Brussels, 17 May 2019

ECOS Position Paper for the Public consultation on the

ECHA Proposal for a Restriction on Intentionally Added Microplastics

General

In essence, ECOS welcomes ECHA`s proposal to restrict intentionally added microplastics in products. We are glad to see a general acknowledgement of the adverse effects of microplastics and a commitment to prevent their use in various sectors. At the same time, however, we believe the proposal can be strengthened in several aspects, most importantly the concentration limit of 0.01% w/w. This would still allow a certain amount of microplastics in products (to achieve their technical function). We believe this concentration is too high as it still represents millions of particles being added to products with the potential to end up in the environment. To really end microplastics pollution and give a clear signal to the market, we therefore propose a complete ban. This would push industries to search for natural solutions, that have already existed before the introduction of microplastics.
The rest of this document describes more elaborate feedback on the following aspects:

1. Definition
2. Biodegradability
3. Hazards by and exposure to microplastics
4. Transitional period
5. Exemptions

1. Definition

In the ECHA proposal, 'microplastic' is defined as 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" (Page 16, table 3, 2. and Page 29).
Table 3, 2d. also includes the concept of 'polymer-containing particle' which refers to "particles coated with polymers or whose composition has a polymer content of ≥ 1% w/w".

The main criterion used by ECHA to define microplastic is **size**, but in our view this is not sufficient. To exclude naturally occurring particles, the characteristic of synthetic (solid particles or polymeric matrix) should be added to the definition (as proposed by Frias and Nash, 2019[1]). Also, the distinction between primary or secondary origin should be explained, to acknowledge the fact that plastic materials tend to disintegrate into smaller particles. We do not propose to refer to the solubility of microplastics because chemical substances may then leach into the environment.

Based on the size range defined by ECHA, the proposed definition includes nanoplastics. Gigault et al., 2018 (https://doi.org/10.1016/j.envpol.2018.01.024) define “nanoplastics”, among other characteristics, as particles whose size varies between 1 nm and 1 µm.
A recent report from the Food and Agriculture Organization of the United Nations[2], define nanoplastics as “materials with at least one external dimension in the nanoscale, approximately in the region from 1 nanometre (nm) to 100 nm (EFSA, 2016).
As possible to see by both definitions, size is a matter of on-going debate, so therefore, the classification/concept/definition needs to have more parameters than solely size.

Paragraph 2d, should also fall into the category of paragraph 2a, to avoid misinterpretation or distinction between coated and uncoated particles. Still in this topic, and to address what is described in Paragraph 2d., ‘polymer-containing particle’, according to table 83 of the Annex to the Annex, this means that microplastics are ‘intentionally added’ to paints and coatings with functions other than film-forming. Therefore these ‘intentionally added’ microplastics should be list in the ingredients of such products.

Table 64, page 192, on functions provided by different types of polymers fails to include all ingredients described in Annex F., Appendix D.1 Table 88: List of polymers assumed to meet the microplastic definition. In this topic, similarly to allergens in food, it would be relevant if microplastics were marked bold in the ingredient list or chemical formulation of all products containing them.

Both documents should be revised to ensure consistency of definitions and other relevant information.

2. Biodegradability

ECOS does not agree with ECHA’s proposed exemption for polymers that are (bio)degradable. Biodegradable plastics are plastics still, and as a result, ECOS supports a comprehensive scope that is coherent with the objectives of the restriction proposal. There are no grounds for exempting such types of plastics as they can mostly be easily replaced with naturally occurring substitutes.

[1] “Microplastics are any synthetic solid particle or polymeric matrix, with regular or irregular shape and with size ranging from 1 µm to 5 mm, of either primary or secondary manufacturing origin, which are insoluble in water” https://doi.org/10.1016/j.marpolbul.2018.11.022
[2] http://www.fao.org/3/a-i7677e.pdf

The risk assessment criteria in section 1.4 of the Annex XV report and their subsequent application to biodegradable polymers outlined in section 2.2.1.6. wrongfully assume that polymers that are claimed to biodegrade will actually not persist in the environment. The reasons for this relate to the fact that biodegradable polymers are claimed as such by means of existing standards which, today, are not suitable nor ambitious enough to guarantee no biodegradable polymer fragments will persist in the environment.

Available standards cannot guarantee that a polymer intended to biodegrade in a specific environment will also biodegrade in another environmental compartment. Biodegradable polymers require a controlled fate in order to kickstart the expected biodegradation process and as a result, it is nearly impossible to manage the uncertainties related to their improper use and disposal. For example, a soil biodegradable polymer coating for a slow release fertiliser will only biodegrade in soil, it will not biodegrade in the expected manner in case it is blown away and ending up in another environmental matrix such as water.

Furthermore, currently available criteria are not ambitious enough to ensure no polymer fragments will persist in the environment. Available standards should urgently be made more stringent in order to ensure no adverse environmental effects are created as a result of the use of biodegradable polymers. In order to do so, a minimum biodegradation pass level of 90% should be introduced in all standard specifications, as well as a requirement for the separate testing of added constituents present in a proportion of 1-15%.

3. Hazards by and exposure to microplastics

Firstly, the *Scientific Advisory Mechanism* report of the European Commission on “Environmental and Health Risks of Microplastics Pollution” (SAM, 2019), defines hazard as “the intrinsic potential of a substance to cause harm to human health or the environment. Hazard does not necessarily imply that harm will occur: this depends on the risk, which is a product of both hazard and exposure.”

Hazard

The known impacts of microplastics in biota, reported at various levels of biological organisation, are summarised in the following figure (SAPEA, 2019).

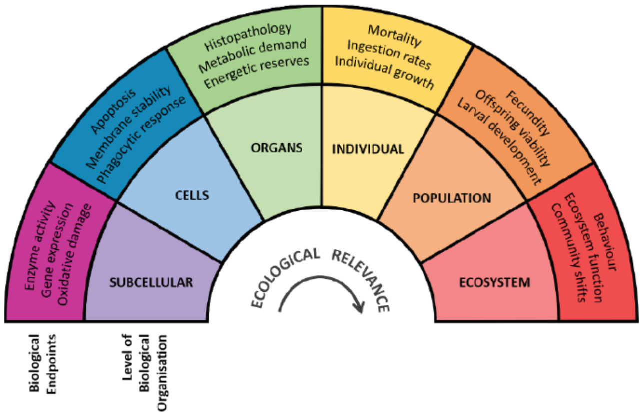

Figure 1 *– Impacts of nano and microplatics on biota reported at various levels of biological organisation (a biological endpoint is a marker of disease progression). Most studies have been at sub-organismal levels and studies at a community or ecological level are relatively sparse (SAPEA, 2019)*

In general, microplastics (and nanoplastics) can induce physical and chemical toxicity in terrestrial and marine biota, negatively affecting food consumption, growth, reproduction and survival across all population groups. Zooplankton, non-mollusk macroinvertebrates and juvenile fish appear to be especially sensitive.

Particularly problematic is the fact that microplastics adsorb persistent and bioaccumulative toxic substances (PBTC) such as persistent organic pollutants (POP), trace metals and bacteria (biofouling). The most common POP are polycyclic aromatic hydrocarbons (PAH), polychlorinated biphenyls (PCBs), Dichlorodiphenyltrichloroethane (DDT), nonylphenols, to name a few. The International Pellet Watch (IPW) project[3] produces worldwide maps of pollutants adsorbed to pellets, with their threshold levels, in an attempt to quantify risk areas for each group of PBTC.

Because microplastics adsorb PBTC from its surrounding environment, they represent multiple stressors whose synergistic interactions can significantly increase their impact on marine biota[4,5,6].

In the following paragraphs we would like to highlight a number of studies that give a good insight in the (potential) hazards posed by microplastics.

In the marine environment, microplastics can be ingested by a wide range of species from sea birds to fish[7], causing adverse effects such as internal blockages and disrupted digestion[8], biomagnification of harmful chemicals associated with plastics up the food web[9,10], and a growing list of sub-lethal

3 http://www.pelletwatch.org/maps/
4 https://dx.doi.org/10.1098/rstb.2008.0284
5 https://dx.doi.org/10.1038/srep14340
6 https://doi.org/10.1016/j.marpolbul.2010.10.009
7 www.grida.no/resources/6927
8 https://doi.org/10.1016/j.envpol.2013.02.031
9 https://doi.or/10.1016/j.envpol.2013.01.046
10 https://doi.org/10.1098/rstb.2008.0284

effects including morbidity[11], liver toxicity[12], endocrine disruption and neurotoxic effects[13].
Tanaka et al 2013[14] were the first to report bioaccumulation of polybrominated diphenyl ethers (PBDEs) in seabirds, showing that there is potential for those pollutants to accumulate in fatty tissues. A second study by Tanaka and Takada[15] in pelagic fish, identified microbeads for the first time. The authors state: "We investigated microplastics in the digestive tracts of 64 Japanese anchovy (*Engraulis japonicus*) sampled in Tokyo Bay. Plastic was detected in 49 out of 64 fish (77%), with 2.3 pieces on average and up to 15 pieces per individual. Eighty percent of the plastics ranged in size from 150 µm to 1000 µm, smaller than the reported size range of floating microplastics on the sea surface (...)."

Exposure

Exposure is largely determined by the occurrence of microplastics in our environment. Recent studies suggest that 5.25 trillion plastic items have accumulated in the oceans and will likely persist there for several decades[16,17,18] as a result of global single-use product consumption, poor waste management and insufficient recycling practices. It has been estimated that 10% of all plastics produced end up in oceans[19,20], comprising 60% - 80% of the marine litter[21]; and more recent estimates show that plastic is rapidly increasing in the open ocean[22,23].

Over two-thirds (by weight) of microplastic pollution comes from the break-up of large pieces of plastic litter[24]. The other third enters the environment already as microplastic, either intentionally produced (e.g. plastic pellets, *microplastics added to products*), or as a result of wear and tear during the normal life-cycle of plastic-containing products (e.g. synthetic textile fibres, tyre abrasion, automotive brakes, artificial turf, etc.).
Estimates of overall emissions from each of these sources vary but, by and large tyre abrasion and synthetic textile fibres represent two of the biggest proportions. City dust and plastic pellets also account for sizeable proportions, though with higher ranges of uncertainty. The estimated annual

[11] https://doi.org/10.1016/j.envpol.2013.12.020
[12] https://doi.org/10.1016/j.scitotenv.2014.06.051
[13] http://dx.doi.org/10.1016/j.ecolind.2013.06.019
[14] http://dx.doi.org/10.1016/j.marpolbul.2012.12.010
[15] http://dx.doi.org/10.1038/srep34351
[16] https://doi.org/10.1371/journal.pone.0111913
[17] https://doi.org/10.1371/journal.pone.0100289
[18] https://doi.org/10.1126/science.1260352
[19] http://www.grida.no/resources/6929
[20] https://doi.org/10.1126/science.1094559
[21] https://doi.org/10.1016/j.envres.2008.07.025
[22] https://doi.org/10.1073/pnas.1314705111
[23] https://doi.org/10.1038/s41598-018-22939-w
[24] https://www.iucn.org/content/primary-microplastics-oceans

release of microplastics intentionally added to products is 36,000 tonnes (ECHA, 2019) – similar to the estimated loss of plastic pellets (41,000 tonnes[25]).

Also, humans are exposed to microplastics. A recent study[26] lead by the team of Dr Phillipp Schwalb (Div. of Gastroenterology & Hepatolology, Dept. of Internal Medicine III, Medical University of Vienna, Austria) has identified microplastics in human stool (faeces) by assessing 8 individuals living in the following countries: United Kingdom, Netherlands, Italy, Austria, Poland, Finland, Russia and Japan. 100% of the individuals tested positive for microplastics in stool. Polypropylene (62.8%) and PET (17%) were the most frequent polymers found, although PS, PE, PC, PVC, PA and PU where also present. 3-7 different plastic types where collected in each sample.

Concluding remarks on hazard assessment

In general, our scientific understanding of the environmental and health effects by microplastics is still incomplete, being limited (amongst other factors) by sampling methods and ability to identify particles. Our current knowledge of environmental concentrations is thus likely to be an underestimate of the actual concentration, particularly when considering very small particles. Most laboratory studies have assessed the effects of microplastics on individuals rather than cells, organs or populations. All these uncertainties, however, do not undermine the intrinsic potential of microplastics to cause harm to living organisms, as described above. In our view, measures should therefore be based on the precautionary principle, addressing all potential sources of microplastics.

Intentionally added microplastics in products do not make up the largest source of microplastics but they still contribute significantly to the problem. And even though there is not yet conclusive (quantitative) evidence on the pathways through which intentionally added microplastics in products end up in the environment, we can assume a high likeliness that this occurs on a structural basis through inadequate waste(water) treatment. Particularly during and after application in agriculture and horticulture there are significant risks of dispersion into the surrounding environment.

Lastly, it is important to critically evaluate the scientific robustness and reliability of academic papers when talking about hazards and risk assessment. Section C of the Annex to the Annex lists a number of studies. However, the quality of some of the references can be questioned. Most notably, on page 59, the study by Auta *et al.* 2017*,* which uses as reference the 2016 paper from Lönnstedt and Eklöv, which was retracted from Nature for data forgery (https://www.nature.com/news/controversial-microplastics-study-to-be-retracted-1.21929).

[25] https://www.eunomia.co.uk/reports-tools/investigating-options-for-reducing-releases-in-the-aquatic-environment-of-microplastics-emitted-by-products/
[26] https://doi.org/10.13140/RG.2.2.16638.02884

4. Transitional period

Several transitional periods are suggested for different sectors. ECOS considers many of these too long and lenient, particularly given the global attention and concern relating to the eco-toxicological effects of (micro)plastics. Responsible product designers, developers and manufacturers will already have begun reflections and testing on product reformulation, particularly as a strong signal was already given by individual countries banning the use of microbeads in cosmetic products followed by the EU's agreed ban by 2020. If REACH is to be used as an effective market innovation tool, derogations and transitional periods should be ambitious.

Therefore, we propose the following changes:

- Rinse-off and leave-on cosmetic products: These should be subject to the same EiF period as the 2020 period for microbeads in cosmetic products, as reflection and testing would already be underway for the latter products;
- Controlled-release fertilisers: the 'relatively long' transitional period should be shortened to a maximum of 5 years, rather than the proposed 5-10 years, and this would also be in line with the transitional period proposed for 'Capsule suspension plant protection products and biocides';
- Detergents, waxes and polishes containing microplastics other than microbeads: the 2020 deadline should apply to these products as well, given that manufacturers of detergents and maintenance products are already reformulating products to end use of microbeads.

5. Exemptions

In our view, exemptions from the ban are not justified, except for polymers that occur in nature and microplastics that are essential and irreplaceable for vital medicinal products or medical and research purposes. The argumentation to exempt the use of microplastics at industrial sites and film-forming in paints, coatings, cosmetics is lacking and there is insufficient evidence that leakage to the environment can be prevented. We believe the ban should be applied as widely as possible, being a more consistent and effective approach.

Our concerns regarding biodegradable polymers have already been elaborated above. We foresee the exemption of microplastics that are "contained by technical means throughout their life-cycle" or "permanently incorporated into a solid matrix at the point of use" may become loopholes that companies use as an excuse to continue the application of microplastics. In practise, little is known about microplastics release from the principle matrix along the product lifecycle and there are often few guarantees that `technical means` are actually effective under different conditions.

Regarding the proposed derogations; it has to be noted that even though they might be subject to labelling and/or reporting, this does not necessarily always prevent leakage to the environment. Close monitoring is therefore recommended.