all commenting CAs and the EBB and the EurEau support this need. Also industry interest groups recognize the need for the protection of drinking water sources.

The AT CA clearly sees a need for RMM, “supports the proposal to protect sources of drinking water” and evaluates “ensuring uncontaminated drinking water sources as an important issue”. In addition “the potential for pollution needs to be regulated before [substances] can be monitored in the respective compartment” and “a precautionary approach for vPvM substances is necessary, avoiding exposure and costly remediation measures”.

The ES CA states that “Legislation should cover the protection of the sources of our drinking water if there is a concern.” And that “vPvM substances can pose a concern, similarly to vPvB substances even if no toxicity is demonstrated”.

The FI CA “supports the need to prevent emissions into the environment by substances, which have the intrinsic substance properties that indicate a hazard to the sources of our drinking water.”

The FR CA “fully supports the need to regulate PMT substances” and sees this “in line with the 2018 conclusion of SCHEER1 that identified mobile substances as an emerging health and environmental issue of high importance”. This includes that the “concerns raised by PMT/vPvM substances is very much similar to the concerns raised by PBT/vPvB substances”.

The IE CA „agrees that it is important to collectively protect drinking water sources from chemical contamination.“

The NL CA “shares the concern that [PMT/vPvM] substances could be a threat to human and environmental health and can currently be of direct concern to drinking water (certainly those substances that show no or only very limited degradation, are very mobile and as a consequence are extremely difficult to filter out of drinking water sources)”.

The NO CA share “the concern regarding contamination of the aquatic environment in general, and especially drinking water, with substances that are mobile in combination with persistence” and “fully agree that there is a need to minimise emissions of substances with such properties.” “Such substances also tend to enrich in plants, which can be an additional exposure route for humans.” The NO CA would like to further discuss the concern related to “the steady state concentration predicted in biota for substances with relatively low BCF values”.

The SE CA is “of the opinion that persistent and mobile substances […] are a problem for the environment and health through their potential for contamination of drinking water resources for a long time to come” and “that it is more cost effective to regulate the substances before such contamination occurs.”

The UK CA “support closer alignment of the aims of REACH and water resource legislation, and therefore believe[s] that substances that meet agreed PMT criteria should be subject to appropriate risk management measures if supplied in relevant quantities.”

The EEB “strongly support[s] the need for risk management measures for PMT/vPvM substances posing a threat to drinking water and the environment.”

The EurEau “advises the European institutions that more must be done to close the knowledge and regulatory gaps, in order to prohibit the continued release of PMT and vPvM substances into the environment” and calls for “clear instruments within chemical legislation”.

The JRC shares the drivers and brings up the question if persistent chemicals not meeting neither the bioaccumulation or mobility criteria are really safer chemicals. JRC would like to set sustainability criteria for chemicals in association with defined exposure attributes.

CEFIC states that “the impact of chemicals on drinking water resources – whether they are mobile or not – is already part of chemical safety assessments performed by the Industry.” and that “existing regulations provide a high level of protection”. However, also CEFIC sees that existing regulations and practice can be improved. They state that no “clear regulatory framework [exists] to implement” the identification of PMT/vPvM substances. On the other hand CEFIC only wants to act “if the levels detected are of particular concern to human health” and they emphasise that “exposure may also occur as a result of other emission routes” than uses under REACH.

Concawe “recognizes the need for protection of drinking water sources”. Concawe “is of the opinion that criteria that characterize organic chemicals as PMT/vPvM should balance protection of water resources and costs for society and industry”.

The German VCI recommends to evaluate how to use existing instruments on the protection of drinking water and water bodies to solve problems with detected substances. The VCI states that “the detection of a substance” is not equate to “risk to ground and drinking water”.

The Japan Chemical Industry Association suggests to determine whether it is appropriate as a classification method for hazardous substances after accumulating exposure status and monitoring data […].

If yes, which options would you prefer?

Concerning the most preferred option for risk management, all CAs supports the SVHC identification followed by restriction, which is mentioned by 5 CAs, the EEB, and the EurEau as an option. Revision of REACH Annex I and Article 14(4) is also an option for 5 out of 9 CAs.

The AT CA highlights the precautionary principle, which is laid down in REACH Art. 1 (3) “This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle”. The AT CA concludes that substances with PMT and vPvM properties may already now be identified as SVHC based on Art. 57 (f) on a case by case basis. This explicitly includes vPvM properties which are in the view of the AT CA sufficient to fulfil the ELoC requirements. Another option is “a regulation of PMT and vPvM substances via restriction without or sub-sequent to SVHC identification.”

The ES CA requests that “If the PMT/vPvM [criteria] is accepted for the identification as SVHC the authorization [regime] may be applied.”

The FI CA wants to further discuss the option “that REACH Annex I calls for the assessment of PMT/vPvM substances within the registration dossier similar to PBT/vPvB substances, and that Article 14(4) could also include an exposure assessment and risk characterisation for PMT/vPvM substances.” In addition the FI CA supports the SVHC identification under 57 (f) and they ask for “a holistic approach with other relevant legislations”.

The FR CA also “calls for an alignment of management measures with PBT/vPvB substances. […] Systematic assessment of PMT/vPvM properties in REACH (inclusion into Annex I) and inclusion as a criteria to justify assessment of exposure and risk assessment (art. 14(4)) seems straightforward to implement with a limited workload for registrants.” In addition the FR CA also supports for PMT/vPvM substances the identification as an SVHC as well as the restriction. Also the call for a regulatory link to other frameworks.

The IE CA is of the opinion that “prior to identifying the most appropriate risk management measures for PMT/vPvM substances […] further discussion should first take place on the development of the PMT/vPvM criteria. […] and how the criteria could be used or incorporated under REACH.”

The NL CA agrees that “substances with PMT/vPvM like behaviour can also be identified as SVHC via art. 57(f) on a case-by-case basis” and that “placement on Annex XIV of REACH could be an appropriate RMM”. In addition they mention restriction as an option. The NL CA emphasises that it is “important to have a clear understanding about the final objective and the RMM deemed necessary.”

The NO CA supports “a case-by-case approach to identify a substance as SVHC in accordance with Equivalent Level of Concern, ELoC, (Article 57 (f)) for specific substances or substance groups with PMT/vPvM properties.” And “to implement further risk management measures like REACH restrictions”. They state that these substances “could also be considered for e.g. relevant water regulations as well”

The SE CA sees “REACH Annex I regarding provisions on the obligation for assessment, as valid options”.

The UK CA highlights the “responsibility of the registrant” and specifically the “trigger for further (eco)toxicological investigations under evaluation processes”. Separate new hazard classes under CLP without agreement under the UN GHS first is not supported. Also the option to classify as Aquatic Chronic 4 is discussed critically. Instead the UK CA “suggest that PMT concerns should be formally included under REACH in the same way as PBT concerns (i.e. with criteria in a specific Annex and detailed related guidance about data interpretation and risk management approaches), so that it will automatically trigger a risk management response by Registrants.” This includes the amendment of REACH Annex I and “the requirement for a laboratory determined adsorption/desorption partition co-efficient at lower tonner tonnages” since this “may be valuable for Chemical Safety Assessment in general”. The UK CA also supports both, the option of restriction (without vPvM substances) and authorisation regime.

The EEB proposes regarding the registration process the “need for an PMT/vPvM assessment as part of chemical safety assessment” as well as “communication of the results with the SDS”. The preferred regulatory option is the identification of “these substances as SVHC following REACH Article 57, followed by authorisation requirements and / or restriction.” In addition it is supported “if the classifications in the CLP regulation can be expanded – addressing PMT / vPvM substances as well as PBT / vPvB substances as well as the individual endpoints P, B, M, vP, vM.”

The EurEau requests that “industry must promptly assess their substances for persistent, mobile and toxic properties” and “if this effort is inadequate, competent authorities should utilise the mechanisms under the REACH Regulation to restrict their manufacturing, import and use.” EurEau “estimates the cost for reverse osmosis, specifically, would raise the price of water treatment by more than €1/m³ equalling circa €200 added to the water bill for the average household per year.” The EurEau calls to use all available regulatory instruments including the CoRAP, the identification as SVHC and the authorization regime, restrictions and the amendment of the CLP hazard classes.

Would you see the need for the implementation of PMT/vPvM criteria?

Concerning the implementation of PMT/vPvM criteria, this is supported by 6 out of 9 CAs, the EEB, the EurEau and also by the industry interest groups.

The AT CA sees that “the implementation of the PMT/vPvM criteria and transparency in decision making at European level will bring clarity and predictability for the identification of certain undesired effects as described above, which is important for manufacturers, importers and downstream users, authorities and water management bodies.” The AT CA further states that: “the agreement of PMT and vPvM criteria will further facilitate the decision making (MSC agreement).”

The ES CA highlighted the difference to the normal PBT/vPvB assessment and expects this helps to clarify the intrinsic PMT/vPvM substance properties.

The FI CA is cautions “to expand the Article 57 to identify PMT/vPvM substances by default as SVHC”. In contrast they highlight that “SVHC identification can already be done in case-by-case approach under article 57(f).”

The FR CA evaluates that “the P criterion is not overprotective” and hopes that “implementation of regulatory processes for PMT substances could lead to an increase of the persistency data”. The FR CA discusses the M criterion and support that threshold criteria could “trigger an SVHC identification as PMT or vPvM”.

The IE CA considers that “criteria to identify substances as PMT/vPvM could form part of an overall pollution prevention strategy to further help safeguard Europe’s drinking water and freshwater environments for future generations.”

The NL CA states that “PMT/vPvM criteria may especially be valuable as a tool to priorities substances for further analysis of a possible need for regulatory management measures (RMM)” and that “depending on how the criteria are used, the […] criteria need some further discussion.”

The NO CA is reluctant to the proposal to establish PMT/vPvM criteria as a separate entry under Article 57.

The SE CA states that they have not finalised a “discussions on the questions posed regarding implementation of PMT/vPvM criteria and requests for assessment”.

The UK CA supports agreed criteria under REACH. “On the assumption that PMT criteria can be formally agreed and become legally binding, the UK CA would support the identification of PMT substances as SVHCs in future.”

The EEB concludes that “the regulatory options developed under REACH to control substances of very high concern should be used for PMT/vPvM substances too”.

If yes, which options would you prefer?

Concerning the most preferred option for the implementation of PMT/vPvM criteria 4 CAs see that the criteria should be formally included under REACH in Article 57 and/or Annex XIII.

The AT CA states that “the integration of PM and vPvM properties into the GHS for classification should be taken into consideration.”

The ES CA support the integration of the criteria into Article 57 because they want “to identify PMT/vPvM substances as substances of very high concern (SVHC) following article 57”.

The FR CA proposed to have well discussed and defined threshold values “to define substances of concern due to their mobility in water and trigger an SVHC identification as PMT or vPvM” and in addition proposes for P/vP substances “on a case by case basis for identification as an equivalent level of concern in application of article 57(f)”.

While the NL CA supports the development of PMT/vPvM criteria they do not clear state how these should be implemented.

The SE CA sees the inclusion of [PMT/vPvM] criteria for example in separate Annexes to REACH (c.f. Annex XIII for PBT/vPvB) or in REACH Annex I […], as valid options”.

The UK CA suggest that the criteria should be formally included under REACH in a specific Annex (Article 57 and Annex XIII) and detailed related guidance about data interpretation.

The EEB sees “an urgent need for clear criteria which can be used by the different actors, especially registrants of substances and experts from MS CA (involved in substance evaluations)”. In the middle term they see the “inclusion of the PMT /vPvM criteria in Annex XIII” as well as “the establishment of new hazard classes for P, M, vP, vM, B, vB and combinations.”

Conclusions

Comments received on the DE CA discussion paper (Doc. CACS/MS/19/2019) clearly demonstrate the need and the support from CAs to implement Risk Management Options for PMT/vPvM substances under EU REACH Regulation (EC) No 1907/2006. Some CAs support action under 57 (f) on a case by case basis, however, the majority wants to implement PMT/vPvM criteria. Options to do so include REACH Annex I and REACH Article 14(4), REACH Article 57 and Annex XIII or the PMT/vPvM criteria paper which than can be used under REACH Article 57 (f). Also the implementation of new hazard classes under CLP/UN GHS is still a supported option and need to be discussed further.