To: Mrs Sharon McGuinness, Chair of the Management Board of ECHA

Cc: Mr Björn Hansen, Executive Director of ECHA
Mr Karmenu Vella, Member of the Commission - Environment, Maritime Affairs and Fisheries
Mr Kestutis Sadauskas, Director Dir B (DG Environment)

5 June 2018

Call for evidence on microplastics: concerns and recommendations

Dear Mrs McGuinness,

On behalf of ClientEarth, the European Environmental Bureau (EEB), the Health and Environment Alliance (HEAL), the International Chemical Secretariat (ChemSec), Women in Europe for a Common Future (WECF) and Greenpeace, we would like to raise our concern that ECHA will unduly limit the scope of upcoming restriction proposals, by taking on board industry concerns before RAC and SEAC are in a position to give their scientific opinions. This may ultimately make it more difficult for the Commission to adopt a restriction that would be broad enough to adequately control the risk.

In particular, we are concerned about ECHA's management of the call for evidence closed on 11 May 2018 relating to the potential restriction under REACH of microplastics intentionally added to products. During this call for evidence, we witnessed ECHA, in its external communication: (i) lacking the objectivity required by its role in the restriction process; (ii) misinterpreting the conditions that may justify the addition of derogations to the restriction.

We are concerned that the restriction of microplastics, long overdue, will be undermined by ECHA's current approach. It also shows that ECHA has not yet fully integrated the lessons

learned from the REACH review, which clearly identified the need to adopt a stricter approach to derogations requested by industry.[1]

We detail further below what ECHA should have done in the context of this call for evidence, what it did instead and how to break with this maladministration and misinterpretation of REACH in this case and in the future.

First, ECHA **lacked objectivity in the organisation of the call for evidence.**

ECHA is bound by the Code of Good Administrative Behaviour adopted by the Management Board in 2008,[2] and in particular:

> *"When taking decisions, the staff of the Agency shall strike a fair balance between the interests of private persons and the general public interest"* (Article 6 of the Code)
>
> *"When taking decisions, the staff shall take into consideration the relevant factors and give each of them its proper weight in the decision, whilst excluding any irrelevant element from consideration"* (Article 9 of the Code).

ECHA is also bound by REACH and by the EU Court's interpretation of this text. The Court of Justice made very clear that the "main purpose" of REACH is to ensure a high level of protection of human health and the environment.[3] This means that ECHA's priority should be to protect human health and the environment, not the financial results of businesses that have to comply with REACH. The implications of these obligations, in the context of the organisation of the call for evidence, is that **ECHA's priority should be to ensure that no risk is overlooked or underestimated**.

This is not what emerges from ECHA's communication. In the background document, it specified for example that: "*It is especially important for stakeholders to make us aware of the intentional use of microplastic particles in products that we have not mentioned above to prevent us from inadvertently restricting their use without considering the impact of this*."[4] By contrast, the importance of making ECHA aware of studies revealing or confirming the extent of the risks, in order to prevent ECHA from inadvertently *failing* to restrict some uses without considering the full extent of their potential harmful impact on public health and the environment, was not mentioned.

This excessive focus on protecting the interests of the industry, rather than human health and the environment, is confirmed by the 'list of information to be collected' as set by ECHA. In light of its obligations detailed above, ECHA **should have included in the list all necessary and relevant information listed under Annex XV**, including in particular, data on the **hazard and risk** for human health and the environment. What happened was quite different.

The background document called specifically, *inter alia*, for data on uses, alternatives and socio-economic impact, but not on the hazards and risks of microplastics. ECHA stated in this document that, even though it would accept information beyond this list, it planned to do its own research on the risks, hereby implicitly discouraging the submission of potentially relevant evidence showing that the risk is underestimated. ECHA also specified that, should anyone submit data on the risk anyway, it would be interested only in ongoing research that might be published during 2018-2019. Again, this sends the wrong signal to third parties, inviting them

[1] Action 8 (1) of the Communication of the Commission on the REACH evaluation
[2] Decision of the Management Board MB/11/2008 of 14 February 2008, amended by Decision MB/21/2013 of 20 June 2013.
[3] Case C-558/07, S.P.C.M and others, ECLI:EU:C:2009:430, para. 45.
[4] Background document available at: https://echa.europa.eu/documents/10162/d7237d21-0e0f-b32d-0fe7-5db3a4507d90

not to provide interesting data that could strengthen evidence on the risks. The Q&A document published in April continued to discourage stakeholders to provide evidence on the risks.[5]

We understand that to be able to build an Annex XV dossier, as requested by the Commission, ECHA might have focused on information that it considered was missing the most from the Commission's file. However, we do not understand why ECHA assumed, on the one hand, that it did not have sufficient evidence on the different uses of microplastics in products, and on the other hand, assumed that it was not going to learn more from third parties on the hazards and risks. This could indicate that ECHA considers that the dossier is already very strong on the risk side. But, even in that case, framing the call for evidence as it did raises serious concerns of objectivity and could lead to missing an opportunity to get new or confirmatory evidence on risk.

Second, in the call for evidence, **ECHA misinterprets REACH regarding the evidence needed to justify a derogation to the restriction, a misinterpretation that benefits industry**. In the Q&A in April, ECHA stated that: *"it is very important for us to obtain information on uses and alternatives early on in the process to avoid unintended consequences. It will help [ECHA] to ensure we exclude uses from the scope of any proposed restriction where risk cannot be demonstrated or where there are no technically or economically feasible alternatives.*"[6]

ECHA seems to suggest first, that when a "*risk cannot be demonstrated*" for a specific use of microplastics, a derogation is justified. However, when there is positive evidence showing an unacceptable risk arising from the general use of intentionally added microplastics, the existence of uncertainties, or lack of data on the risk arising specifically from a particular application of microplastics, is not an evidence of an absence of risk (or adequate control of the risk) for this specific application.[7]

ECHA needs to take into account the reminder given by the REACH review in relation to restrictions: the precautionary principle "*could be invoked by ECHA where there are indications of potential risks while the insufficiency of data, their inconclusive or imprecise nature makes it impossible to determine with sufficient certainty the risk in question*".[8] In the context of microplastics, for a derogation to be justified, the company would have to bring detailed, up-to-date and specific evidence proving that the risk is adequately controlled in its clearly defined use. However, the background documents do not explicitly require from stakeholders this information. This is despite Action 8 (1) of the Communication of the Commission on the REACH evaluation requiring from ECHA to "*Improve the restriction procedure*" by clarifying "*the information needed from the public consultations, including the minimum information to be submitted by industry when requesting derogations (time-limited or not) from restrictions*".

[5] See Question A.14 in Q&A available at: https://echa.europa.eu/documents/10162/09dbda4c-fcc9-4ede-0786-a13c6041ceec.
[6] See for example Question C.1 in Q&A available at: https://echa.europa.eu/documents/10162/09dbda4c-fcc9-4ede-0786-a13c6041ceec.
[7] See European Environment Agency, Late lessons from early warning (Volume I), chapter 5 p. 53, describing the "common fallacy" that "no evidence of harm" is the same as "evidence of no harm". This fallacy, according to Gee and Greenberg, "has inhibited the identification of many dangerous substances which were initially considered to be harmless ('false negatives')". It is surprising to see that ECHA, in 2018, still relies on this flawed reasoning.
[8] See Annex 4 to Staff Working Document p 111.

In addition, ECHA seems to consider that "*where there are no technically or economically feasible alternatives*",[9] a derogation is automatically justified. This interpretation of REACH is erroneous. Article 68 and its reference to Annex XV do require to "*take into account*" the availability of alternatives. However, it absolutely does not exclude the adoption of a restriction when there is no alternative, so long as the evidence shows that the risk identified is not adequately controlled. The existence/absence of alternatives is simply one of the factors covered by the assessment. ECHA should be careful not to confuse the conditions for rejecting an authorisation under Article 60 with the conditions for adopting a restriction under Article 68.

In light of all of this, we respectfully ask the Management Board to correct this maladministration and misinterpretation of REACH:

1. Regarding the microplastic dossier:

   a. In deciding whether to make a restriction proposal or not, and in shaping the scope of the restriction proposal, by **ensuring that ECHA gives "a proper weight" to the evidence showing risks** to human health and the environment versus other factors and does not require a higher level of proof to demonstrate a risk than to demonstrate the justification for a derogation.

   b. When the next public consultations open, by **clarifying publicly** that:

      - Evidence on the negative impact on human health and the environment are extremely important and relevant and should be submitted in the public consultation, so that the final restriction does not fail to protect human health and the environment due to an unduly limited scope;

      - Derogations can only be granted if there is *positive* scientific evidence (as opposed to absence of evidence) showing that the risk arising from the specific use/product is adequately controlled;

      - The absence of alternatives does not guarantee a specific use to be carved out of the scope of the restriction.

2. In all future restriction dossiers, ECHA needs to adopt an approach fit to meet the original expectations of the restriction process, which involve ensuring that no information on risk is overlooked and that derogations are considered *only* when the risk is proven to be adequately controlled.

Please note that this letter was sent in view of resolving the problem as early as possible in the microplastic file. Our objective is also to prevent similar problematic external communications and approach in future restriction files and in general in the implementation of REACH. If the Management Board does not provide us with tangible commitments, we reserve our right to contact the European Ombudsman within the meaning of Article 2 of its Statute.[10]

Yours sincerely,

[9] See for example Question C.1 in Q&A available at: https://echa.europa.eu/documents/10162/09dbda4c-fcc9-4ede-0786-a13c6041ceec.

[10] Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom) (OJ L 113, 4.5.1994, p. 15).

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