



Brussels, 16 December 2013

To: Geert Dancet, Executive Director, European Chemicals Agency (ECHA)

CC: Frank Büchler, Secretary to the Management Board & Inter-institutional Relations Coordinator, ECHA

Dear Mr. Dancet,

We, the undersigned environmental and health organizations, are writing to express our concerns about the current implementation of the REACH authorization process. During the last few months, ECHA has developed approaches and taken decisions that, we believe, are not in line with the aims of REACH or are not consistent with the REACH legal text.

Our concerns relate to the following five points:

1. ECHA has established standard review periods which are not consistent with REACH provisions.

ECHA has proposed standard review periods of 4, 7 and 12 years. In contrast, the REACH text (article 60.8) states that the review period should be *“determined on a case by case basis taking into account all relevant information ...”* Therefore, a case by case determination of review periods, as intended by REACH, would better target the respective needs and context.

Considering that SVHCs may have already been on the candidate list for 6 years before the manufacturer submits an application, plus the duration of the (post-application) authorization procedure itself (1.5 years), this basically permits identified SVHCs to remain on the market for 10-20 years. This time span provides only a very weak incentive for placing safer alternatives in the market.

2. There is no established procedure for reviewing authorizations when information on new substitutes becomes available as provided by REACH Art. 61.2

REACH foresees that authorisations may be reviewed at any time if a) the circumstances change and there may be a risk to human health and environment and b) if new information on possible substitutes

become available.

We have brought this issue to the attention of ECHA during several Risk Assessment Committee (RAC) meetings. Ensuring that an authorisation can be reviewed increases the possibility that the substance under review could be substituted as the applicant cannot dismiss the possibility of having their application reviewed. Moreover, companies producing substitutes would know that they still have a possibility to market their alternative. While on the surface this may seem to pose uncertainties for business. This ensures that they understand no advantage can be gained from procedural loopholes, and increases the incentive to research and develop of safer substitutes. Ensuring that a procedure is already established before such a case arises is in our view necessary.

3. Participation of observers during discussions of REACH applications at ECHA Committees has been restricted.

ECHA has decided not to allow observers to speak/participate during authorization discussions in the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) meetings. This decision undermines the participation of stakeholders in the authorization process. By denying stakeholders representatives the opportunity to express their views in the meetings of SEAC and RAC, ECHA promotes debate behind closed doors rather than allowing open and transparent debates during the plenary of the committees. We understand the difficulties of managing a potentially high number of interventions from observers be they NGOs, trade unions or industry associations, but suggest there are other ways to address this without categorically excluding observers.

4. ECHA accepts all confidentiality claims by the applicant

Despite a process involving all stakeholders to decide and agree on what information is useful for public consultations on authorisation; ECHA is accepting any claim of confidentiality in authorisation applications. As a consequence only meaningless exposure and risk information have been made public.

As an example, the total tonnage used in some of the applications for authorisation is confidential, so stakeholders wishing to contribute to the public consultation cannot make an informed choice on which applications are more relevant.

Furthermore, according to several SEAC members much information that should be in the public domain is being claimed as confidential despite the fact that ECHA's manual on confidentiality claims does not foresee this possibility.¹ As a result, relevant information is not accessible to third parties during the public consultation, hindering stakeholders' meaningful and effective participation in the authorization process. The European Environmental Bureau and ClientEarth have therefore submitted an access to documents request (reference ATD 54/2013), but has been informed that due to the high volume of documents ECHA will not be able to provide information within the deadline of the public consultation on alternatives. All information provided during the authorisation process should be made publicly available as it refers to substances of very high concern with wide dispersive use, produced in high volumes or with PBT/vBvP properties.

5. The quality of the applications for authorization is not adequate

ECHA is accepting applications where crucial information is missing as conforming to REACH

¹ ECHA-12-G-38-EN, Part 16 - Confidentiality Claims: How to make confidentiality claims, and how to write Art 119(2) confidentiality claim justifications

requirements. This is how applications for Bis(2-ethylhexyl) phthalate (DEHP) in consumer articles passed the conformity check despite the uses applied for are excessively broad and the scope unclear. What these applications are seeking is a general authorization rather than a use-specific authorisation.

Further concern was expressed in ECHA's scientific committee about the completeness of the information provided (e.g. the exposure scenarios are not relevant to the specific uses).

Since ECHA communicates with the applicant in pre-submission meetings, it should strive for meaningful and compliant applications for authorisation.

We believe these current approaches and decisions threaten to undermine REACH's goal of ensuring a high level of protection and of substituting Substances of Very High Concern (SVHC) with safer alternatives. Moreover, we foresee that unless action is taken on these points, future applicants will not treat the authorisation application as a serious process to document and judge the acceptability of the risks and the benefits from the use of substances of very high concern in the EU.

We call on you to address these points in order to ensure that the process is credible and the different stages of the authorisation process can be anticipated and effective stakeholder participation.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'J. Wates', written in a cursive style.

Jeremy Wates

Secretary General of the European Environmental Bureau (EEB)

On behalf of: ChemSec, ChemTrust, ClientEarth, EEB, Greenpeace, Health and Environment Alliance (HEAL), Health Care Without Harm (HCWH) and Women in Europe for a Common Future (WECF).