AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Reflections on the ECHA draft restriction on intentionally added microplastics

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The American Chamber of Commerce to the EU (AmCham EU) has been actively engaged on microplastics, highlighting the need for a science-based and European approach to tackle this global issue. It is of upmost importance to protect the aquatic environment and support European, as well as global goals to significantly reduce the amount of plastic marine litter. In that respect, the European Commission's decision in the Plastics Strategy to address microplastics via the chemicals legislation framework and mandating the European Chemicals Agency (ECHA) to propose a draft restriction by January 2019 was warmly welcomed. Since the publication of the draft restriction proposal[1], AmCham EU has considered its content and implications very carefully and would like to highlight some concerns, reflections and comments.

Definition and scope

The definitions laid out in the draft restriction are broad and in their current state also encompass non-plastic substances. The proposal considers that almost all polymers (>1nm) are microplastics. However, *while all plastics are polymers, not all polymers are plastics*. The terminology should be refined to avoid confusion or disproportionate regulatory measures from being adopted that do not lead to any real benefit to the environment.

Similar issues pertain to the scope of the restriction, which can also be seen as too broad, unclear and even disproportionate. Instead of enforcing a restriction that covers all polymers and is then limited through definitions and derogations, the restriction should be precise, so as to only target materials and uses that result in a significant exposure and possible risks. The restriction should not be unreasonably wide with the intention of collecting additional data through reporting requirements on otherwise exempted products and uses. As it is now, the restriction will lead to uncertainty in the scope and the legal requirements.

One essential component that was left out altogether from the microplastics definition is the notion of solubility. This criterion is a key feature of existing EU and non-EU Member State legislation governing microplastics (including the EU Ecolabel) and the reasons for its removal from the ECHA restriction remains unclear. The annex claims that solubility can be understood very differently due to every polymer being soluble in one or more organic solvents. This however does not reflect natural conditions and for the purposes of this restriction solubility should be limited to water, including different salinities and different pH values.

Equally, the OECD 120 test method to determine the solution/extraction behaviour of polymers in water was wholly dismissed on the basis that it only provides experimental conditions but no methods to quantify the polymer. However, the OECD 120 test method does actually provide for a variety of analytical methods enabling the quantification of soluble polymers water[2]. Solubility is an important criterion for the definition of microplastics and needs to be reintroduced.

[1] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

[2] OECD Guidelines for the Testing of Chemicals, Test No. 120: Solution/Extraction Behaviour of Polymers in Water

The proposed definition of "solid" in the restriction is also broad i.e. not liquid and not gas and leaves unclear as to how to consider semi-solid materials. However, these substances (e.g. waxes) do not behave in the same way as solid plastic particles, nor do they share the same environmental fate. The restriction refers to a melting point and sets the cut-off at 20°C but some materials do not have precise melting points. The proposal should therefore more clearly exclude semi-solid materials from the scope of the restriction.

Unacceptable risk

AmCham believes that the proposed Restriction should comply with EU law and should not set a poor precedent. In this case, ECHA is itself the Annex XV dossier submitter and not a MSCA. Just as ECHA correctly demands REACH registrants to submit fully compliant REACH registration dossiers, it should abide to this standard and submit a robust, targeted, and fully justified Annex XV proposal.

A REACH Restriction can only be adopted where there is "*unacceptable risk*" (Article 68(1) REACH). However, the ECHA Annex XV dossier does not demonstrate or address "*unacceptable risk*", nor does it sufficiently establish that there is an unacceptable risk. The Annex XV dossier states that: "*microplastics are considered to be similar to PBT/vPvB substances*" and that "*any release to the environment [is] assumed to result in risk*", and, that the aim is to "*…minimise [all] releases of microplastics to the environment*".

The legal requirement for a REACH Restriction to be adopted is to establish unacceptable risk. The Annex XV dossier proposal and the risk assessment fail to clearly establish unacceptable risk, as is legally required. A proposed restriction cannot be regarded as proportionate if there is no established "*unacceptable risk*". While the core aim of the proposed restriction is to "minimise emissions", it should be to comply with EU law including the fundamental EU legal principle of proportionality.

Proportionality

Considering the elements above, it becomes even more critical to ensure that the microplastics restriction is proportional. Adequately weighing the proposed measures for the different substances against their environmental benefit and their broader socio-economic impact on the industry and the availability of safe/effective products for consumers, patients and other downstream users. For example, despite only representing 2% of the overall emissions of intentionally added microplastics to products, leave-on cosmetic producers will bear 79.3% of the costs of the restriction. The proposal equally affirms that 95% of the total restriction costs are linked to reformulation, 90% of which will affect cosmetic products. Unfortunately, these significant and very targeted costs will deliver very little benefits to the environment because the cosmetics sector is responsible for 0.3% to 0.5% of the *total* plastic marine litter[3].

Furthermore, the restriction proposal fails to adequately balance the socio-economic benefits of some of the products in scope against the restriction terms. Medicines and Medical Devices for example fall under the restriction and will be subject to labelling and reporting obligations within 12-18 months of

[3] Amec Foster Wheeler, "Intentionally added microplastics in products" (October 2017, produced for the European Commission, DG Environment).

the entry into force. While the restriction recognizes the societal benefits of these products, it ignores the burden that the proposes restriction will still impose on these highly regulated products. Particularly for Medical Devices, the short transition periods granted do not reflect the complexity of relabelling such products, nor do they consider the current implementation constraints of the Medical Devices Regulation. The proposed restriction will also have a major impact on the availability of sunscreens, which are essential healthcare products in the prevention of one of the most common forms of cancer, namely skin cancer[4].

The proportionality of the draft restriction is equally undermined by the assessment of the availability of alternatives across the product categories. In many cases, the evidence submitted by industry during the call for evidence has been disregarded, as some substances do not have suitable alternatives on the market yet and while others do, these are often dramatically more expensive and producers do not have the capacity to supply increased demand as a result of a restriction. Other available alternatives fail to meet performance, safety and environmental requirements and some substances cannot be one-to-one substituted, which mean profound increases in cost and lengthy reformulations. The draft restriction equally assumes that industry has the technical and financial capacity to reformulate many products at the same time (NB: the reformulations for some sectors will be in the 100s) and that it would not have to deviate funding from normal R&D activities and innovation. Some product lines could therefore be withdrawn entirely.

Moreover, the proposal makes sweeping assumptions regarding SMEs, in some cases affirming that the restriction might not impact them. In the cosmetics sector for example, ECHA has simply ignored the composition of the EU and National trade associations despite their substantial contribution (from an SME perspective) to the call for evidence.

Predictability and enforcement

The ECHA proposal also represents a shift away from restrictions that are focused on specific ingredients, their uses and the associated risks. Instead of targeting a precise list of substances like in other restrictions, the broad definitions and loose clarifications of what is covered or not, creates uncertainty and distorts legal clarity that industry needs before investing in alternatives. This also raises implementation and enforcement questions. If industry cannot understand whether the scope of a restriction applies to its own products, governmental agencies in different EU Member States could enforce the restriction differently.

Beyond this, the restriction dossier seems to suggest in various sections that the key element to carry out controls is labelling. ECHA affirms that the need to test for the presence of microplastics will be minimal as products can be enforced primarily via the information on the label. However, for cosmetics for example, the INCI lists (International Nomenclature Cosmetic Ingredient) on the products do not provide information on the physical state of the substance and whether it is being used as a solid particle. The stated enforcement costs of €55 000 per year therefore seem significantly underestimated, especially in the absence of standardised tests methods to detect microplastics in the various products targeted by this restriction.

[4] One in every three cancers diagnosed is a skin cancer (Skin Cancer Foundation Statistics)