Helsinki 26 October 2012

ECHA response to the report from EEB and ClientEarth on the implementation of REACH

ECHA appreciates the interest shown by the EEB and ClientEarth in our work and their commitment to our shared ambition of making REACH a success. Both organisations are Accredited Stakeholder Organisations of ECHA and have been working with us – in the EEB's case, for over four years now – to help realise the legislation's ambitious aims and we value that contribution.

The report contains a number of critical statements, many of which are based on misunderstandings which could have been corrected had we had the opportunity to comment beforehand. We are correcting them here.

The report's recommendations come at an opportune time as we are hosting our regular Accredited Stakeholder Workshop to collect input for ECHA's five-year strategic programme. EEB and Client Earth are both invited. We are seeking the Stakeholders' input on the best ways to achieve the strategic objectives that were agreed with our Management Board earlier this year.

General misunderstandings

We agree that the implementation of REACH can be improved and have been open about the potential improvements on many occasions – see the formal reports on our website, in particular "*The Operation of REACH and CLP 2011"*[1]. Nevertheless, to categorise the undoubted achievements of companies, the European Commission, the Member States and ECHA in implementing REACH as a failure, paints a picture which the recent Commission funded report by Eurostat disproves ("*The REACH baseline study, 5 years update, 2012*"[2]). It demonstrates how far we have come on chemical safety in Europe in five years. We have the most ambitious chemicals legislation in the world; a unique database on chemicals and their impact on human health and the environment; an early substitution of some of the most toxic substances; and a chemicals industry galvanised to comply. We should all take pride in that – without in any way being complacent about REACH's imperfections or the amount of work that we still need to do.

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[1] http://echa.europa.eu/documents/10162/13634/operation_reach_clp_2011_en.pdf

[2] http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-12-024/EN/KS-RA-12-024-EN.PDF

The report misunderstands ECHA's legal role and responsibilities. For example, the legislation explicitly gives the power of enforcement to the Member States. The mandate and powers of ECHA have been precisely described in the legislation and cannot be altered without a change in that legislation. We must await the European Commission's review of REACH to see whether it will propose any such changes.

Finally, REACH is a shared responsibility. It is a dynamic vehicle, with many moving parts, each playing a crucial role if the vehicle is to reach cruising speed. As the engine or driving force of the vehicle, ECHA certainly plays a vital part, but equally so do the European Commission, the Member States, industry and other stakeholders including NGOs like EEB and ClientEarth. There is not a single regulatory process in REACH (registration, evaluation, risk management) that does not require the contribution of the key players. To speak of any of the players as a bottleneck is to misunderstand the cooperative processes of REACH.

Registration

ECHA receives tens of thousands of dossiers containing up to 15,000 fields of information on substances and their impact on human health and the environment. The first thing we do is an automated completeness check. This check is done on every single dossier which arrives and, as the name suggests, it is to check that everything which REACH requires to be present in the dossier, is actually there or, as foreseen in REACH, contains a justification explaining a deviation from the standard information requirements. REACH specifically prescribes that it is not a check of the quality of the information provided nor is it a check of its adequacy. A registration number is only given when a full dossier has been provided.

The report praises ECHA's approach to intermediates. The information requirements are much lower for such substances and therefore, an incorrectly registered intermediate could be a cause for serious concern. We have actually gone much further than the report suggests. We are currently following up each and every one of the more than 2,000 cases where substances appear to be incorrectly registered as intermediates, to require companies to either provide proper justification for their registration as an intermediate, or else to complete a full registration dossier.

Evaluation

After the completeness check comes the compliance check. As the name suggests, this is much more detailed, done by scientists, to verify that the information provided is in compliance with the law in terms of its quality and adequacy. Where we find that a dossier contains information of a poor quality as part of our compliance check, the registrant will be legally obliged by us to improve it. REACH sets a minimum level of 5% of dossiers to be compliance checked. There is no legal timeline for achieving this minimum target. However, we have committed ourselves to reaching it by the end of 2013 -

for the dossiers submitted for the 2010 deadline, meaning a total of 1,000 dossiers. In order to enhance the probability of picking up poor quality dossiers, we also systematically screen and target compliance checks on those issues in dossiers that matter most for their safe use. This strategy was agreed with Member States and the European Commission and already includes a number of the recommendations made in the report.

Imprecise substance identity is an issue which ECHA has highlighted repeatedly in the Annual Evaluation Reports, available online[3]. Precise substance identity is indeed the basis for the formation of Substance Information Exchange Forums (SIEFs), data sharing and joint submission obligations as well as for all subsequent processes under REACH. The main ambiguities on substance identification concern UVCB substances[4], which represent 30% of all registered substances. These substances are, by their nature, complex and decision making on them is not straight forward. ECHA's targeted compliance checks look at substance identity and if we remain unable to understand what the substance is, the registration will be confirmed as invalid, leading *de facto* to the revocation of the registration number.

Generation of information

ECHA has published two databases on chemicals: the classification & labelling inventory with 5.3 million notifications, and the database of registered substances containing information on over 27,000 registrations. They are the largest chemical databases of their kind in the world and among the most visited parts of ECHA's website. The data ECHA disseminates under REACH and CLP is on individual chemical substances as defined by the legislation and not on end-user products. We agree that this is very technical in nature and would be more useful for citizens if linked to products that we use every day. We are unable to do that because we simply do not have the necessary information. That said, we have started to collect the views of stakeholders on how best to restructure the databases to try to make them more user friendly.

We are fully in line with the provisions of the Access to Documents (ATD) Regulation and the Aarhus Implementing Regulation. In the last 18 months, ECHA has processed over 100 requests, 95% of which have been responded to within the legal timeline. In the few remaining cases, because of the need to consult the data owner in line with the legislation, we have taken more time, as foreseen in the ATD Regulation and in agreement with the requester.

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[3] http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports

[4] Substances of unknown or variable composition, complex reaction products or biological materials.

Authorisations

The Member States and the Commission - not the Agency - have the right to initiate the regulatory risk management processes of authorisation, restriction and harmonised classification. Nevertheless, ECHA supports them in this process and is devoting considerable resource to risk management.

ECHA has contributed substantially to the EU goal of having all relevant SVHCs[5] included in the Candidate List by 2020 and resources have not been a limiting factor in this. We are stimulating the substitution of SVHCs by pushing for more and better notifications of these substances in articles and by assisting the Commission in finding suitable substances for the Candidate List. Of course, inclusion in the Candidate List is only one of the risk management tools available to ensure that identified concerns are properly addressed. The RMO (risk management options) approach ECHA uses was agreed with Member States and the Commission.

ECHA's committees

The provisions of REACH are underpinned by the precautionary principle and hence, it is integrated in the legislation as a whole. Policy principles do not play a role in decision making in ECHA's scientific committees. Their role is to provide science-based opinions for the European Commission. RAC and SEAC have so far produced opinions on five restriction proposals and RAC on 59 proposals for harmonised classification and labelling, in almost all cases by consensus. These opinions have provided a scientifically robust, consistent and transparently documented basis for the Commission's regulatory decision making, and are accelerating the introduction of risk management measures.

ECHA's transparency and independence

ECHA has made transparency one of our founding values and we have worked hard to bring that about. We believe that ECHA is one of the most open legislative bodies in Europe - we have interested parties represented in our Management Board; we invite observers from Accredited Stakeholder Organisations to participate in all our committee meetings and to discuss strategic issues in workshops with us; we organise stakeholder days open to all; we hold public consultations; and we publish our policies and procedures online[6]. We are also about to start publishing ECHA's decisions that are addressed to registrants. We are not complacent in making this claim of transparency. We constantly challenge ourselves to be more transparent but there is always a balance to be struck between transparency and the rights of individuals and companies for confidentiality where the law demands it.

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[5] Substances of Very High Concern

[6] http://echa.europa.eu/about-us/the-way-we-work

We agree with the authors' comment on the need for ECHA to remain independent. The independence of ECHA's decision making is of the greatest importance to us and it has been a priority from the outset. One of the first decisions of ECHA's Management Board in 2008 was to adopt guidelines for the prevention of conflicts of interest. Those guidelines have been further developed and are applicable to all staff and committee members. We publish the declaration of interest of all managers, Board and committee members and chairs. Recently, new eligibility criteria were adopted for the members of committees, the Executive Director, the Accounting Officer and the members of the Board of Appeal. All of these documents are available on our website and the Management Board discussions are recorded in the meeting minutes, also online[7].

In terms of recruitment, ECHA recruits the most highly qualified experts we can for every position offered and subsequently manages any potential conflicts of interest as described above.

[7] http://echa.europa.eu/web/guest/about-us/the-way-we-work/procedures-and-policies/conflicts-of-interest