VERBAND DER CHEMISCHEN INDUSTRIE e.V.
WIR GESTALTEN ZUKUNFT.

Restriction of Microplastic

VCI-Position to ECHA REACH Annex XV Restriction Report

Proposal for a Restriction:

"*Substances Names*: Intentionally added Microplastics"

Executive Summary

At the request of the European Commission, the European Chemicals Agency (ECHA) has submitted a proposal to restrict microplastics within the framework of a so-called Annex XV dossier in accordance with the REACH Regulation *(title: Proposal for a Restriction: Substance Name(s): intentionally added microplastics).* A public consultation on this Annex XV dossier is ongoing until 20 September 2019.

The title of the restriction and also almost all statements in the dossier (e.g. statements on substance identity or risk assessment) suggest that it is a restriction of microplastics. In fact, however, the proposed restriction addresses all polymers and virtually all polymer-containing or polymer-coated materials. The specifications, definitions and scope of the restriction are so complex and so extensive that it is unclear what exactly should be covered.

In the opinion of the VCI, the restriction proposal infringes important provisions of the REACH Regulation and the tenets of the precautionary principle:

1. Insufficient description of substance identity:

The general addressing of all polymers or microplastics does not fulfil the requirements of the REACH Regulation for a precise identification of the substances to be restricted. Overall, it is unclear in the ECHA Annex XV dossier what exactly should be restricted - polymers or microplastics. The precise identification of the substances to be restricted as required under REACH and a risk assessment and assessment of socio-economic impacts based on this are missing.

2. Lack of identification of hazard and risk

The provisions of Title VIII of REACH are disregarded by proposing a restriction in the absence of the first determining element of the risk - i.e. an identified hazard. Overall, with a simple reference to the "extreme stability" (persistence) of the particles, a fictitious, alleged risk is constructed, without having any evidence of a real risk or - after the scientific risk assessment - having any reasonable cause for concern that can be derived.

3. Lack of detail in the risk assessment

Any risk assessment in accordance with REACH must be substance-related.
A grouping of substances may be possible under certain, closely defined conditions. However, the demonstration required under REACH that all polymers or microplastic materials covered by the restriction have the same properties and thus the same risk is not provided.

4. Disregard of the principles and standards for the application of the precautionary principle

The reasoning presented in the Annex XV dossier to justify the proposed restriction does not come up to the standard required in the European Union for the application of the precautionary principle. Overall, the scientific evidence presented in the Annex XV dossier is inadequate, incomplete and inconclusive.

5. Lack of efficacy, effectiveness and proportionality

With the proposed restriction, only a small fraction of the microplastics introduced into the environment will be covered. The REACH requirement that a restriction must be appropriate to reduce risks to an acceptable level within a reasonable time and in a reasonable way is therefore not met.

Moreover, it will be virtually impossible to analytically demonstrate the effectiveness of the restriction by monitoring environmental concentrations resulting from the definition of the materials to be restricted - given the extremely wide particle size range of 1nm to 5mm and the complex structural requirements of e. g. "continuous polymer surface coatings of any thickness".

6. Lack of legal basis for extensive product labelling and for the proposed disproportionate annual reporting requirement

It is not acceptable that a detailed labelling and an extensive annual reporting requirement are to be introduced for almost all polymer-containing products even if they are exempted from the restriction. Such obligations have to be fulfilled by all downstream users. There is no sufficient legal basis for this.

Conclusions / Recommendations

- The VCI does not reject a restriction of certain specified uses of microplastics in principle.
- The VCI prefers that restriction measures be taken within the framework of the REACH regulation.
- However, in order for the restriction now presented to comply with the requirements of the REACH Regulation, extensive adjustments must be made.
- First proposals for such adjustments are contained in the detailed VCI assessment.

Detailed VCI Evaluation

1. Background / Content of the ECHA Annex XV Dossier

The European Commission asked the European Chemicals Agency (ECHA) to prepare a restriction dossier according to Annex XV of the REACH Regulation, regarding the use of “intentionally added microplastics”.

ECHA submitted a first version of the above Annex XV dossier on 11 January 2019.

For the start of the public consultation, which runs to 20 September 2019, a new version 1.1 of the Annex XV dossier was presented on 20 March 2019. The latter version is the subject of this VCI evaluation.

The preparation of the restriction dossier for “intentionally added microplastics” was launched on the basis of Article 69(1) of the REACH Regulation. Overall, the scope of the proposed restriction includes *“the use of intentionally added microplastic particles to consumer or professional use products of any kind”*.[1]

The now proposed future entry in Annex XVII of the REACH Regulation is structured as follows [2]:

- Initially, it generally addresses polymers according to Article 3(5) of the REACH Regulation.
- Such polymers shall not be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.
- Here, inter alia, the following definitions apply:
  - ‘Microplastic’ means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3.
  - ‘Particle’ is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface.
  - ‘Polymer-containing particle’ means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w.

[1] Original: “Details on the scope of restriction: Restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind.” Source: https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

[2] For a legal interpretation, it is invariably necessary to resort to the integral original text in English language of the Annex XV dossier in its latest version. The German-language summary translation of selected text passages in this VCI position paper cannot make a basis for legal interpretation.

- Transitional periods are planned, inter alia, for certain cosmetic products, medical devices, encapsulated fragrances, fertilisers and plant protection products.
- Fully exempted from the restriction are polymers that occur in nature and polymers that are (bio)degradable.
- Exemptions from the use restrictions are intended, inter alia, for
  - Substances or mixtures containing microplastics for use at industrial sites (4a).
  - Medicinal products for human or veterinary use.(4b).
  - Substances or mixtures where microplastics are contained by technical means throughout their use to prevent releases to the environment and incinerated or disposed as hazardous waste at the end of their life-cycle (5a).
  - Substances or mixtures where the physical properties of the microplastics are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of a microplastic (5b).
  - Substances or mixtures where microplastics are permanently incorporated into a solid matrix at the point of use (5c).
- However, regarding these exemptions
  - very comprehensive additional labelling and communication requirements apply for manufacturers, importers and downstream users, and
  - comprehensive annual obligations to report to ECHA are planned for down-stream users in the supply chain (not for exception 5a).
    ECHA shall publish a report summarising the information received by 31 March every year.

In summary, ECHA justifies as follows the need for its restriction proposal[3]:

- Conclusions from the environmental and health hazard assessment

  (chapter 1.4.4.12, Annex XV dossier)
  - There is only limited evidence that risks are occurring in the environment; despite ingestion and the presence of microplastics in organisms across different trophic levels being clearly observed.
  - The scientific literature does not suggest that microplastics are currently causing significant adverse impacts in the environment or that they are increasing the bioaccumulation of hydrophobic organic compounds into organisms.
  - For nanoplastics, there is insufficient information to undertake any meaningful assessment of either hazard or risk, which is a particularly significant data gap.

[3] Selectively taken from the ECHA Annex XV dossier

- Some previous studies have questioned the perception that microplastics pose an unacceptable risk to the environment. However, based on all the evidence, it is practically impossible to exclude a risk for the environment with certainty.
- Conventional risk assessment approaches, including the use of assessment factors, may not be appropriate to assess the risks of micro and nanoplastics.

- PBT/vPvB Bewertung (Kapitel 1.4.5. Annex XV-Dossier)
  - No PBT/vPvB assessment for microplastics is carried out – as, based on the currently available information, the criteria in Annex XIII of REACH may not be applicable to microplastics. Specifically, the classic concept of bioaccumulation and biomagnification, established on a molecular level, may not be satisfied by polymer particles; despite the evidence that microplastics are present in top predators and can be subject to trophic transfer.
- “Case-by-case” risk assessment (extreme persistence in the environment)

  (chapter 1.4.6, Annex XV dossier)
  - Non-biodegradable microplastics will readily meet the criteria for very persistent substances outlined in Annex XIII of REACH having half-lives of several hundred years or more. Because of this “extreme” persistence, the approaches established for the risk assessment of PBT/vPvB substances are likely to be applicable to microplastics.
  - Extreme persistency of conventional plastics leads to accumulation in the environment. As a result of mechanical degradation plastic particles still remain and may accumulate in the environment.
- Conclusions on hazard (chapter 1.4.7, Annex XV dossier)
  - There is currently insufficient information to derive robust “predicted no effect concentrations” (PNECs) for microplastics, that could be used to underpin a conclusion that risks are adequately controlled, either now or in the future; including in the marine compartment where the hazards of microplastics have been most extensively studied.
  - An important property of microplastics to also bear in mind when considering appropriate risk assessment is their “extreme”, arguably permanent, persistence in the environment. This property will lead to any releases that occur contributing to the “environmental stock” over time, which would eventually exceed a PNEC in the future, assuming that sufficient information becomes available to derive one.
  - Therefore, it is considered that microplastics should be treated as non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH Regulation, with any release to the environment assumed to result in a risk. Thus it is concluded that the risks arising from intentional uses of microplastics that result in releases to the environment are not adequately controlled.
- Risk characterisation (chapter 1.4.8, Annex XV dossier)

- On the basis of the conclusions of the hazard assessment, it is proposed that microplastics are considered non-threshold substances and that releases to the environment are considered as a proxy for risk.
- This would be consistent with recent restrictions of substances where it is not possible to derive a threshold, such as decaBDE, PFOA and lead (in PVC and in gunshot) etc.

In order to determine the level of emissions from intentionally added microplastics, the ECHA Annex XV dossier (chapter 1.6.1) makes the following comparison:

By weight, the emissions of microplastics to fall under the proposed restriction (36,000 tonnes p.a.) would correspond to approximately 0.2% of the total plastic waste that was disposed without proper control in the EU28+ in 2016.

2 Detailed assessment / Concrete proposals for amendments

2.1 Empowerment / Identification of substances to be restricted

The basis for the preparation of the ECHA restriction proposal is Article 69(1) of the REACH Regulation (Annex XV dossier, page 6).

It is worth noting that, as a matter of principle, only the following can be restricted under Article 69 of REACH:

> *"placing on the market or use of a substance on its own, in a mixture or in an article"*

The restriction of articles is not covered by the REACH Regulation.

According to Annex XV no. 3 of REACH, a restriction requires the preparation of a dossier that states in detail the identity of the substances to be restricted.

The restriction proposed in column 1, table 3 of the ECHA Annex XV dossier initially addresses all polymers.

However, the term "polymers" comprises large numbers of different substances which so far cannot be identified in the prerequisite depth of detail for the purposes of risk assessment and registration or, consequently, for restrictions.

This is also made quite clear by the following requirements in the REACH Regulation:

Whereas 41:

> „[…] *Polymers should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria."*

Article 138(2):

> *The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:*
>
> *(a) the risks posed by polymers in comparison with other substances;*
>
> *(b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.*

The general addressing of all polymers for the purpose of a restriction does not fulfil the requirements of the REACH Regulation for a precise identification of the substances to be restricted. A restriction would only be possible if it clearly identified the substances concerned.

The proposed restriction then prescribes (table 3, ECHA Annex XV dossier) that polymers shall not be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.

Examples / quotations from the dossier:

> *"Proposal for a Restriction: Substance name(s): intentionally added microplastics."* (title page)
>
> *"The preparation of this restriction dossier on 'microplastics' was initiated on the basis of Article 69(1) of the REACH Regulation. The scope of this proposal is limited to intentional uses of microplastics as that was the scope set out in the request from the Commission.* ("About this report", page 6)"
>
> *"The term 'microplastic' is not consistency defined, but is typically considered to refer to small, usually microscopic, solid particles made of a synthetic polymer."* (Summary).
>
> *"Microplastics formed in the environment are usually called 'secondary' microplastics and their risk management is outside the scope of this assessment."* (Summary)
>
> *"The request from the Commission was received by ECHA on 9 November 2017 and can be summarised, as follows: - Prepare an Annex XV dossier in view of a possible restriction of synthetic water-insoluble polymers of 5mm or less in any dimension (i.e. microplastic particles)"* (chapter 1.1.2)
>
> *"The study undertaken by the Commission preceding the request to ECHA for a restriction proposal (AMEC, 2017) had also noted that a range of different definitions could be considered for microplastics. The request from the European Commission to develop a restriction proposal on intentionally added microplastics included a further definition, referring to microplastic particles as 'synthetic water-insoluble polymers of 5mm or less in any dimension' (COM, 2017)."* (Chapter 1.2.2. "Identity of the substance(s), and physical and chemical properties" and subchapter 1.2.2.1. "Proposal for a regulatory definition of a microplastic under REACH")

> *"The Dossier Submitter* [ECHA] *has not interpreted the term 'microplastic' in a strictly semantic sense, but rather considers that the term is representative of small, typically microscopic, synthetic polymer particles that resist (bio)degradation."*
>
> *"The intent of the definition is not to regulate the use of polymers generally, but only where they meet the specific conditions that identify them as being 'microplastics'."* (Chapter 1.2.2. "Identity of the substance(s), and physical and chemical properties" and subchapter 1.2.2.1. "Proposal for a regulatory definition of a microplastic under REACH")
>
> *"The substance identification currently proposed for the restriction is 'polymers', as defined in REACH Article 3(5), supplemented with criteria on relevant particle morphology, physico-chemical properties and persistence in the environment."* (Chapter 1.2.2.2 "Justification for grouping")
>
> *"The restriction applies to microplastics that are substances on their own or in mixtures. We assume that microplastics are not substances in articles, based on version 4.0 of the Substances in Articles Guidance, specifically section 2.2 that discusses manufactured solid materials. However, if this understanding changes then relevant wording should be included in the proposed restriction to ensure that relevant articles are also included within the scope."*
> (Chapter 2.2.1 Justification for the scope of the proposed restriction)

Almost all considerations in the ECHA Annex XV dossier – in particular, regarding substance identification and risk assessment – are based on the term "microplastics". However, this term meets neither the "substance" definition of Article 3(1) of the REACH Regulation

> *Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;*

nor the detailed requirements of REACH Annex VI on substance identification. Quite the contrary: Microplastics have highly different chemical compositions so that they can rather be seen as complex mixtures; by no means can microplastics be deemed substances.

Thus, the term "microplastics" also fails to fulfil the ECHA requirements on substance identity; particularly the demands of the "ECHA Guidance on the identification and naming of substances under REACH and CLP" and of the „ECHA Guidance in a Nutshell":

> *„2.1. Why it is important to clearly identify a substance*
>
> *Unambiguous and clear substance identification is an essential preliminary step in order to comply with the requirements for substances falling within the scope of the REACH and CLP Regulations and to establish whether they fulfil the requirements for exemptions from certain provisions of these Regulations. To identify a substance each company needs to use specific identification*

parameters defined in Annex VI of the REACH Regulation which will be required for the different REACH and CLP processes. These will be necessary not only for companies but also for authorities in order to carry out their duties. The approach to identify a substance depends on the substance type, as described in section 3 of this document."

Also a comparison with the "ECHA Guidance for the preparation of an Annex XV dossier for restrictions" shows that the submitted ECHA Annex XV dossier to restrict "intentionally added microplastics" does not come up to the given requirements. Especially the Annexes I and II of this guidance demand to describe in detail the identity of the substances to be restricted.

Conclusion:

Overall, the ECHA Annex XV dossier makes contradictory and unclear statements on what exactly is to be restricted or what precisely is the subject of the considerations and, in particular, of the exposure and risk assessments: polymers (organic/inorganic), microplastics or microplastic particles. While the restriction proposal as such (column 1 of table 3) addresses polymers, the Annex XV dossier largely speaks of "microplastics".

The general addressing of all polymers or addressing microplastics in general for the purpose of a restriction does not fulfil the requirements of the REACH Regulation for a precise identification of the substances to be restricted.
A restriction would only be possible if the substances or narrowly defined substance groups were clearly identified.

The REACH requirements for the preparation of an Annex XV dossier – which provide for a detailed identification of the substances and for a risk assessment and an appraisal of socio-economic impacts based on this – are ignored.

2.2 Definition "Microplastics": polymer definition as a basis

As expounded above in VCI chapter 2.1, according to the title of the Annex XV dossier the ECHA's restriction proposal is to refer to "intentionally added microplastics" – while it essentially refers to the "polymer" definition (inorganic or organic) within the REACH Regulation. However, it is worth noting that this definition is not suitable for restricting the use of microplastics.

In fact, all plastics are polymer-based but not every polymer is a plastic or even organic. For example, starches, cellulose or soaked/swollen gelatine are polymers too – three materials whose physical properties are clearly different from those of microplastics.

Furthermore, not every plastic falls under the REACH polymer definition. A polymer according to Article 5(3) REACH is

"a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily

attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a "monomer unit "means the reacted form of a monomer substance in a polymer;

Thus, the ECHA definition does not include the important class of thermosets: These are plastics such as resins and certain polyurethanes which consist of fully cross-linked polymers so that they no longer have a molecular mass distribution. It is incomprehensible why such typical plastic materials should not be covered by a microplastics restriction – unlike materials with the consistency of swollen gelatine.

Therefore, the definition of “microplastics” – which goes far beyond the generally understood term “plastics” – needs to clearly state the substance identity (chapter 2.1) and be based on the term “polymer”. The VCI supports the definition contributed by the European Chemical Industry Council (Cefic) in the “Call for Evidence” in which the term "plastics" includes both "thermoplastics" and "thermosets ":

Plastic:

“Thermoplastic made of synthetic polymers that can be repeatedly molded or extruded into various solid forms which retains its defined form in the intended applications (or during use).”

and

“Thermosets are capable of being changed into a substantially infusible product when cured by heat or by other means, such as crosslinking by reaction of functional groups or by radiation and which retains its defined form in the intended applications (or during use).“

Microplastic:

“A plastic, water insoluble, microparticle”

Furthermore, a provision to restrict microplastics needs to be closely oriented to the existing international definitions and to the terminology which is set by the international standards ISO 472 and ISO/TR 21960, e.g. for the terms “plastic” and “microplastic”.

Conclusion:

The restriction based on the REACH polymer definition, as proposed in the Annex XV dossier discussed here, is unsuitable.

Instead, a restriction should be based on the description of the exact substance identity and on an unambiguous definition of "plastic".

2.3 Definition microplastics: concentration / dimension

According to the restriction proposal, polymers must be no longer placed on the market as substances on their own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.

"Microplastic" is defined as particles from 1 nm in dimension with a polymer content from 1% or a continuous polymer surface coating of any thickness.

The definitions proposed in the restriction cause the following unclear points and problems:

- Problematic coverage of individual polymer molecules

The lower size limit of only 1 nm already covers single polymer molecules. They are often not polymers, but smaller units of the macromolecules, such as n-alkanes as they occur in nature. For such molecules, a description of their state using the established terms of solid and liquid is not possible, as is shown in a recent report by the Joint Research Centre (JRC)[4]:

"From the above classification it is also evident that single molecules cannot be solid (nor liquid), because the classification can only be applied to ensembles big enough to form a phase for which the state (solid, liquid, gaseous) can be assessed. This is one reason why single molecules, with the exemptions discussed above, do not fall under the EC NM definition, as pointed out previously."

- No possibility of analytical detection / No possibility of control and enforcement

The current state of the art does not enable an analytical detection of single polymer particles or particles of only few nm in size. In particular, this holds true in complex mixtures:

The literature quoted in the ECHA restriction proposal allows a similar conclusion: *„Depending on the setup of the application small particles can also be measured down to the range of 20 µm or if needed even lower to the range of 1 µm using micro-FTIR or micro-Raman (Primpke et al., 2017)"*[5]

Prerequisites for effectiveness, implementation and control of the restriction are validated measuring methods for polymers and for microplastics in various media. Such methods are not available as yet; especially, there are no such methods for the

[4] H. Rauscher, G. Roebben, A. Mech, N. Gibson, V. Kestens, T. P. J. Linsinger, J. Riego Sintes, An overview of concepts and terms used in the European Commission's definition of nanomaterial, JRC 2019

[5] ECHA restriction proposal on microplastics in products, chapter 2.6.1, p. 121

dimension (1 nm) and concentration range (0.01%) – as proposed in the Annex XV restriction dossier.

- The concentration limit of 0.01% for polymers in mixtures as a microplastic is too low

The low permitted content of polymers in mixtures as a microplastic of 0.01% intensifies the earlier described analytical problems. A higher permissible content is set even for PBT substances under REACH.

- Water-soluble polymers fall under the microplastic definition too

The restriction proposal with the ECHA definition of “microplastic” comprises both water-soluble and non-water soluble polymers. According to the separate annex to the Annex XV dossier (p. 19), the following applies: *“Solubility” is […] not proposed for inclusion as an element in the regulatory definition.”* This is problematic, as water-soluble polymers are not in particle form in the environment, e.g. in surface waters – while the whole restriction dossier refers to microplastics as particles in the environment.

Moreover, the currently available methods are unsuitable for detecting e.g. soluble polymers in the environment. As sample preparation provides for a sieving of samples, only particulate and undissolved components are detected. Thus, there is no detection of soluble polymers in environmental monitoring.

Furthermore, the question arises why soluble polymers fall under the restriction proposal – since ECHA was mandated by the commission to look into a restriction of water-insoluble polymers.

- Unworkable requirement of 1% particle content and of the thickness of the coating of a particle, respectively

Beside the small particle size, the polymer content of only 1% or a monolayer of a material seem arbitrary. It is not clear why the properties of a particle consisting of different materials (e.g. a polymer-coated pigment) are determined by the polymer above this lower limit threshold. Also inorganic pigments (e.g. iron oxide, titanium dioxide), which are coated with a monolayer of a water-soluble polymer for use in water-based paints, thus become microplastics and fall under the restriction.

Finally, the low permitted content of particles defined as microplastics of less than 0.01% in mixtures exacerbates the above-explained problems in analysis.

- Consequences in practical implementation

Taken together, all criteria would mean, for example, that in an end consumer product (e.g. a paint or a cosmetic formulation) 0.01% of a 1 nm polymer-containing particle would need to be detected. Then, it would have to be evaluated whether the polymer-containing particles contain more than 1% or a monolayer of a polymer.

Consequently, in theory a total concentration of 100 ppm of a polymer would be enough to ban a product due to the presence of a microplastic (1% polymer content in 0.01% of the particle).

Therefore, the VCI has considerable doubts about the conclusion on page 133 of the Annex XV dossier:

„The Dossier Submitter considers that the restriction is implementable and enforceable, although harmonised analytical methods for detecting microplastics in products are yet to be agreed and a framework of test methods and criteria for identifying (bio)degradable 'microplastics' will likely require additional research and development to progress beyond the criteria proposed here."

Conclusion:

The combination of a lower dimensional limit of 1 nm, a polymer content of 1% or a continuous polymer coating of any thickness in a polymer-containing particle and a permitted microplastic concentration of 0.01% – as proposed for the microplastic definition – results in practically all polymer-containing substances and mixtures falling under the restriction and in the impossibility to draw a borderline.

The restriction proposal in its entirety is very difficult to understand, so that considerable legal uncertainly is created.

Existing analytical methods do not ensure implementation and enforcement, which causes an additional lack of legal certainty.

Therefore, at the very least the following adaptations are necessary:

- Raise the lower particle size threshold to 1 µm.
- Raise the 1% w/w concentration limit of a polymer-containing particle to a concentration above which the polymer is decisive for the properties of the particle.
- Raise the permitted minimum concentration from 0.01% to 0.1%, analogously to PBT / vPvB substances.
- Bring the requirements of the restriction in such a shape that suitable measuring methods are available. This includes the concentration limit too.
- Water-soluble polymers should not fall under the restriction

2.4 Risk Assessment

According to Articles 68 and 69 of the REACH Regulation, it must be demonstrated for a restriction that

> *"placing on the market or use of a substance on its own, in a mixture of in an article pose a risk to human health or the environment that is not adequately controlled and needs to be addressed."*

No such demonstration is made. Quite the contrary, in its Annex XV dossier for a restriction of "intentionally added microplastics" ECHA concludes that

- the available information from scientific literature does not suggest that micro-plastics cause significant adverse impacts in the environment but rather shows that there is no risk;
- overall, no sufficient information is available on risk assessment; and
- the classic concept of bioaccumulation and biomagnification, established on a molecular level, may not be satisfied by polymer particles.

Thus, persistence is the only argument that remains for a risk which might arise in the future.

Consequently, the restriction proposal also stands in contradiction to the tenets that the European Commission lays down in its "Communication on the precautionary principle":

> *"Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection ."*
> [Source: English version, pages 9/10]

The alleged evidence submitted in the Annex XV dossier to substantiate the restriction proposed therein does not come up to the standard required in the European Union for applying the precautionary principle. Overall, the scientific findings presented in the Annex XV dossier are insufficient, incomplete and inconclusive.

For a restriction, moreover, the exact substance identity needs to be described and a risk assessment of the substances to be restricted has to be carried out on this basis. Here, not only hazard but also exposure must be taken into account.

As mentioned above, the ECHA Annex XV dossier only addresses polymers and microplastics in a general approach – even though the individual materials have very different properties and exposures. This is highlighted by the following examples:

- With the studies quoted in its scientific part, the Annex XV dossier points to the potential relation between microplastic and inflammatory reactions. However, the restriction also includes cases where a polymer would contribute to reducing or even preventing inflammation: For example, the coating of solid surfaces with water-soluble or swellable polymers is a way to suppress the foreign body reaction with which organisms typically respond to a penetration of solid particles. The foreign body reaction and the resulting inflammatory reactions are repeated quoted in the restriction proposal: as evidence of potential adverse effects of microplastic. But it is worth noting that a pigment with a surface modified by a water-soluble polymer will have a different effect than a hydrophobic polyethylene particle.
- It is also unclear what ecological relevance there is of where the particle is located in the polymer; whether it is a constituent of the surface coating or distributed in the whole particle. This is particularly incomprehensible for products that are not released to the environment in their form (e.g. coated tablets).

- As hazard and exposure are essential in the risk assessment, they must also be considered for the respective polymers impacted by the restriction. Since polymers are no homogeneous substance group, each polymer as such has to be examined individually:
  - For example, polyolefins and polyvinyl chlorides have different densities. Polyolefins are transported floating at the surface, while polyvinyl chlorides mostly sediment. This difference should have a major role in the risk assessment.
  - Short-chain polyolefins (especially polyethylene) are found all the more frequently in nature the lower the degree of polymerisation. They are also a component of natural waxes, e.g. on apples. A risk assessment must include the degree of polymerisation – ultra high-molecular polyethylene versus short-chain polyethylene wax.

Risk assessment of synthetic polymers and polymers occurring in nature – on the example of polyethylene:

The term “polymer”, which includes innumerable amounts of individual substances and chemicals – does not allow an appropriate risk assessment and justification for a restriction. This can be shown on the example of polyethylene:

Polyethylenes are a group of substances which differ in their molecular weight and distribution. They range from n-alkanes, paraffins and polyethylene waxes to polyethylenes. The scientifically correct term for polyethylene would be n-alkanes which, however, is often used only for short-chain substances of this substance class.

Short-chain n-alkanes with carbon chains up to the range of C30-C40 are found most commonly in nature. Enormous numbers of plants produce these substances as a kind of “natural packaging” for their leaves or fruits.

Plants rather tend to build odd-numbered chains; these can be understood as polyethylenes with a propylene end group. Microorganisms build an equal ratio of even and odd chains. The metabolisation by organisms of n-alkanes, paraffins and short-chain polyethylenes does not constitute a problem in nature and is a natural degradation process.

At a molar mass of ca. 500 Dalton, there is, for example, a C-chain with 36 carbon atoms. The physical-chemical properties of higher molecular, longer chain polyethylene waxes are only marginally different from natural waxes. In the range of ca. 500 molar mass units, the carbon chains are so long that they can endow the material – by way of internal knotting and looping – with a new, much greater mechanical strength. From this moment on, the polyethylenes, n-alkanes, become material-forming plastics. They are able to form mechanically stable articles such as cups and cup chairs etc. This is the field described with the term “plastic” and where this term is thus understood by the general public. A shoe wax is not understood as a plastic and, with its short-chain PE, it is not suitable for the manufacture of articles; chemically identical n-alkane obtained from plant leaves is not suitable for this either.

Aging and degradation are known for long-chain, material-forming polymers that form plastics. This is because of decades of stability studies (literature on the stability of

polyethylenes and other plastics has been extensively available for 40 years in magazines such as Polymer Degradation Stability). Such polyethylenes and plastics age under the influence of natural environmental conditions, sun and temperature. They lose their mechanical stability in the aging process. This loss in mechanical stability comes with a breaking of chains and a shortening of chain length. For polyethylenes with shorter chains, this breaking and the shortening of chain length lead to the formation of n-alkanes. In the course of degradation, the latter reach the range of alkanes that occur in nature and normally exist in the metabolism of organisms.

For the determination of risk as a basis for a restriction, therefore, the different chain ranges of polyethylenes have to be examined and it needs to be assessed how these substances are disintegrated in their use due to natural weathering and thereby returned into the cycle.

The same is true for polyethylene waxes: with their chain lengths they are very close to widespread, short-chain polyethylene, n-alkanes, occurring in nature.

The risk assessment needs to be adapted, given the same chemical structure, comparable reaction and chain cleavage through aging under natural conditions. For these substances, extreme persistence can be brought about only under very specific environmental conditions where also natural polymers (e.g. lignin, wood etc) last thousands of years.

Conclusion:

Overall, the ECHA Annex XV dossier constructs a merely fictitious risk that might possibly arise in the future. This is done by simply pointing to the "extreme persistence" of the particles – without having any indication of a real risk or without any sound reason for concern that can be derived after scientific risk assessment.

As the Annex XV dossier does not provide any justified reason for concern within an objective scientific risk assessment, the reproach of arbitrariness springs to mind. This is not acceptable as a REACH-conforming procedure, neither for industry nor for the public administration.

The risk assessment must be substance-related. The Annex XV dossier does not give a conclusive explanation of why the same ecological effect and the same risk should be expected from all polymers and microplastic materials covered by the restriction.

2.5 Efficacy, effectiveness and proportionality

Annex XV to the REACH Regulation prescribes that

> *"the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk."*

This requirement to the future restriction must be expounded in detail according to the ECHA Guidance for the preparation of an Annex XV dossier for restrictions.

The submitted Annex XV dossier for the restriction of "intentionally added microplastics" does not come up to this requirement.

The dossier itself states that, calculated by weight, the proposed restriction of "intentionally added microplastics" (covering 36,000 tonnes) would only correspond to 0.2% of the total of plastic waste that was disposed without proper control in the EU28+ in 2016.

A study mandated by the German Environment Agency (UBA) entitled *"Sources of microplastics relevant to marine protection in Germany"* arrives at the following estimates regarding primary and secondary microparticles from plastics:

> *"Fragmentation of plastic debris is the most significant source of secondary microplastics. While here, too, there is a lack of detailed information on the precise quantity of plastic debris entering the environment across Europe, as well as on the rate at which these give rise to secondary microplastics, rough estimates by the scientific community and the United Nations Environment Programme indicate non-negligible inputs from these sources. According to these estimates each year between 6 and 10% of global plastics production ends up as marine litter. For Europe, this is equivalent to 3.4 to 5.7 million tonnes."*

> *"In Germany, between 60,000 and 111,000 tonnes of microplastics are caused each year by abrasion of car tyres. The figure for Europe is between 375,000 and 693,750 tonnes. Thus the debate on microplastics cannot ignore car tyre abrasion as a source."*

Table 6 Sources of secondary microplastic in Germany and Europe (Source: Authors' own table)

Sources of secondary microplastic	Germany*	Europe*
Fragmentation of plastic debris	unknown	3,400,000 to 5,700,000
Tyre abrasion	60,000 to 111,000	375,000 to 693,750
Pellet loss	21,000 to 210,000	57,000 to 570,000
Shedding of synthetic fibres	80 to 400	500 to 2,500

* all figures in tonnes per year

Source: Nova Study for the UBA „Sources of microplastics relevant to marine protection in Germany" (p.34)

> *"The table shows that fragmentation of plastic debris is the main source of microplastics in terms of quantity, with tyre abrasion also playing a significant role."*

Even though the estimates in the ECHA Annex XV dossier und by the UBA, respectively, rely on different conditions, methods, source information and statistics, they concur in that the release of primary microplastics only accounts for a fraction of the total release.

Conclusion:

A restriction that reduces the total release of microplastics by only 0.2% while requiring much bureaucracy is neither efficient nor effective or proportionate.

2.6 Product restriction / Transitional periods

The wording in the existing draft for a restriction of microplastic gives rise to the danger of all polymer-containing products from the following fields being affected:

- Cosmetic products (“leave on” / “wash off”)
- Medical devices
- Encapsulated fragrances
- Detergents and cleaning products
- Fertilizers
- Plant protection products / biocides
- Food supplements
- All products that contain polymers and do not fall under one of the exemptions

Conclusion:

The title of the restriction and almost all statements in the dossier (e.g. on substance identity or risk assessment) suggest that this is a restriction for microplastics.

In fact, the proposed restriction addresses all polymers and practically all polymer-containing or polymer-coated materials. The requirements, definitions and the scope of the restriction are so complex and extensive that it is unclear and incomprehensible what exactly is to be covered.

Many industries only gradually realise that they are impacted. Therefore, a narrower and substance-specific definition is needed.

2.7 Labelling and reporting requirements

For products exempted from the restriction, inter alia,

- industrial use of microplastic or mixtures;
- medicinal products for human or veterinary use;
- substances or mixtures where the physical properties of the microplastic are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of a microplastic (e.g. soluble polymers);
- substances or mixtures where the microplastic is permanently incorporated into a solid matrix when used

a labelling requirement and an elaborate, bureaucratic requirement of annual reporting are planned for all downstream users who place these products on the market.

The labelling requirement includes, inter alia, products such as medicines for which comprehensive labelling rules are already in place *("Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.").* An additional labelling requirement under a REACH restriction would cause duplicate regulation and should be refrained from.

The same holds true for the labelling of food supplements which should remain governed by food law (Food Information Regulation and Directive on food additives).

Detergents and cleaning products – which contain e.g. dissolved dirt removal polymers, polycarboxylates, colour transfer inhibitors – would be affected too. Such polymers are usually added to mixtures as solids and only fall in the mixture under exemption 5b of the restriction proposal. It is not clear how instructions for use for soluble polymers would have to be worded to prevent their release into waste water. Therefore, soluble polymers in their entirety should be exempted from a restriction and labelling requirement, as they are not present in isolated form in the waste water and, consequently, do not contribute to a release of microplastic in the meaning of the restriction proposal.

Furthermore, the labelling requirement would also affect almost all manufacturers of paints, coatings and printing inks. This is about ca. 2.5 million tonnes of paints, coatings and printing inks in Germany alone. Manufacturers of paints, coatings and printing inks should be allowed to provide their own "instructions for use" in accordance with the specifications of the products. Labels for consumer products already contain instructions for proper disposal of liquid ink residues and empty containers. For professional users, the information on use and disposal is made available via the Technical Data Sheet or the Safety Data Sheet if necessary. Inks, varnishes and printing inks should be exempted from an additional labelling requirement.

The elaborate annual reporting requirement affects practically all downstream users who place a synthetic polymer on the market. Given the broad definition, this means an enormous bureaucratic effort. The whole supply chain would be impacted. As downstream users, both manufacturers and industrial users of paints, coating and printing inks would fall under the annual reporting requirement.

Conclusion:

For all polymer-containing products exempted from the restriction, detailed labelling and a comprehensive annual reporting requirement are to be introduced

through the proverbial backdoor. These obligations are to be met by all downstream users. There is no sufficient legal basis for such requirements.

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