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WIR GESTALTEN ZUKUNFT.

Restriction proposal "intentionally added microplastics"

VCI position on the preliminary draft of the SEAC opinion on the ECHA restriction proposal for "intentionally added microplastics"

The Committee for Socio-economic Analysis (SEAC) has published a draft opinion on the Annex XV dossier of the European Chemicals Agency (ECHA) for "intentionally added microplastic" as part of the restriction procedure. The VCI welcomes the opportunity to take position and would like to use it to comment hereinafter on certain aspects of the SEAC opinion. Furthermore, we would like to answer the Specific Information Requests raised by SEAC as part of the public consultation. In our view, the SEAC opinion is based on a partly fundamental lack of information. For this reason, the socio-economic assessment could only be carried out superficially for certain points. If the restriction is put into practice in the form presented, this problem will lead to a lack of legal certainty for both the chemical industry and the implementing authorities.

Executive summary

The VCI do not generally disagree with a restriction of "intentionally added microplastics". The analysis carried out in the SEAC opinion draft identifies information deficit and gaps in the socio-economic assessment. According to the VCI, the following elements require further consideration in the final SEAC opinion on the ECHA restriction proposal of "intentionally added microplastic":

- Compliance with the principles of the REACH Regulation, such as the description of substance identity or sufficient identification of hazard and risk to enable a socio-economic analysis according to Article 68 of the REACH Regulation,
- Considering the term "manufacturing" in the derogation for "intentionally added microplastics" at industrial sites (§4a),
- Improvement of the definition of "intentionally added microplastics" to make a realistic assessment of the socio-economic consequences feasible,
- Considering supply chain-specific costs resulting from the implementation of transition periods in the restriction of "intentionally added microplastics",
- Equal treatment of manufacturers inside the EU as opposed to manufacturers/importers outside the EU, by a definition of "intentionally added microplastics" which can be controlled by suitable and workable analytical methods,
- Examination of the divergent interpretation of the term "downstream user" and the related unclear obligations in the proposed reporting,

- Establishment a passing of information along the supply chain, which provides a workable and inexpensive reporting obligation with safeguarding CBI by using e.g. the established SDS.

Background

The restriction proposal of the European Chemicals Agency (ECHA) on “intentionally added microplastics” within an Annex XV dossier was reviewed and evaluated by Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) from March 2019 to July 2020 and separate opinions were given. Contrary to the RAC opinion[1], which is final, the draft SEAC opinion[2] can be commented until 1 September 2020. During the period of the review process by RAC and SEAC, ECHA as Dossier Submitter (DS) developed – based on the public consultation (May 2019 - September 2019) – a revised proposal on the restriction text of "intentionally added microplastics", which shows partly significant changes to the original restriction text. We partly support the changes made here, however, we deplore that there is no possibility to discuss the revised restriction text with stakeholders outside CARACAL.

Therefore, we are glad to support the process of elaborating a well-founded SEAC opinion with the following VCI comments[3] and would like to emphasize once again that we do not generally reject a restriction of "intentionally added microplastics" under REACH. But in our view, the basic principles of the REACH Regulation must be fulfilled for a restriction to be legally compliant. Only in this way is it possible to achieve a high degree of legal certainty for the respective industries. [4]

In the following, we would like to address – in accordance with the public consultation guidance[5] – the socio-economic statements of the SEAC opinion and answer the Specific Information Requests identified by SEAC. We take into account in our

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[1] RAC-Opinion on an Annex XV dossier proposing restrictions on intentionally-added microplastics, ECHA/RAC/RES-O-0000006790-71-01/F, June 2020, https://echa.europa.eu/documents/10162/b4d383cd-24fc-82e9-cccf-6d9f66ee9089

[2] SEAC-Opinion Draft on an Annex XV dossier proposing restrictions on intentionally-added microplastics, June 2020, https://echa.europa.eu/documents/10162/28a04d6e-3c6c-3416-44ef-1b40240d8534

[3] This VCI document is prepared, inter alia, in coordination with associations of consumer products manufacturers. Regarding the details on certain consumer products (e.g. cosmetics), we would refer to the specific statements by the respective sector associations at national and European levels, due to the summer and holiday season.

[4] VCI position on ECHA REACH Annex XV restriction proposal, May 2019, https://www.vci.de/themen/chemikaliensicherheit/reach/vci-position-zum-echa-reach-anhang-xv-beschraenkung-von-microplastic.jsp

[5] ECHA- Public Consultation Guidance, https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf

comments that, as described in the guidance, points concerning the RAC opinion are not considered. However, when reading the Specific Information Requests identified by SEAC, it becomes clear that this Committee continues to have a great need for additional socio-economic data, especially where RAC or SEAC depart from the DS proposals. Therefore, from our perspective there is a noteworthy link between the socio-economic considerations in the draft SEAC opinion and the scientific considerations in the RAC opinion. Consequently, a strict separation between the RAC and SEAC opinions in connection with the ECHA restriction proposal of "intentionally added microplastic" is, as we see things, not possible in all points.

Detailed VCI comments on the draft SEAC opinion draft

"Intentionally added microplastics" is a highly complex issue. In the currently discussed restriction proposal with its broad definition of microplastics, it involves various different industries.[6] Taking into account the fact that the described definition leads to an enormous need for information, which in some cases cannot be fully identified in its dimensions as yet, we see an obvious information deficit. On this basis, only unclear socio-economic consequences for impacted industries can be appraised. Therefore, in our view, a specification of the restriction on this point would be necessary – in order to allow the assessment of realistic socio-economic consequences based on a more comprehensive RMOA analysis. Within the draft SEAC opinion, the information deficit is also noted at certain sections:

> *SEAC highlights that the presented cost estimates cannot be regarded as precise figures, because the data to underpin the cost assessment are limited and significant uncertainties to assess the economic impact of the proposal remain. Therefore, the cost figures rather illustrate the range of costs that may result from the proposed restriction.*
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> [Page 43, SEAC opinion draft]

Therefore, we would point out that due to an information deficit, the assessment of some of the socio-economic impacts is only estimated or described qualitatively in the following VCI document, comparable to the SEAC opinion draft.

Implementation and workability of the restriction proposal for “intentionally added microplastics” – appraisal by SEAC and RAC

SEAC holds in its opinion that the DS has proposed a definition of microplastics which fulfils the Commission’s requirements:

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[6] VCI position to ECHA proposal for a restriction of polymers as "intentionally added microplastics", September 2019, https://www.vci.de/themen/chemikaliensicherheit/reach/vci-position-echa-vorschlag-beschraenkung-polymere-als-absichtlich-eingesetztes-mikroplastik.jsp

> *It is outside of the remit of SEAC to comment on the validity and appropriateness of the definition itself, but the overall approach is considered to be well-justified by the Committee. SEAC notes that the updated definition is fit for purpose, i.e. it is in line with the objectives set out by the Dossier Submitter and the request by the Commission.*
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> [Page 16, SEAC opinion draft]

This definition is to meet the European Commission's concern that the restriction should not be limited to individual substances, but rather to generic "groups" of synthetic polymers with common physical, persistent properties:

> *Indeed, it is quite possible for some forms of a substance to be within the scope of the restriction, whilst others are outside e.g. based on differences in polymer chain length, degree of branching, cross-linking or particle size, etc.*
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> [Page 11, RAC opinion]

Therefore, RAC concedes in this connection:

> *It is generally difficult to anticipate all the possible issues related to broad definitions.*
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> [Page 10, RAC opinion]

For this reason, we see the need to check compliance with the basic principles of the REACH Regulation (e.g. description of substance identity or sufficient identification of hazard and risk) for a restriction under Article 68 of REACH, among other things, to allow for a socio-economic analysis in conformity with existing legislation. Among other things we would like to point out that under REACH, man-made fibres have been defined as ‘articles’, made from polymers and are neither ‘substances’ nor ‘mixtures’. As a matter of principle, articles cannot be themself subject to a restriction process under REACH.

For a reporting on 31 January of each year under the proposed restriction of "intentionally used microplastics", the SEAC estimates the costs as moderate and agrees with the RAC on feasibility.

> *In terms of the ‘instructions for use and disposal’ as well as the reporting requirement SEAC points out that the costs of their implementation are likely to be moderate and the benefits in terms of lower releases (along the supply chain) and a better evidence base to facilitate future action seem likely. With regard to reporting, SEAC considers that biennial reporting (compared to annual as proposed by the Dossier Submitter) may also be sufficient to achieve a sound evidence base within a reasonable time frame and will reduce the resources needed for industry as well as authorities to process the information generated.*
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> [Page 64, SEAC opinion draft]

We would like to emphasize that such a complex annual reporting of the quantity of microplastics placed on the market, including information on their use, identity and estimated quantity released, means a considerable additional workload for industry and, therefore, also involves considerable extra costs. For this reason, we would

consider it necessary, following an examination of the legal compliance of such a reporting obligation within the REACH Regulation, to review the proposed submission deadline of 31 January – in order to realistically enable the proposed data to be brought together in the first place. In this context, we also welcome the biennial reporting proposed by the SEAC.

Lacking socio-economic assessment of the derogation for the use of "intentionally added microplastics" at industrial sites by SEAC

In principle, we welcome the establishment of exemptions, which were supplemented by the DS on the basis of the public consultation. However, we are aware of the fact that the SEAC has not determined a socio-economic evaluation of the consequences of the derogation described in §4a.[7]

The term use is not very precise in this context, since not only users and importers but also manufacturers of microplastics could be affected by the restriction. However, the current wording of §4a does not take it into account, since the manufacture of microplastics is not covered by the REACH definition of use.[8] This fact is supported on the one hand by the fact that manufacturing[9] is defined separately within the REACH regulation and on the other hand by the ECHA guidelines, such as "Guidance on Information Requirements and Chemical Safety Assessment Chapter R12: Use Description".

In our opinion, the socio-economic consequences of not taking manufacturing (manufacturing) into account under §4a could, in the worst case, lead to a withdrawal of the license to operate for some producers of Microplastic, although the manufactured products no longer contain "intentionally used Microplastic" at the end of the supply chain, e.g. due to further processing by downstream users. This would affect e.g. PTFE micro powders, which are very important as coatings or additives for high-performance greases in the automotive industry, as they allow smooth movements in a wide temperature range.

Conclusion: We propose to examine the socio-economic consequences of not considering the manufacturing under §4a in order to determine the described connection between use and manufacturing.

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[7] §4a Substances or Mixtures containing Microplastics for Use at Industrial Sites [Page 12, SEAC opinion draft].

[8] use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization [Article 3, No. 24, REACH Regulation].

[9] manufacturing: means production or extraction of substances in the natural state [Article 3, No. 8, REACH Regulation].

Definition of microplastics – Characterisation of mixtures – Significance of an enforceable lower limit

> *SEAC stated earlier in this opinion that practicality and enforceability should have no bearing on the microplastics definition, but that these issues should be taken up when defining the target of the restriction. SEAC therefore recommends to include a temporary lower size limit of 100 nm.*
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> [Page 23, SEAC opinion draft]

With regard to the revised restriction proposal submitted by the DS, we welcome the changes to the lower limit for the definition of "intentionally added microplastics" to 0.1 µm for particles and 0.3 µm for fibre-like particles. This adaptation takes into account the current "state of the art" in identifying micro-plastics. All the same, we are critical of the SEAC's position to consider this lower limit only as temporary.

Studies within the industry, which were shared with representatives of the European Commission at a Cefic workshop (28/29 October 2019), show that the present analysis of particles as small as from 1 µm requires a great deal of effort and major financial resources – while only slow further development of the necessary methods is expected. Moreover, the current state of method development does not allow a reliable estimate of when suitable methods for the analysis of even smaller particles in the nanometer range, especially in mixtures, will become available. Therefore, a future change in the definition of microplastics would directly lead to increased R&D costs and thus have significant negative impacts on innovation. For this reason, we see considerable potential for an implementation problem in the chosen formulation ("temporary"), which involves more legal and planning uncertainty for the industry.

Conclusion: We expect the implementation of a restriction that will lead to a high degree of legal certainty for companies. In this respect, we welcome the raising of the lower size limit as a first important step, but we still see a clear need for further improvement in the partly unclear definition of the term "intentionally added microplastic", especially in order to be able to assess the socio-economic consequences.

Socio-economic consequences of the transposition periods for the restriction and labelling

> *From [EiF + 24 months] any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastics to the environment, including at the waste lifecycle stage.*
>
> [Page 3, SEAC opinion draft]

> *Shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture [...]*
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> [Page 1, SEAC opinion draft]

As VCI, we welcome the definition of transition periods and the consideration of the industry's comments during the public consultation. However, we would like to stress that, in contrast to other regulations within the EU, there is no differentiation of the term "placing on the market"[10] within the REACH regulation. Due to this undifferentiated approach, it is unclear to us how to ensure that no products with restriction-relevant components or incorrect labeling are available on the market at the time the restriction takes effect. While manufacturers or downstream users can ensure that only compliant products are placed on the market when the restriction becomes effective, it cannot be excluded that non-compliant products are still in the supply chain (e.g. in retail outlets) at the time of the restriction becoming effective. The resulting measures e.g. recall actions with subsequent destruction or relabelling of such products have to be analysed and compared to the ecological benefit in a socio-economic assessment.

Conclusion: As part of the socio-economic assessment, there should be an analysis of supply chain-specific costs by establishing implementation transition periods, which we welcome in principle.

Unequal treatment of manufacturers inside the EU as opposed to manufacturers/importers outside the EU

> *Similarly, SEAC notes that the impact of the proposed restriction on emission sources outside the EU is limited, although some reduction in the use of microplastics is likely because the restriction will apply to mixtures imported to the EU.*
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> [Page 59, SEAC opinion draft]

The control of the implementation of the restriction of "intentionally added microplastics" by the competent authorities differs significantly from the type of microplastics and the time of analysis in the product life, especially since microplastics are currently still needed in some products to maintain their function[11] (e.g. plant protection products formulated as microcapsule suspensions (CS) or polymeric binders as well as pigments and fillers in paints, coatings and printing inks). For the detection

[10] placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market [Article 3, No. 12, REACH-Regulation].

[11] Concrete examples of problems and impacts of the restriction proposal in the various sectors: https://www.vci.de/vci-online/themen/chemikaliensicherheit/reach/vci-position-echa-proposal-restriction-polymers-as-intentionally-added-microplastics.jsp

of currently irreplaceable microplastics or for the control of "microplastics-free" products it will be necessary to identify the polymer as well as the aggregate state of the polymer. A lack of suitable analytical methods, especially for microplastics in mixtures, would constitute a major task for the implementing authorities in enforcing the restriction and would lead to inherent disadvantages for EU manufacturers compared to importers. In our view, this point has not been fully taken into account in the socio-economic analysis.

For a comprehensive socio-economic assessment, we see a need for a realistic appraisal that takes into account the negative consequences for products that are at the same time both manufactured in the EU and imported into the EU. In particular for mixtures, such as emulsion paints with an import share of approx. 20% (53,000 tonnes out of a total of 266,000 tonnes[12]), we see an immense distortion of competition due to the proposed restriction of "intentionally added microplastics" which favours producers/importers outside the EU over producers in the EU.

Conclusion: Products imported into the EU are subject to European legal rules, but without suitable and workable analytical methods, EU manufacturers will not be able to voluntarily prove the absence of microplastics in their "microplastics-free" products and public authorities will not be able to check imported mixtures for microplastics. In our view, this problem can also occur in product classes that are currently not significantly affected by imports, especially if certain functionalities are lost due to the restriction of "intentionally used microplastics" in products manufactured in the EU.

Divergent interpretation of the term "downstream user" from the official REACH text and the related unclear obligations in the proposed reporting

> *Therefore, a company in the supply chain might have multiple different roles under REACH: for example, a REACH manufacturer can also be a REACH downstream user of the microplastics they are manufacturing. In this case, the company will have to fulfil all obligations associated with the different roles.*
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> [Page 154, RAC & SEAC (draft) Background document]

When looking at the definition of "downstream user" in the background document[13]t to the RAC opinion/ SEAC opinion draft, contradictions to REACH arise, especially with

[12] Figures for European imports of 2019 (Chem Research).

[13] https://echa.europa.eu/documents/10162/e592006a-b84a-c22a-c8c7-1e7b8f04ab80

regard to the distinction between "downstream user"[14] and "manufacturer"[15]. However, in contrast to the background document, within REACH a clear distinction is made between these two terms.

Due to this inconsistency, according to the RAC & SEAC Background Document all industrial manufacturers using their newly manufactured microplastics according to the uses defined in REACH Article 3(24) would be required to report under §8 of the proposed restriction, despite the fact that this is not in line with the REACH definition of „downstream user". The VCI considers a different definition of these central terms within the REACH Regulation to be extremely problematic, as this causes much legal uncertainty.

Furthermore, we find the resulting reporting obligation for manufacturers of microplastic particles disproportionate. This becomes clear in the exemplary consideration of plastic granulates, which also fall under the definition of microplastics. The production of these granulates in industrial chemical plants is subject to high requirements regarding their emissions into the environment, which is already ensured by appropriate risk management measures. These already strict legal provisions are partly supplemented by voluntary commitments of industry, such as Zero Pellet Loss/Operation Clean Sweep (obligation to minimise the loss of plastic raw materials through optimisation processes and broad-based information campaigns).[16]

Because of the framework described above, the VCI considers an extension of the reporting obligation to industrial manufacturers to be disproportionate. In particular, this applies to a number of mainly medium-sized industries, as such bureaucratic effort means heavy tasks for them which are out of proportion to the effect achieved for human health and the environment.

Conclusion: The definition of the term "downstream user", which differs from the REACH Regulation, considerably increases the complexity of the restriction proposal and stands in the way of legal certainty for the entire industry. Assuming that there is a legal basis within the REACH Regulation for the proposed reporting obligation, we see – particularly, but not exclusively, for small and medium-sized industries – that the extended reporting obligation does not contribute to safer handling of the products

[14] downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. […] [Article 3, No. 13, REACH Regulation].

[15] manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community [Article 3, No. 9, REACH Regulation].

[16] https://www.opcleansweep.org/

concerned, while the bureaucratic effort for manufacturers increases disproportionately.

Including the labelling obligation in safety data sheets

> *In terms of the 'instructions for use and disposal' as well as the reporting requirement SEAC points out that the costs of their implementation are likely to be moderate and the benefits in terms of lower releases (along the supply chain) and a better evidence base to facilitate future action seem likely.*
>
> [Page 64, SEAC opinion draft]

The protection of confidential business information (CBI) is of central importance for an innovation-friendly industry. In this context, we welcome the current revision of the proposal on product information subject to mandatory labelling. This proposal ensures both the transfer of relevant information along the value chain and, at the same time, allows companies to protect their trade secrets regarding polymer identities used. In order to safeguard this also in future, the information requirements for polymer identity should not exceed existing requirements in the safety data sheet (SDS), especially since there is no legal obligation to create an SDS for chemicals with non-hazardous properties, including polymers, which would mean a huge administrative burden for companies.

In addition, we expect that the upcoming restriction draft of the European Commission will allow the industry a certain freedom to label products with "intentionally added microplastic" (e.g. SDS, labels and leaflets). The information transfer on the safe handling of chemicals within the industry can be carried out cost-effectively through the already established SDS, which has been proven to work for decades. An extension of the information requirement to include additional labels would not provide any additional safety-relevant information for downstream users. Additional labels on containers and drums increase the costs of information transfer by an estimated factor of 4 - 5, which would be passed on in the supply chain and lead to a major economic factor for downstream users. The increased costs stem mainly from the use of special label printers, which would need to be purchased, set up and operated in addition to existing printers for standard CLP labels. Usually, it is not possible to refit existing printers to new label templates.

Particularly with small containers, there is also a considerable cost factor for the management of both stock levels and upstream and downstream supply chains. A multiplication of product numbers cannot be ruled out for such small products, as the affixing of additional information on the product packaging might no longer be possible due to lack of space. This results in several product numbers for products of the same content. That course of action causes extra costs; so manufacturers of ink cartridges can incur annual costs of €20,000 per product on average. With a possible product

variety of about 750 different products, these costs add up to about €15 million for one manufacturer.

Conclusion: When establishing the passing of information along the supply chain, we welcome a workable and inexpensive reporting obligation, using the well-established SDS and safeguarding CBI.

Comprehensive Valuation

The analysis carried out in the SEAC opinion draft identifies numerous fundamental information deficit and gaps in the socio-economic assessment, which is based, inter alia, on an inaccurate definition of microplastics and an inappropriate RMOA analysis by ECHA. The partly imprecise definition leads to a lack of legal certainty for industry and implementing authorities alike. In order to comprehensively assess these fundamental deficiencies in a socio-economic evaluation, VCI advocates that the points discussed in the paper be taken into account:

- Implementation and workability of the restriction proposal for “intentionally added microplastics” – appraisal by SEAC and RAC,
- Lacking socio-economic assessment of the derogation §4a,
- Definition of microplastics – Significance of an enforceable lower limit,
- Socio-economic consequences of the transposition periods for the restriction and labelling,
- Unequal treatment of manufacturers inside the EU as opposed to manufacturers/importers outside the EU,
- Divergent interpretation of the term "downstream user" from the official REACH text,
- Including the labelling obligation in safety data sheets.

We would once more emphasize that we do not generally oppose a restriction of "intentionally added microplastics" under REACH but that basic principles of the REACH Regulation must be fulfilled for a restriction in conformity with the law, which offers a high degree of legal certainty for the respective industries.

Specific Information Requests

1. RAC's evaluation of the Dossier Submitter's proposal (see draft Background Document for details) resulted in several recommendations for revised conditions. Please tell us about the impacts of these recommendations (as detailed in the RAC opinion and briefly summarised below):

*a. RAC's recommendation for appropriate test methods and pass criteria used to identify **biodegradable polymers** (derogated under paragraph 3b), including any impacts on the availability of alternatives within the transitional periods proposed in paragraph 6. Please provide supporting evidence.*

VCI comment: The degradation of microplastics, can take place both abiotically and biotically. With regard to the biodegradability of polymers, the biotic degradation, we welcome the development of the biodegradation test scheme (Table 22, background document), as it provides important information for fulfilling the exemption criterion described in §3b. Focusing the test requirements on the most relevant compartment is an innovation-friendly approach which recognises that biodegradability testing follows a similar trend in all three compartments. For example, it was shown that mineralisation half-lives, which is a leading indicator of biodegradation, were comparable for a large number of chemicals in different compartments (e.g. river water, soil and seawater) (Federle et al. 1997; Vashon et al. 1982; Shimp et al. 1987).

Furthermore, the intended use of products with microplastics usually only leads to particle distribution in a limited number of compartments. Often there is only one compartment that is of importance. Therefore, mandatory testing of biodegradability in all compartments is not necessary in most cases because of the degradation behaviour and would also cause immense costs (see below). Modelling of the degradation behaviour is a well-established method to identify the relevant compartments, depending on polymer and application type (see e.g. Holmes et al. 2020, Gouin et al. 2019).

However, the test methods listed in table 22 still pose an immense challenge and involve a great deal of cost and effort, which does not exclusively lead to the generation of relevant data on the biodegradation of microplastics. For this purpose, we see a high demand for adapted specifications for microplastics as well as for the further development of test methods and thus the full exploitation of test potentials (e.g. a modified OECD 302B in group 3).

Furthermore, the test methods and procedures should be technically feasible with the given test material. For this reason, the test specimen is examined here in powder form and not in the particle size in which the product is placed on the market. This makes it possible to adequately compare the results with the powder form reference materials, which increases the informative value of the studies. Moreover, the interaction between abiotic and biological degradation of

polymers has not been sufficiently considered so far; this could be done in a weight-of-evidence approach. However, methods should consider upstream or in parallel abiotic degradation to represent a realistic assessment of environmental conditions (Ojeda et al. 2011).

When looking at the costs of carrying out one single OECD screening test, it emerges that this would amount to ca. 5,000 - 7,000 euros (with a test duration of about 6 months). The ISO tests, group 4 of the proposed test scheme in table 22, already amount to 10,000 - 40,000 euros per test and take up to two years. These costs would inevitably multiply if several tests were conducted (e.g. if several polymer components are tested in one microplastic or for testing within different compartments). Against this background, e.g. the proof of biodegradability in several compartments would be a disproportionate financial burden, especially for SMEs.

Such a definition of the (bio)degradability of microplastics, which is not adapted to polymers, would massively impair the innovation of durable products.

Literature:

Federle et al. Extrapolating mineralization rates from the ready CO 2 screening test to activated sludge, riverwater, and soil. Env Tox and Chem. 16. 1997;

Gouin et al. Toward the Development and Application of an Environmental Risk Assessment Framework for Microplastic, Environ. Tox. Chem. 38:2087-2100. 2019;

Holmes et al. A National-Scale Framework for Visualizing Riverine Concentrations of Microplastics Released from Municipal Wastewater Treatment Incorporating Generalized Instream Losses, Environ. Tox. Chem. 39: 210-219. 2020 ;

Vashon et al. Mineralization of Linear Alcohol Ethoxylates and Linear Alcohol Ethoxy Sulfates at Trace Concentrations in Estuarine Water. Environ. Sci. Technol 16:433 436. 1982;

Shimp et al. Comparison of OECD and Radiolabeled Substrate Methods for Measuring Biodegradation in Marine Environments, Ecotoxicol and Environ Safety, 14:223 230. 1987;

Ojeda et al. Degradability of linear polyolefins under natural weathering, Polymer Degradation and Stability 96:703-707, 2011.

b. RAC's preference for a ***ban on the placing on the market of infill material*** *(meeting the definition of a microplastic) for synthetic turf sports pitches after a transitional period of six years. Specifically, will alternative synthetic turf systems that meet relevant performance standards be available in sufficient quantities for all types of pitches by the end of the six-year transitional period proposed? How many pitches would need to be replaced before the end of their expected lifetime and what would*

the impacts of such a replacement? Furthermore, is there evidence to suggest that indoor artificial pitches should be treated differently from outdoor pitches? Please provide supporting evidence.

VCI comment: No comment

c. The RAC opinion refers to a ***"hybrid restriction option"*** *that would allow existing pitches using artificial turf with infill material meeting the definition of a microplastic to continue to be used beyond the introduction of the ban until the end of their useful life (as long as risk management measures were introduced). What would be the impacts of such a 'hybrid' restriction option? Please provide supporting evidence.*

VCI comment: No comment

*d. RAC's recommendation that a l****ower size limit for a microplastic is not strictly necessary*** *as part of the conditions of a restriction as compliance/enforcement can be achieved by non-analytical means (such as via supply chain certification). Please tell us about the practical implications of this recommendation, including the costs and compliance as well as current analytical barriers for microplastics <100 nm. Please tell us whether setting a lower size limit would be justified for compliance/enforcement reasons. Please provide supporting evidence.*

VCI comment: see above "Definition of microplastics – Characterisation of mixtures – Significance of an enforceable lower limit" and "Unequal treatment of manufacturers inside the EU as opposed to manufacturers/importers outside the EU"

e. RAC agreed with several other revisions to the conditions of the restriction proposed by the Dossier Submitter (as reflected in the Background Document); including a ***clarification of the conditions to define natural polymers****,* ***a derogation for soluble polymers****,…. What are the impacts of such changes? Please provide supporting evidence.*

VCI comment:

Definition "natural polymers"

The restriction procedure on "intentionally added microplastics" discussed here is, in our view, in a clear context with the Single-Use Plastics Directive (SUPD).

For this reason, definitions relevant to both procedures must be applied congruently, such as the exemption criterion "polymers which are not chemically modified" described in the draft DS.

It emerges from a preliminary draft of the SUPD that the natural polymer (raw material) is to be compared with the final product in its chemical structure. If the structure is identical, as is the case e.g. with viscose fibres and lyocell, the end products fall out of the scope of the SUPD. Whether chemical processes, such as extraction methods, were used is not taken into account here, which we welcome.

Thus, for a comparability of different legislations in the EU, we think that it is necessary, inter alia, to add a "comparison between natural raw material and end product" for the presented restriction of "intentionally added microplastics".

Solubility

We see the inclusion of solubility as a criterion for identifying "intentionally added microplastics" as a useful addition to the restriction text, as it excludes polymers that were not included in the European Commission's request to ECHA and thus do not fall in the scope of the restriction. For example, although some polymers are produced in solid form, they dissolve when used in the product and remain dissolved also after intended use. Therefore, this is no microplastic. This fact is also recognised by RAC and DS.

We think that the proposed limit value of 2 g/l is incompatible with the existing REACH "Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.11: PBT/vPvB assessment". This guidance document considers all substances as poorly soluble in water if they have a solubility of 1 mg/l or less at 20°C. The said value is supported as a limit value in the RIVM Letter report 2015-0116 "Towards a definition of microplastics: Considerations for the specification of physico-chemical properties". To achieve consistency in the established rules and guidance documents under REACH, we see the need to revise the lime value for solubility.

Furthermore, we would point out that the method stated for determining solubility (table 23, RAC & SEAC (draft) background document) has to be checked as to its workability. Due to the broad definition of microplastic, we see the need to develop alternative methods or definitions for the different fields of application in the various industries, where necessary.

2. Any uses of microplastics that are not specifically identified in paragraph 6 of the proposal would be subject to the conditions of the restriction without any transitional period. Please tell us about the impacts of the proposed restriction on ***any uses not specifically identified and assessed by the Dossier Submitter,*** *including appropriate transitional periods (please refer to the background document). For*

example, the consultation highlighted that the supply of (bulk) ion exchange resins to consumers/professionals could be affected, as could various uses in fashion, arts, crafts or as toys (e.g. play sand). Information on any relevant uses of ***inorganic polymers*** *should also be provided.*

VCI comment:

Lack of a general transition period for non-identified industries

Against the backdrop of the planned very wide scope of application and the unclear definition of microplastics, it is doubtful whether all microplastics applications concerned have been identified so far. This prevents both a correct assessment of socio-economic consequences and the early implementation of certain measures, such as developing of substitutions. The decision to avoid a general transition period, which is often part of restrictions under REACH, should therefore be considered in conjunction with the already identified transition periods.

Inorganic polymers

Inorganic polymers differ from organic polymers in that they do not contain carbon atoms in their chemical structure. Typical examples are e.g. ammonium polyphosphates. The unjustified inclusion of these inorganic polymers in the restriction proposal would have significant socio-economic impacts, as everyday products for which there is no alternative (flame retardants) would be affected. In the existing socio-economic analysis, we do not see any consideration of these polymers. For this reason, we assume that they do not fall in the scope of the restriction. We welcome this, as a restriction of these inorganic polymers would, in our view, not reduce the release of "intentionally added microplastic" as described by the European Commission. Therefore, the comparison with carbon-containing microplastics is not justified from our perspective, given the different chemical composition.

At present, the risk of persistence of polymers described in the restriction proposal is not based on a clear scientific definition and the tests available for carbon-containing substances cannot be used for inorganic substances. For example, inorganic substances are not described in the description of persistence within REACH (Annex XIII) for the identification of PBT and vPvB substances:

> *This Annex shall apply to all organic substances, including organo-metals.*
>
> [Annex XIII, introduction]

In our view, the stigmatization of inorganic polymers would therefore lead to more uncertainty among customers, as they do not have the necessary

background knowledge to distinguish relevant differences between organic and inorganic polymers.

3. The Dossier Submitter has proposed a transitional period of six years for ***substance-based medical devices*** *on the basis that the potential and timeline for substitution in these products is comparable to cosmetic products. Substance-based medical devices includes certain toothpastes, denture adhesives and products used for sun protection regulated under the Medical Devices Regulation (EU) 2017/745 rather than the Cosmetics Products Regulation (EU) 1223/2009. Please tell us about the impacts of the proposed ban, as well as of the six-year transitional period. Please indicate whether there are significant differences (function of microplastics, level of performance required for the product,…) between such substance-based medical devices and cosmetic products. Please tell us if you believe that a different transitional period would be justified, with supporting evidence.*

VCI comment: It is true that pharmaceuticals and substance-based medical devices are different in their respective mode of action, but their excipient formulation is often similar. Consequently, also the manufacturing processes for these products are similar and, quite frequently, identical. This means that the procedures, the technical aids used and the process materials are similar or identical in the vast majority of cases. Both product categories are used for medical purpose. For this reason, an unequal treatment of substance-based medicinal products and pharmaceuticals with regard to the transitional period is not comprehensible.

4. The Dossier Submitter has proposed transitional periods of either five or eight years for the ***encapsulation of fragrances in detergents, cosmetic products or other mixtures****. We welcome additional information (i.e. which has not already been provided in the previous consultation or call for evidence) on the suitability of these proposed transitional periods, including the timeline for developing alternatives, reformulating products and any other relevant issues affecting the time needed to comply with the proposed restriction.*

VCI comment: This document was elaborated in consultation with other associations of consumer product manufacturers. Due to the summer and holiday season, we would like to refer to the specific statements of the respective industry associations at national and European levels for details on certain consumer products (e.g. cosmetics).

5. Paragraph 7 of the proposal describes a requirement (24 months after entry into force of the restriction) to provide relevant ***'instructions for use and disposal'*** *for*

certain uses derogated from the ban on placing on the market. The proposal was revised by the Dossier Submitter during opinion-making in response to information submitted in the consultation (see background document). Please tell us about the practical implications of this revised requirement as well as the resources (including costs if possible) needed to comply with it? For example, please provide information about the supply chains, processes and number of actors that could be affected by this requirement as well as expected costs and other relevant impacts.

VCI comment: see above “Including the labelling obligation in safety data sheets” and the following contribution:

It is already mandatory for package inserts of finished medicinal products to include information on the correct disposal of rests of pharmaceuticals. This information has been agreed EU-wide and, like all other items of information in the package insert, is subject to examination and approval by the competent public authorities. Decisions on the inclusion of further information or the extension of the existing information are made by the competent public authorities, too, regularly in consultation with the European Commission. For medical devices there are instructions for disposal laid down in the Medical Device Regulation (Annex I, 23.4 letter v).

*6. Paragraph 8 of the proposal describes a requirement (36 months after entry into force of the restriction) to **report information on uses and releases** of microplastics for certain uses derogated from the ban on placing on the market. The proposal was revised by the Dossier Submitter during opinion-making in response to information submitted in the consultation (see background document). Please tell us about the practical implications of the revised requirement as well as the resources needed (including the costs) to comply with it, including the potential for joint sectorial submissions? Please provide information about the supply chains, processes and number of actors that could be affected by this requirement as well as expected costs and other relevant impacts.*

VCI comment: Pharmaceuticals and substance-based medical devices are mixtures of many substances. Their analytical examination is a technical and scientific challenge. A quantitative analytical determination of mostly inert microplastics is not possible – while it would be a basic requirement for estimating the release of microplastics into the environment. The costs for analytical development are difficult to estimate concretely in this scenario, however, high costs can be assumed due to the complexity of the matter.

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The VCI represents the politico-economic interests of around 1,700 German chemical companies and German subsidiaries of foreign businesses. For this purpose, the VCI is in contact with politicians, public authorities, other industries, science and media. The VCI stands for over 90 percent of the chemical industry in Germany. In 2018 the German chemical industry realised sales of 203 billion euros and employed ca. 462,500 staff.