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Additional comments to RAC on the biodegradability exemption proposed in the restriction on intentionally added microplastics

Following the RAC-50 meeting, ClientEarth and ECOS would like to take this last opportunity to provide to the RAC additional comments on the biodegradability exemption.

The below information has been compiled with the technical support of Nike Mortier,[1] Study Director (Biodegradation, Composting & Ecotoxicity) at OWS, a company that has been, for more than 30 years, specialized in evaluating the end of life of biodegradable and compostable products (plastics, packaging, cosmetics, fertilizers, etc.) and is very active in the field of standardisation (on national, European, American and international level).

The ECHA proposal for restricting intentionally added microplastics includes a broad exemption for 'biodegradable' microplastics. As explained in our previous joint contribution to the public consultation and presentation made during the RAC-50 (available on CIRCA), **the biodegradability criteria proposed for the exemption are not adequate** to ensure microplastics are degraded in real conditions and in all environmental compartments. Such exemption would thus call into question the appropriateness of the restriction in reducing the risks assessed, risks detailed in the dossier at length. More research, work and consultation with independent researchers and experts is needed to define appropriate biodegradability criteria for microplastics.

For example, **key data is missing** in the current scientific literature to support the biodegradability criteria and tests currently available: there is a general assumption that what happens at 20°C (normal laboratory testing), happens at 12°C (average temperature in fresh/estuarine water, fresh/estuarine water sediment and soil). This assumption, to be reliable, needs to be backed-up by evidence. Currently there are no data analysing the relationship between the biodegradation rate at 20°C when compared to the biodegradation rate at 12°C (average temperature in fresh/estuarine water, fresh/estuarine water sediment and soil) or to the biodegradation rate at 9°C (average temperature for marine water and marine sediment).

That is why ClientEarth and ECOS consider that the most appropriate way forward for this restriction - to truly prevent emissions of microplastic persisting in the environment - is **no exemption for 'biodegradable' microplastic, at this stage**. No exemption today does not mean no exemption tomorrow for (truly) biodegradable microplastics. It is indeed possible to adopt a restriction and then review it to take into account new scientific developments, as highlighted by the Dossier Submitter in the proposal. Adopting the restriction with this exemption today would take away the incentive to improve the biodegradability criteria and tests. It will set in stone inadequate criteria with repercussions beyond the scope of this restriction.

[1] Nike Mortier participated to RAC-50 as ClientEarth's expert.

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We therefore invite RAC to conclude in its final opinion that the current state of science on biodegradability of microplastics does not support such an exemption to the restriction today. We strongly hope that RAC will consider following this recommendation.

If RAC were to decide to recommend maintaining an exemption based on biodegradability, ClientEarth and ECOS call for, **at the very least, addressing the obvious flaws in the current criteria**. The below table presents our recommendations to improve Table 21 of the restriction proposal entitled "Criteria for demonstrating the (bio)degradation of microplastics according to Paragraph 3b (APPENDIX X)".

In essence, since microplastics are most often mixtures of different polymers and other substances, **each polymer and substance of the microplastic should be evaluated separately on soil and water biodegradability (including in freshwater, marine water and sediment).** Subsequently, we invite RAC to recommend to replace the text in Table 21 of the restriction proposal by the following:

Taken into account that microplastics can be mixtures of different polymers and substances, each polymer and substance of the microplastic should be evaluated separately on biodegradability. The polymer/microplastic shall not contain additives that exceed a concentration limit of 0.1 % (w/w), which meet the criteria for PBT/vPvB set in REACH Regulation No 1907/2006 Annex XIII. A test material can be considered to be (bio)degradable, and therefore derogated from the restriction, if it meets the 'screening-tier' criteria described under elements 1 and 2, below. If the 'screening-tier' criteria described under elements 1 and 2 are fulfilled, the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments, so that it ultimately decomposes only into carbon dioxide, biomass and water. If the test material does not meet any of the criteria described under elements 1 and 2, further 'higher-tier' assessment (3) can be conducted to demonstrate (bio)degradability under relevant environmental conditions. The (bio)degradation potential of each polymer and substance included in the microplastic shall be demonstrated by the following: **Demonstrating (bio)degradability using screening criteria.** A test material can be considered to be (bio)degradable, and therefore derogated from the restriction, if it meets the 'screening-tier' criteria described under element 1 (biodegradation in water) and element 2 (biodegradation in soil), below. **1. Biodegradation in water** • Ultimate degradation of ≥ 90 % relative to the degradation of the reference material within 60 days in an aquatic test and 6 months in water/sediment interface tests and seawater tests.

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- Result shall be reported as the maximum level of biodegradation determined from the plateau phase of the biodegradation curve (or the highest value if the plateau has not been reached).
- Potential reference materials; micro-crystalline cellulose powder or ashless cellulose filters as positive controls and polyethylene (PE) or polystyrene (PS) as negative controls. The form, size and surface area of the reference material should be comparable to that of the test material.
- Permitted test methods:
    - Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium (EN ISO 14852:2018 or EN ISO 14851:2019), pre-adaption of the inoculum is not allowed.
    - Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sediment interface (EN ISO 19679:2016 or EN ISO 18830:2006), pre-adaption of the inoculum is not allowed.
    - Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in the Marine Environment by a Defined Microbial Consortium or Natural Sea Water Inoculum (ASTM D 6691: 2009)
- Test temperature marine biodegradation test methods: 15°C – 20°C

2. Biodegradation in soil

Bio(degradation) relative to a reference material

- Ultimate degradation of ≥ 90 % relative to the degradation of the reference material within 24 months in soil.
- Result shall be reported as the maximum level of biodegradation determined from the plateau phase of the biodegradation curve (or the highest value if the plateau has not been reached).
- Potential reference materials; micro-crystalline cellulose powder or ashless cellulose as positive controls and polyethylene (PE) or polystyrene (PS) as negative controls. The form, size and surface area of the reference material should be comparable to that of the test material.
- Permitted test method:
    - Ultimate aerobic biodegradability of plastic materials in soil (EN ISO 17556:2019), pre-adaption of the inoculum is not allowed.

Demonstrating (bio)degradability using higher tier assessment

Where higher tier tests are necessary, they shall be conducted under relevant environmental conditions. Relevant environmental compartments depend on the fate of the microplastic after use and could include fresh/estuarine water, fresh/estuarine water sediment, marine water, marine sediment, and soil as specified in corresponding testing guidelines. (Bio)degradability shall be demonstrated in water or sediment and in soil. Relevant test temperatures correspond to average temperatures in the EU and are 12 °C for fresh/estuarine water and fresh/estuarine water sediment and soil and 9 °C for marine water and marine sediment.

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Demonstrating (bio)degradability if microplastics are deliberately applied to soil or foliage

The screening criteria above (1 and 2) may also be used to assess the (bio)degradability of microplastics that are directly applied to soils, e.g. controlled release fertilising products.

The application period in soil may be taken into account when demonstrating the biodegradability of microplastics with direct soil application. The allowed time for reaching the screening criteria as specified in (2) for soil, ultimate degradation of 90 % relative to the degradation of the reference material within 24 months, may be extended by the application period in soil, but not to exceed 48 months in total.

Test material in (bio)degradation tests

The test material should be comparable to the microplastic on the market in terms of the composition, form, size, and surface area as these parameters have an influence on the (bio)degradation behaviour of the microplastics.

When the degradation is assessed in relation to a reference material, the form, size and surface area of the reference material should be comparable to that of the test material.

In case, test material is used as capsulation agent of organic materials, when performing the (bio)degradation test, the organic core should be replaced with an inert material such as glass if possible. Test material should be with comparable thickness to the produced microplastic coating.

Tests shall be conducted by laboratories accredited to ISO 17025.

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