IDENTIFYING THE BOTTLENECKS IN REACH IMPLEMENTATION

The role of ECHA in REACH's failing implementation

PUBLISHED BY EEB & CLIENTEARTH **OCTOBER 2012**

ClientEarth

EUROPEAN ENVIRONMENTAL BUREAU

About EEB & ClientEarth

The European Environmental Bureau (EEB) is a federation of over 140 environmental citizens' organisations based in most EU Member States, most candidate and potential candidate countries as well as in a few neighbouring countries. These organisations range from local and national, to European and international. The EEB's aim is to protect and improve the environment by influencing EU policy, promoting sustainable development objectives and ensuring that Europe's citizens can play a part in achieving these goals. The EEB stands for environmental justice and participatory democracy. Our office in Brussels was established in 1974 to provide a focal point for our members to monitor and respond to the EU's emerging environmental policy.

www.eeb.org

ClientEarth is an organisation of activist lawyers committed to securing a healthy planet. We work in Europe and beyond, bringing together law, science and policy to create pragmatic solutions to key environmental challenges.

www.clientearth.org

EUROPEAN ENVIRONMENTAL BUREAU

ClientEarth

EEB October 2012

Publisher EUROPEAN ENVIRONMENTAL BUREAU (EEB)
Boulevard de Waterloo 34,
B-1000 Brussels, Belgium
Tel +32 2 289 1090 Fax +32 2 289 1099
E-mail eeb@eeb.org
www.eeb.org

Authors: Christian Schaible & Vito Buonsante with thanks to Tatiana Santos, Tony Tweedale & Rosemary Simpson

Editor responsible: Jeremy Wates (EEB Secretary General)

Editing and Design: Arc Communications

The EEB gratefully acknowledges financial support from the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Danish Ministry of the Environment and the European Commission.

The sole responsibility for the content of this document lies with the EEB & ClientEarth. This publication reflects the authors' views and does not commit the donors.

Contents

Foreword

REACH - for years that abbreviation absorbed more of my time than any other dossier. Every single Article and Annex was discussed and negotiated. While it was triggered by major concerns about an inadequate level of protection of human health and the environment from dangerous chemicals, others were more concerned about alleged impacts on competitiveness. It turned into a tug of war.

Many claims were made about REACH: about what it would or would not deliver, about wanted and unwanted impacts. More than five years after the entry into force, it is appropriate to assess where we stand now.

According to its own mission, the European Chemicals Agency (ECHA) "is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation". It is thus most relevant to have a close look at the work of the Agency over the last years, as was done in this report. This assessment by the NGOs is all the more relevant as according to REACH, "the Agency should be central to ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public".

I cannot judge whether all the points made by the NGOs are fully justified but this study certainly contains many useful observations and constructive criticism is a necessary tool for improvement. This study, in combination with the official PWC-study, provides many thoughts on how to improve ECHA and the implementation of REACH.

For years we had a policy of "market first and let us see what happens" but with REACH we now have "no data, no market". ECHA plays a key role in ensuring the proper application of this by making a completeness check of every registration dossier. I find it very worrying to hear that ECHA does not check the relevance of the data provided by industry as part of the completeness check. This undermines this principle.

I am even more concerned about the poor quality of many registration dossiers, even though ECHA has acted against the attempts by industry to escape proper registrations by unduly claiming that their substance would be an intermediate. I am looking forward to similarly determined action by ECHA to ensure that registrations comply with the requirements of REACH. An important element in that is to strengthen cooperation with national authorities who are able to give worst offenders hefty fines.

It is always difficult to break away from the social logic that the people you spend most time with are not always the ones needing you the most. ECHA spends a lot of time with chemical companies, and rightly so. However, as a public agency its primary "client" is society at large. REACH was not created to please the chemical industry, but to protect human health and the environment from dangerous chemicals.

The chemicals producing companies fought REACH until the bitter end, and continue to try to make REACH less useful than it could and should be. While they also stand to win from proper chemical regulation, they all too often continue to defend their old habits. It is thus important that ECHA involves and enables civil society more to play its role to get REACH up to cruising speed.

In that context, transparency is crucial both to show to which extent REACH works and for ECHA to prove that the general public and interested parties can be confident in REACH. Transparency also means that an average person must be able to make use of the data provided: it should be easy to see which chemicals are in which products, what are their properties, and how one should use them and protect oneself against any unwanted effects. This is especially the case for the substances of very high concern (SVHC), for which consumers also have a right to know. It would be particularly useful - both for manufacturers, downstream users as well as consumers - if the information that is publicly available on the internet could be also shaped to give examples of chemicals that can substitute dangerous substances, in particular SVHC.

As a public agency ECHA's mission includes the need to provide information on chemicals and address chemicals of concern. It should therefore welcome requests for access to documents as a confirmation of public interest in its work, rather than seeing such requests as a nuisance. REACH would be completely meaningless if the Agency were to function merely as a central storage-place for confidential business information with no public access.

We also need to improve cost-benefit studies so that equal weight is put on both sides of the equation.

Finally, my constant concern that lobbyists become too powerful is again highlighted in this report. It is important to avoid revolving doors, and make sure significant cooling-off periods are used.

ECHA has a bold vision: it aspires to become the world's leading regulatory authority on the safety of chemicals. By carefully taking into account the recommendations from the official evaluation by PWC as well as those of this shadow report by the NGOs, ECHA should get a boost towards realising its vision.

Too often we adopt laws and leave them to their destiny. This evaluation report is an outstanding achievement and a brilliant eception to the rule of forgotten EU laws. It shows that civil society is committed not to forget about the deliverables we expect from REACH and ECHA. Together we can make REACH work.

Carl Schlyter

Member of the European Parliament,
Vice-Chair of the Environment Committee

Executive summary

REACH brought a paradigm shift in the way chemicals are regulated in the EU. The responsibility of public administrations for assessing the properties and risks related to the use of a substance has been switched to the commercial operators who must demonstrate that any substance they place on the market is safe and provide all the evidence for it. The European Chemicals Agency, created under REACH Article 75, plays a central role ensuring that REACH objectives are met and was established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects. ECHA has been subject to a review that should have been published by 1 June 2012. At the time of the publication of this report, the results are not available for the public. [1]

This report is by the EEB and ClientEarth who have invested significant efforts into following REACH implementation. It provides a complementary assessment of the bottlenecks in the implementation that contribute to the failure or success of REACH, focusing in particular on the role of ECHA.

Methodological aspects

For this assessment we have used publicly available information on the ECHA website (e.g. reports, work programmes, statistics, minutes of ECHA's Committees and Management Board meetings), publicly available European Commission documents, information extracted from certain CARACAL meetings as well as other publicly available information (e.g. positions and publications by industry and NGO stakeholders, occasionally press articles from ChemicalWatch). We also used information generated through access to document requests by the EEB and ClientEarth, and information obtained through oral communications with key players in institutions and industry. The report is based on information collected until July 2012. However, the report also addresses the recent developments related to the candidate list

When assessing ECHA's role in the first five years of implementation of REACH, the following two indicators were used to assess ECHA's performance: first, the primary objectives of REACH and, second, ECHA's own values. Regarding the objectives of REACH, the following were taken into account:

- A high level of environmental and health protection
- Substitution of hazardous chemicals (as a driver for "innovation")
- A precautionary approach in the decision-making

We then assessed ECHA's work performance against its own stated values: [2]

- Transparency [3]
- Independence [4]
- Trustworthiness [5]
- Efficiency [6]
- Commitment to well-being [7]

1 ECHA's official review was not released to the public at the time of publication of this report.

2 http://echa.europa.eu/about-us/who-we-are/values.

3 ECHA describes itself as transparent stating "We are open and transparent in our actions and decision-making. We are easy to understand and to approach".

4 ECHA describes itself as Independent stating " We are independent from all external interests and impartial in our decision making. We consult members of the public openly before taking many of our decisions."

5 ECHA describes itself as Trustworthy stating "Our decisions are science based, consistent and impartial. Accountability and the security of confidential information are cornerstones of all our actions."

6 ECHA describes itself as Efficient stating: "We are goal-oriented, committed and we always seek to use resources wisely. We apply high quality standards and respect deadlines."

7 ECHA describes itself as 'Committed to well-being', stating " We stimulate the safe and sustainable use of chemicals to improve the quality of life of all citizens in Europe and the environment."

In support of this assessment, an in-depth Registration Audit, was carried out by ISTAS[8] and RISK.[9] which analysed information on substances published by ECHA in order to assess the reliability and compliance of the information provided by registrants. The 40 substances selected for the Registration Audit are those identified on the S.I.N. List (ChemSec's Substitute it Now!) with endocrine disrupting as well as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties. The assessment has been carried out on the basis of information made available in ECHA's dissemination portal on registered substances and ECHA's Classification and Labelling (C&L) inventory[10], between the period end-2011 until mid-March 2012. The information elements which have been audited refer to classification issues,derived safe exposure thresholds compared with occupational exposure limits, safe use comments, endocrine disruption and overall quantity and quality of submitted toxicity data. Updates in the database after the 1st June 2012 have not been taken into account.

Main findings of the review

ECHA was set up in a relatively small amount of time and had to deal almost immediately with enormous tasks such as managing pre-registration. ECHA's management did exceptionally well in setting up the Agency, employing and training about 500 people. Further it ensured that the administrative obligations for industry were met. That said, ECHA has taken a number of decisions that have seriously undermined its own ability to achieve REACH objectives. It has chosen to effectively support industry efforts to withhold data and to limit the transparency of REACH processes, thus making it more difficult for NGOs to participate in the implementation of REACH, reinforcing the perception of an Agency lacking independence from the chemical industry. The following findings are presented section by section in this report.

8 Spanish Trade Union's Institute (Instituto Sindical de Trabajo, Ambiente y Salud).

9 Rebutting Industry Science with Knowledge Consultancy.

10 http://Echa.europa.eu.

Registration

ECHA has to guarantee that the underlying principles of REACH - "no data, no market" and "one substance, one registration" - are respected. The industry has attempted to undermine the REACH system in a number of ways: giving an unclear identification to a substance so that several substances can be registered under one dossier (with a considerable saving in costs); unduly claiming that the substance is an intermediate (as the information requirements are simplified), and submitting very poor quality dossiers including irrelevant information or empty fields which are not compliant with REACH requirements. Faced with this, ECHA decided to grant registration numbers nonetheless. As a result, numerous substances for which essential information is missing continue to be marketed and used in the EU.

Worse, the lack of data has made it harder for ECHA to take decisions on restrictions and authorisation later in the process. ECHA should ensure pre-emptive measures to prevent the granting of registration numbers to incompliant dossiers by checking (as far as possible) the relevance of the information submitted through strengthening completeness checks. Further it should review the identity of the substances to be registered for the upcoming registration deadlines for phase-in substances. Finally, ECHA should verify compliance with REACH information requirements and pro-actively disseminate information on chemicals in order to guarantee public scrutiny.

Generation of information

ECHA has failed to recognise the importance of generating and making available information to the public as a primary goal of REACH. Its contribution to raising the awareness of the public on risks and hazards of chemicals on the market has been marginal. ECHA's dissemination portal is not useful for consumers or civil society to make informed decisions about their use of chemicals and get a clear understanding of ECHA's processes and decisions. Further, ECHA has invested considerable efforts in making it harder for civil society to obtain access to information through requests based on Regulation 1049/2001, in some cases failing to meet deadlines set by law. ECHA should review its transparency policy based on Article 109 which as it stands does not give any information on what information may be considered confidential and ensure that the policy as well as the related practices are fully compliant with Regulation 1367/2006 and the Aarhus Convention. A road map to make decisions consistent and transparent should be elaborated with the cooperation of all stakeholders.

Findings from the Registration Audit

Since ECHA has provided a registration number for the audited substances, one should be able to conclude that ECHA considers that those registrations have satisfied the "no data, no market" principle and that the information provided is complete. The main finding of the registration audit is that most of the analysed dossiers have serious compliance deficiencies. 28 out of the 40 SIN SVHC reviewed have some type of classification and labelling shortcoming such as missing, incorrect or incomplete classification. Diethyl phthalate and Benzophenone had no toxicological information at all and were not classified[11]. For 10 substances the calculated DNEL values are higher (less protective) than known and enforceable OELs.

European legislation provides a hierarchy of measures to prevent or reduce the exposure of workers to dangerous substances. In most cases the registrants had only proposed personal protective equipments (PPE) as the main risk management measure to be applied.

In regards to "safe use comments", seven registrations have suggested too general, confusing measures or insufficient statements such as "no special precautions necessary if used correctly". One dossier is unreadable due to an internal mistake.

Despite the fact that REACH requires registrants to gather all available test data on the substance to be registered, which also includes a literature search for relevant information on that substance, only two of the 40 audited substances (registration dossiers) submitted contain substantially more than the number of published toxicity studies identified for the specific substance through search in PubMed. Many of the toxicity studies submitted by the registrant are "grey literature" - non peer-reviewed industry or government studies. For 18 chemicals listed for being known or suspected endocrine disrupting chemicals (EDCs), the submitted study summaries relating to endocrine disrupting (ED) endpoints have been reviewed, in particular, looking for ED related toxicity findings. Only one gave an incidental mention of ED activity and two out of the 19 SIN List EDCs audited submitted also a few background studies used by ChemSec to establish endocrine disrupting properties.

11 by mid-March 2012.

Evaluation

ECHA has made little effort in the evaluation of registration dossiers. Most importantly, it restricts its powers to require registrants to update their dossiers by giving a limited interpretation of the scope of Article 41. Instead of using its power provided by law, for several points of non-compliance to ensure the safety of chemicals for european citizens, ECHA merely requestsvoluntary improvement of the dossiers (through QOBLs). ECHA should exercise the full powers provided to it by REACH and its compliance check decisions should require companies to correct and bring their dossiers in compliance. Further, ECHA should coordinate its efforts with enforcement authorities in case of non-compliance by companies and start to publish all its draft decisions and QOBLs or at least a list thereof, including the names of the substances and the identity of the companies. ECHA has undertaken useful coordination and prioritisation tasks in setting the Community Rolling Action Plan (CoRAP) but should identify and overcome bottlenecks within Member State reluctance to carry out the job. The annual evaluation rate of the CoRAP should be increased by a factor of three to cover a minimum of 95 substances per year, in order to reach the Commission's target to include roughly 950 substances to be evaluated over a period of ten years between 2012 and 2021.

Authorisations and Restrictions

ECHA has not prioritised REACH's objective of substitution and thus dedicated a limited amount of resources to the development of the Candidate List and to restrictions. By limiting its resources to developing only five SVHC dossiers per year, ECHA undermines the Commission's goal to include all known SVHCs by 2020. Indeed, Member States also have their share of responsibilities. Countries like Italy and the United Kingdom, who have among the biggest chemical industries in the EU, have provided little to no contribution to the substitution objective of REACH. On the other hand, countries with a relatively small chemical industry such as Austria, Denmark and Sweden have made good efforts. France and Germany have been the biggest promoters of the candidate list, however further resources should be dedicated to the development of the candidate list and to restrictions. It follows that, given the limited resources of most of Member States to submit Annex XV dossiers, the simplified procedure for the identification of SVHC should be considered in order to increase the efficiency of nomination[12]. Further, the Risk Management Options (RMO) analysis should be moved to the prioritisation phase only, where substances with high volumes, wide dispersive use or PBT/vPvB properties would normally be prioritised for listing within Annex XIV.

12 At the time of finalising this report the Commission requested ECHA to complete 38 Annex XV dossiers in order to REACH the goal of including 136 substances in the candidate list by the end of 2012.

ECHA's governance bodies and Committees

Overall, the performance of ECHA's governance bodies and committees varies. On the one hand, the Member States Committee (MSC), the Management Board and the Forum have provided positive inputs in addressing the challenges that a regulation like REACH presents. On the other hand, the Risk Assessment Committee (RAC) and to a limited extent the Committee for Socio Economic Assessment (SEAC) have ignored REACH's mandate to apply a precautionary approach in protecting human health and the environment and got stuck in the pre-REACH "paralysis by analysis" non-decision-making which only benefits the less responsible elements in the chemical industry. RAC and SEAC have set the bar so high that it is even more difficult to restrict a substance than it was before REACH. Indeed, who benefits from the uncertainty against restrictions game is the industry which is even less motivated to submit reliable information on hazards and risks. SEAC and RAC have not implemented the "reversal of burden of proof objective" of REACH in their decision-making process. From what we have observed so far it seems that RAC and SEAC members have a limited understanding about the approaches and objectives of REACH, and the underpinning of the precautionary principle.

The participation of stakeholders has been guaranteed in all bodies to a certain extent, however decisions on what meetings and documents are of a confidential nature has often been arbitrary.

ECHA's independence

ECHA is an institution dedicated to highlighting hazards and risks of chemicals and to manage the process of their phase-out and restriction. For this reason ECHA should be extremely careful in its recruitment process and in appointing members for its committees proposed by Member States and avoid appointing people who are likely to have a strong bias towards the chemical industry, in particular lobbyists. However it is the responsibility of Member States to be vigilant since it is they who propose candidates. Further ECHA, and in particular its executive director, should balance its approach towards public interest versus private interest stakeholders as it is perceived by many as an institution strongly biased towards industry.

Acronyms

ATD	Access To Document request, see section 2.4
BoA	The Board of Appeal of the European Chemicals Agency
CA	Competent Authority
CARACAL	Competent Authorities for REACH and CLP
CBI	Confidential Business Information
C&L	Classification and Labelling
CLH	Harmonised Classification and Labelling
CLP	Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, OJEU L 353 of 31.12.2008;
CMR	Carcinogens, Mutagens and Reprotoxicants
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DG	Directorate General of the European Commission
ECHA	The European Chemicals Agency
EDC	Endocrine Disrupting Chemical
EEB	European Environmental Bureau
ID	Identification, Identity of a substance
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
ISTAS	Instituto Sindical de Trabajo, Ambiente y Salud (Spanish trade union research institute)
MB	Management Board of the European Chemicals Agency
MSC	The Member State Committee of the European Chemicals Agency
MSCA	Member State Competent Authority
NGO	Non-Governmental Organisation
PBT	Persistent, Bioaccumulative and Toxic substance in accordance with the criteria set out in Annex XIII, REACH
PPORD	Process Orientated Research and Development as defined according to Art. 3(22) of REACH
RAC	The Risk Assessment Committee of the European Chemicals Agency
REACH	Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJEU L396 of 30.12.2006. It entered into force on 1 June 2007.
SEA	Socio-Economic Assessment
SEAC	The Socio-Economic Assessment Committee of the European Chemicals Agency
SIEF	Substance Information Exchange Forum
SIN List	Substitute It Now! List of hazardous chemicals recommended for inclusion in Annex XIV by ChemSec www.sinlist.org
SVHC	Substance of Very High Concern
QOBL	Quality Observation Letter
QSAR (modelling)	Quantitative Structure-Activity Relationship modelling
vPvB	Very Persistent and very Bioaccumulative substance in accordance with the criteria set out in Annex XIII of REACH

Introduction

The regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals[13] (hereafter referred to as "REACH") brought a paradigm shift in the way chemicals are regulated in the EU. The responsibility of public administrations for assessing the properties and risks related to the use of a substance has been passed to the commercial operator who must demonstrate that the substance they place on the market is safe and provide all the evidence for it. REACH therefore aims to collect and generate information about thousands of chemicals on the market about which very little is known. REACH is based on the principle that any actor who places on the market, or uses, a substance needs to ensure that it does not adversely affect human health or the environment. Therefore, every operator needs to demonstrate that the intended use of their substance is safe. This system is based on the obligation to provide enough data to describe the hazard properties of the substance. Further, it is necessary to prove what effective risk management measures are in place for each use to guarantee a safe use of the substance. In principle, a substance that is not safe should not be used.

This system would then guarantee that the hazardous properties of substances are identified and their existence on the market is controlled or phased out through the authorisation or restriction mechanisms established by REACH.

13 Regulation (EC) No 1907/2006, O.J. L 396/1 of 30.12.2006.

After five years of implementation of REACH, the performance of the new regulatory framework is failing to meet its objectives. Out of the 1,283 substances already recognised under the Classification and Labelling Regulation (CLP Regulation) as CMR substances[14], 84 have been formally recognised as Substances of Very High Concern (SVHC) under REACH[15], and almost no new substances have been restricted in use. By July 2012, only one restriction had been approved under REACH which deals with mercury in measuring devices. A further three restrictions[16] have been approved, but not yet published.

This review aims at identifying the bottlenecks causing REACH's slow progress and failing to realise its potential to benefit European citizens and to provide recommendations to ECHA to achieve its aims, in a cooperative manner with public interest organisations.

14 Regulation (EC) No 1282/2008 of the European Parliament and of the Council of 16 December 2008, OJEU 31.12.2008, L353 p.1.

15 By 27th September 2012.

16 On phenylmercury compounds, lead and its compounds, and Dimethylfumarate (DMFu).

Registration

"No data, no market" or "no registration number, no market"?

ECHA has to guarantee compliance with the principle "No Data-No Market". No registration numbers should be assigned to registrants that do not provide dossiers which include all the relevant data required by REACH.

Under REACH, operators must prove that the substances they place on the market are safe. Article 5 of REACH (No data, no market) prohibits substances that are not registered to be placed on the market. The registration phase requires manufacturers and importers to generate data on their substances, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. The registration dossier sent to ECHA should be a transparent tool that enables the public authorities to ensure that these obligations are met and to allow decision-makers to implement additional risk management measures for these substances, when necessary.

Further, the information generated by REACH should be used by the relevant actors in the application and implementation of EU legislation such as products, water protection and workers protection.[17]

Therefore, reliable and verifiable information constitute the cornerstones of REACH. When a substance is registered, it is assigned a registration number. This is proof that a manufacturer or importer has registered a substance and it can legally place it on the market. After a registration number is assigned, there are no mechanisms established within REACH on the basis of which ECHA could withdraw the permission to place a substance on the market.[18]

17 See recital 14 of REACH.

18 The possibility to withdraw a registration number has been mentioned in ECHA's Multi Annual Work Plan 2013-2015 in cases, not better defined, of "continued incompliance".

In order to verify that the principle "no data, no market" is complied with, REACH mandates ECHA to reject the registration of a substance if shortcomings are identified by performing a completeness check of all registrations dossiers submitted[19]. The completeness check of each registration is done "in order to ascertain that all the elements required in Articles 10 and 12 or under Articles 17 or 18 […] have been provided." However, the text further states that "[t]he completeness check shall not include an assessment of the quality or the adequacy of any data or justification submitted". This last sentence was used as a pretext for ECHA to limit its completeness check to an automated procedure which does not actually check whether "all the elements required" have been provided. This may seriously hamper the effective implementation by the Agency of the "no data, no market" principle.

According to the current approach on completeness checks, ECHA implements a totally automated technical completeness check which verifies if data fields have been filled out (with any text, even without a meaning) in order to pass the completeness check. However, this process does not verify whether the information provided is in fact relevant[20]. Millions of Euros of taxpayers' money have been used on REACH information technology tools but the technical completeness check is a purely automated system which does not check the relevance of the data submitted for registration purposes.

19 See Art. 21(1) and 20(2) of REACH.

20 See ECHA approach on completeness checks.

Even when an inconsistency is highlighted by the technical completeness check tool, ECHA does not reject the dossier but gives it a priority for a subsequent compliance check. It follows that a substance could be on the market for years without having to comply with REACH. As a result, a large number of substances have likely been registered with very poor or irrelevant data, and some cases have been discussed of substances registered only by including random alphanumerical values in the data fields. Unfortunately, due to ECHA's policy of protecting data provided by industry, information about specific examples of bad dossiers and of the registrants responsible for them have not been made available to the public nor publicly denounced.

In spite of ECHA having recognised that a large proportion of the examined registration dossiers raise compliance or quality concerns,[21] this approach has resulted in the identification of only a small minority of dossiers which failed the technical completeness check by the 1st December 2010 deadline[22]. Despite the large amount of dossiers, only two decisions of incompleteness have been appealed and both were subsequently rectified by the Executive Director.[23] Thus, there is no "jurisprudence" of the ECHA BA[24] that could define the boundaries of the power of ECHA's completeness check to reject dossiers.

21 See Evaluation under REACH: Progress Report 2011, in particular section 2.1.5. and Evaluation under REACH: Progress Report 2010, in particular sections 2.1.2 and 2.1.5 on intermediates status.

22 See ECHA Newsletter n 6, December 2010, page 3.

23 See Case A-001-2011 and Case A-002-2011.

24 See Section 6.6 for more information on the work of the Board of Appeal.

Assessment against REACH objectives and ECHA's values

When developing the tools for the first registration deadline, ECHA designed a system that would allow it to perform its work in the most time-efficient manner. Indeed, the uncertainties about reaching the objective of successfully processing a large number of registrations due by 1st December 2010 were high and the process burdensome. Although from an administrative point of view the registration process was a success, ECHA appears to have failed to implement one of the fundamental purposes of REACH that is to allow only substances without adverse effect on human health and the environment. Allowing, by granting a registration number, the marketing and use of a substance for which part of the basic hazard information and the risk management measures are missing, or clearly irrelevant, is in breach of the basic principle of REACH of "no data, no market". Nor does ECHA's approach reflect REACH's aims: substances allowed on the market with irrelevant dossiers are not guaranteed to be safe. Moreover, it does not guarantee good functioning of the internal market because it allows free riders to have the same market access as those companies who have taken REACH seriously and invested time and money in submitting good quality dossiers.

ECHA has not been transparent when dealing with completeness checks and registration. Dossiers considered to be of poor quality have not been highlighted by ECHA and discussions about non disclosure of potential confidential business information have delayed the dissemination of the registration dossiers for several months, thus not allowing anyone the possibility to screen the dossiers. We have also noted that many dossiers that were subject to a compliance check have not yet been disseminated[25].

25 See list of dossiers under dossier evaluation in additional resources. The search was performed in July 2012.

The appalling quality of the data submitted by industry and automatically validated by ECHA has undermined the entire data submission system and resulted in significant inefficiencies for ECHA. Having allowed a non-quantifiable number of bad registrations, ECHA's task on compliance checks will now be overloaded with dossiers that are obviously non-compliant. As a result, the 5% minimum target provided by REACH for compliance checks is totally inadequate to ensure that registrants are in compliance.

In its June 2011 report on the functioning of REACH, ECHA blames REACH for giving a "competitive disadvantage to diligent companies" because Article 20(2) does not allow an "assessment of the quality or the adequacy of any data or justifications submitted".[26] However, this is not the case because REACH is worded in a way which requires all registrants to submit relevant information. **ECHA showed a lack of independence** as it was driven by the fear of appeals and court cases from industry rather than by the need to meet REACH goals.

ECHA's way of assigning registration numbers to almost any dossiers raises **serious concerns about how trustworthy the institution is in guaranteeing the achievement of REACH's goals**. By allowing substances to be placed on the market without having received the elements required to be able to assess that they can be used in a safe way, ECHA has failed in its commitment to guarantee the safe use of chemicals and improve the quality of life of citizens and the environment.

26 See ECHA 2011 report "The operation of REACH and CLP' (ECHA-11-R-003-EN), page 13.

Recommendation

The founding principles of REACH must be observed by ECHA. Thus, the relevance of the information submitted has to be checked without necessarily having to scrutinise its adequacy or quality. Modern IT systems can be designed in such a way to prevent any seriously deficient dossier where boxes are filled with irrelevant information.

According to REACH Article 20(3), only "complete" dossiers may receive a registration number. Therefore, for the next registration deadline of 1st May 2013[27], ECHA should only issue a registration number if all the elements submitted in the dossier, including the elements listed in Annex I for the CSR, are in fact relevant information provided according to the registration provisions of Article 20(3). ECHA should also apply this new policy to completeness checks required for any update of registration dossiers.

Further, we call on ECHA to enhance the transparency of how it assigns registration numbers by providing the date on which the registration was accepted so that watchdog organisations can monitor the correct and timely implementation of REACH.

Finally, ECHA should consider using a "naming and shaming" mechanism to contribute to ensuring that companies submit compliant dossiers.

A future increase in the number of appeals against completeness check decisions may be a signal of ECHA's efforts to demonstrate independence from industry and guarantee that registrants provide relevant data in their dossiers.[28]

27 ECHA announced in its Multi-Annual Work Programme 2013-2015 (ECHA-MB/04/2012, page 20) that only from 2014 registration dossiers will have to pass a more strict completeness check.

28 See section 6.6 on Board of Appeal.

The issue of intermediates and ECHA's role

Many chemicals manufacturers and importers are abusing the intermediate status in order to avoid the costs of complying with REACH registration. ECHA should accept registrations of substances identified as intermediates only when it is proved that they comply with the definition of intermediate used in "strictly controlled conditions" as clarified in ECHA's Guidance. Coordinated efforts with enforcement authorities should be put in place in order to avoid false intermediates registrations for which companies have reduced registration requirements.

REACH provides for exemptions to the obligation to submit a full registration dossier for substances that are intermediates, provided that certain conditions are met. An intermediate is a substance that is manufactured for, and consumed in, or used for, chemical processing in order to be transformed into another substance[29]. Non-isolated intermediates are exempted from registration (Article 2(1)(c)), while on-site isolated intermediates (Article 17) and transported isolated intermediates (Article 18) benefit from reduced information requirements if enough evidence is provided that the substances are used "under strictly controlled conditions" (Article 17(3) and 18(4)). If the "strictly controlled conditions" are not documented, a full registration must be submitted.

29 See Article 3(15) of REACH.

Not only NGOs, but also MSCAs and ECHA had a different view from industry in relation to what can be considered as "strictly controlled conditions". In fact, industry produced its own guidance on intermediates[30] which was objected to by the MSCAs and the Commission in May 2009. It became apparent that industry had also interpreted the ECHA Guidance[31] of February 2008 differently. Therefore, ECHA's guidance was updated, in particular to clarify what is meant by "strictly controlled conditions".

According to REACH, a substance needs to be "rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure". The exact meaning of "rigorously" is subject to interpretation, but should be understood according to the spirit of REACH aiming at a high level of environmental and health protection.

Industry could not provide a clear illustration of how the strictly controlled conditions are fulfilled and so the common approach was shifted from demonstrating completely rigorous containment to an indication of some of the technical means to achieve it. The second version of ECHA's guidance on intermediates was published in December 2010.

However, Article 18(4) sets out a list of cumulative conditions that must be fulfilled in order to consider the substance as "strictly controlled", otherwise a full registration dossier needs to be prepared.

For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation requirements apply[32]. Thus, it is clear that having a substance registered under the "intermediate" status brings considerable advantages for a registrant in terms of escaping regulatory requirements and consequential economic costs. Due to the fact that no emissions are foreseen from their use, chemicals registered as intermediates are not subject to authorisation, and will therefore not trigger mandatory innovation within the industry to substitute these chemicals, even if they are recognised as SVHCs.

30 See briefing note 6 June 2011 of CEFIC about the revised guidance; and CEFIC position on definition of intermediates (legal note) and the In-house Guidance of CEFIC, CONCAWE and EFCG of June 2010 on intermediates .

31 See ECHA's Guidance on intermediates (ECHA-2010-G-17-EN).

32 See Art. 49 REACH.

Some Member States, such as Italy and Poland, have been prompted to challenge the definition of intermediates and to re-open the guidance on intermediates once again, in order to please industry. The Italian CA also proposed that substances used for the production of articles should be treated as "intermediates"[33].

ECHA reported[34] that about 25% of the 25,000 dossiers submitted for registration were for intermediates. ECHA's screening of over 400 of these registration dossiers has indicated that 86% of them appear not to contain sufficient information to demonstrate that the Article 18 conditions are fulfilled.[35] The following identified shortcomings give particular cause for concern:

- Status of intermediates
- Specifications of "strictly controlled conditions"
- Plausibility of risk management measures

By the end of 2011, ECHA sent 40 letters to registrants according to Article 36 requesting further information in order to verify the intermediate status.[36] Apart from the extremely high percentage of seriously deficient intermediates dossiers processed (86%), it is particularly worrying that three out of the 17 substances concerned are recognised SVHCs[37].

As no dossier or substance evaluations can be undertaken for on-site isolated intermediates, action on intermediates depends on the willingness of the MSCA, in whose territory the site is located, to evaluate whether there may be a risk to human health or the environment and then to take the appropriate measures to ensure compliance.

Assessment against REACH objectives and ECHA's values

ECHA has correctly recognised problems with those substances registered as intermediates which are not used under strictly controlled conditions. Evading the requirements of ensuring safe use of the chemical through making use of the intermediates loopholes amounts to a breach of the obligation of manufacturers and downstream users to ensure that such chemicals do not adversely affect human health or the environment. The assumption of the REACH policy makers is that these chemicals are used in strictly controlled conditions and this would prevent any such adverse effects during their life cycle.

Given the likelihood and effects of industry making use of these loopholes, ECHA and the MSCA must be particularly vigilant and pro-active in ensuring rigorous application of this intended result. ECHA rightly refers to Article 36 REACH which gives competence to ECHA to request the information which the registrant relied upon in order to make the intermediates status assessment. ECHA indicated that "a follow-up on the responses to Article 36 letters is ongoing and may lead to the opening of compliance checks in 2012". Another "potential" follow-up action is the "on-site verification of the intermediate status by national enforcement authorities of the Member States". In an attempt to address this situation, ECHA's forum has established a pilot project on inspections of intermediates where the Article 36 letters sent by ECHA have not resulted in any significant updates of the registration dossiers concerned. A first exchange of experience on this project will take place by the end of 2012.

33 Italian position paper on the Guidance on Intermediates (ECHA 2010) for REACH Implementation dd. 28.12.2012 communicated via e-mail dd 29.12.2012.

E-mail exchange of the Polish MSCA to ECHA regarding the understanding of the Guidance on intermediates by a copper producer dd. 01.07.2011.

34 See ECHA registration statistics of the General Report 2010.

35 See Report on the Operation of REACH and CLP 2011 (ECHA-11-R-003-EN), page 20.

36 See Evaluation Report Under REACH: Progress Report 2011, page 10, and section 2.3.1.

37 See Evaluation Report Under REACH: Progress Report 2011, page 27.

On the downside, the ECHA Forum should have addressed this important issue in a more efficient and transparent manner. The operational phase of the pilot project of the Forum started only in July 2012 and interim results on replies and follow-up action to Article 36 letters have not been publicly disseminated. Therefore, it is highly probable that a large number of registrants of intermediates have been non-compliant for more than 1.5 years and that this problem is far from being solved. Strong signals are needed before the upcoming 2013 registration deadline to avoid similar attempts to circumvent the REACH information requirement rules.

The 2011 Evaluation Report contains some general information on the status of intermediates dossier but a detailed update, including actions undertaken by ECHA, substances concerned and the names of registrants that wrongfully benefited from the intermediate status is crucially lacking.

Overall, ECHA has acted in a goal-oriented manner and has demonstrated genuine attempts to verify whether these intermediate substances are, indeed, used under strictly controlled conditions so they do not adversely affect human health or the environment, in line with the REACH objectives.

Recommendations

Reliance on the intermediate status needs to be thoroughly checked at a very early stage, i.e. during the general completeness check phase. ECHA needs to be transparent about substances and uses that are registered as intermediates. ECHA should not only publish the justifications provided by the registrant on its intermediates status, but also effectively verify that all the elements of information submitted ensure that strictly controlled conditions are met in a "rigorous" manner.

If shortcomings are identified, it is not sufficient to just require additional information from the registrant and play for time. ECHA cannot guarantee the reliability of information provided by the registrant that affirms that the strictly controlled conditions are met and that there is a commitment from downstream users that they have to use the substance in strictly controlled conditions. A description of manufacturing or reaction processes will not guarantee that these processes are effectively used on the production site in question. On-site verifications by enforcement authorities should be coordinated on an ongoing basis with the Forum. Prioritisation of on-site verification could be concern-driven (hazard profile and amounts and potential exposure of substance) but consideration could also be given to the track record of compliance of the manufacturer, who bears the responsibility under REACH to make sure that the substance does not adversely affect human health
or the environment.

The inspection report with details regarding the verification of strictly controlled conditions should be disseminated through the ECHA dissemination portal. Enhanced cooperation with national enforcement authorities is key and ECHA must maintain its involvement with the matter. **We recommend that the pilot project on intermediates becomes an ongoing project aimed at putting pressure on industry to apply the correct interpretation of the REACH text.**

Substance identity issue

In order to avoid the cost of compliance and having to undergo evaluation and SVHC recognition, certain chemical companies are providing ambiguous substance identities. ECHA should make sure that the principle "one substance, one registration" is respected. It is therefore necessary that the identity of a substance is clear before a registration number is assigned. ECHA should review the identities of the pre-registered substances in order to verify that the information provided by the registrants allows an unambiguous identification of the substances concerned. For existing dossiers, it should carry out a thorough verification of the identities of the substances and coordinate with the national enforcement authorities, and the results should be made publicly available.

A fundamental principle of REACH is that for each substance there should be only one registration (Article 11). Also, it should not be possible for one dossier to contain information on different substances, but only on different uses of the same substance(s). This is logical since REACH aims to collect all the available information for one specific substance. However, ECHA reported (again without mentioning any specific example) in its 2011 report on evaluation that there are many cases in which ECHA was "unable to determine accurately the identity of a substance because the information provided was ambiguous".[38]

38 Evaluation under REACH - Progress Report 2011 (ECHA-12-R-02-EN), page 7.

Obligations under REACH are based on the concept of "substances". The term "substance" is defined in Article 3(1) of REACH. This definition clarifies the circumstances under which a substance is obtained through a manufacturing process and outlines how to identify the constituents which should be considered as part of its composition. In practice, the composition of a substance is normally never limited to the presence of one individual constituent but includes other constituents such as impurities. For an accurate identification of a substance it is, therefore, essential that the registrant provides information not only on the chemical identity of each individual constituent but also on their respective concentration. Annex VI(2) of REACH provides a list of information which should be sufficient to identify a substance. Further, an ECHA Guidance on the identification and naming of substances[39] specifies in great detail how to record and report the identity of a substance within the context of REACH.

ECHA highlighted that 72% of the shortcomings in dossier evaluations (through compliance checks Article 41) were related to substance identity.[40] It is clear that if substances are not well identified, the REACH system can be completely undermined and much of the data rendered meaningless. If the identity of the substance is uncertain, no meaningful substance evaluation can be carried out and, therefore, any evaluation and risk management measure related to the substance cannot be applied. Further, ECHA is not able to examine testing proposals if the identity of the substance is not clear.

Under REACH, there is an obligation to jointly submit data on substances and all potential registrants that have pre-registered the same substance under the same Substance Information Exchange Forum (SIEF)[41]. It follows that registrants can exercise significant discretion when determining the "sameness" of the substance. However, it should not be possible under REACH for registrants to, in effect, agree a derogation from the "one substance, one registration" principle.

39 http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf .

40 Ibid, page 32.

41 e.g. according to Art. 11, and provisions of Title III of REACH.

It is argued that it is highly unlikely that chemical companies are not aware of the exact identity of chemicals they place on the market, especially for high production volume phase-in substances. Companies have a clear advantage in submitting ambiguous identifications: they can avoid harmonised classification and labelling as hazardous[42], expensive tests for substances for which very little information exists and submitting additional registrations. It would be naïve to treat ambiguity in substance identification as ignorance or a mistake. The submission of data on several different substances under one registration is a way to circumvent the burden and costs of having to register several substances. Further, ambiguous substance identity may avoid the application of harmonised classification for a specific substance. This is possibly the case of Di-Hexyl-Nonyl-Undecyl-Phthalate (DHNUP) which is included in the Candidate List of SVHC as it is classified reproductive toxicant category 1B and it is a substitute of DEHP. The substance was pre-registratered for the 2010 deadline but finally it was never registered. Instead 5-8 other phthalates in the C7-C11 range without harmonised classification were registered. None of these registrations included an exposure assessment in the CSA, therefore Denmark, who had proposed DHNUP in the Candidate List, selected five of these for Substance Evaluation in 2014[43]when the issue of substance ID will be sorted out by ECHA.

42 According to CLP Annex VI.

43 Diundecyl phthalate; 1,2- benzenedicarboxylic acid, benzyl C7-9- branched and linear alkyl esters; 1,2- benzenedicarboxylic acid, di-C9-11- branched and linear alkyl esters; 1,2- benzenedicarboxylic acid, di-C11-14- branched alkyl es-ters, C13-rich; and diundecyl phthalate, branched and linear.

In order to address substance identity issues, ECHA says that it has performed targeted compliance checks and, in its latest Evaluation Report, it has issued the following recommendation to registrants:

"Define your substance precisely. Ambiguous identity of the substance weakens not only the connection between the registration dossier and the substance on the market, but also puts into question the relevance of the hazard data in the dossier for the registered substance and consequently the information on how to use it safely. This also applies to information yet to be generated in proposed tests. Dossiers are routinely filtered and when the substance is not clearly identified, the likelihood of the dossier being selected for compliance check is higher."[44]

Assessment against REACH objectives and ECHA's values

The "one substance, one registration" principle constitutes the basis for the generation of data on substances under the REACH system. ECHA has provided guidance on the matter to avoid any ambiguity but this does not fully ensure that the "one substance, one registration" principle is not undermined by registrants. ECHA has raised general concerns on the matter but has failed to be transparent and highlight those cases where the issue of substance identification is at stake. ECHA has not been sufficiently goal-oriented and committed in its action to prevent the issue arising in the first place.

44 See Evaluation under REACH: Progress Report 2011 (ECHA-12-R-02-EN), page 10.

Recommendations

We argue that much more incisive action is necessary in order to prevent registrants from undermining REACH through ambiguous substance identification. For the future, ECHA should be able to predict which pre-registered substances will be registered in 2013 and 2018.[45] Pre-registration information already includes sufficient information to identify substances thus ECHA can review the substance ID of the substances foreseen for registration in 2012. Further, after SIEFs are formed, ECHA should review the substance identity information submitted according to Article 28 of REACH. Further, when it performs completeness checks ECHA must double-check the identification information submitted by companies. It should ensure that all elements required by Annex VI(2) are provided and reject any dossiers that do not allow the identity of the substance to be clearly identified. Thus, the checking of the substance identity should be done before the registration number is provided, as it is clear from REACH that SIEFs must be formed by the reference to the same substance (Article 29 and Recital 54). This check should assess whether the information given in this section is sufficient to enable each substance to be identified and a review of the explanation for not providing any of the items referred to in Annex VI(2). In the meantime, it is essential that ECHA highlights existing problem cases and takes strong and transparent action on evaluation and coordinates with Member States for enforcement actions, where necessary. Strong signals and a pro-active approach from ECHA are needed before the next registration deadline of 2013.

45 ECHA has made already available on its website, a list of Substances identified by industry to be registered by 31 May 2013.

Generation and dissemination of information on chemicals

Dissemination portal review

ECHA's portal on the dissemination of information on chemicals is not useful for consumers or civil society who want information on chemicals and their risks. In particular, little or no information about substances in consumer products can be gathered from the information which ECHA disseminates. ECHA should redesign its dissemination portal in a way that is user friendly and easily accessible for a non-specialised audience. It should constitute a useful tool for substitution of substances of concern.

The dissemination of information on chemicals is one of the main reasons why REACH was enacted. REACH provides for the right for consumers to know about the chemicals to which they are exposed. Such a "right to know" was included in REACH in two ways: through the right to know whether SVHCs are included in products they may purchase (Article 33 REACH)[46], and through the mandate[47] for ECHA to create a public database with information on chemicals. Article 119 of REACH lists the minimum information to be made available by ECHA. This includes the IUPAC name, the classification and labelling, the results of toxicological and ecotoxicological studies, tonnage bands, etc.

ECHA must also make available to the public "brief profiles of hazardous properties, labelling requirements and relevant EU legislation including authorised uses and risk management measures". EU citizens should have "free and easy access" to information "in order to allow them to make informed decisions about their use of chemicals" (Recital 117).

46 See the EEB "Fight to know?" report for more information on the implementation of the citizens right to know request (Art. 33) by certain retailers across the EU.

47 See Art. 77(2)(e).

In addition to REACH provisions, ECHA has to comply with the obligations deriving from the provisions of the UNECE's Aarhus Convention[48] relating to access to environmental information.

Before REACH, the only comparable database of information on chemicals was contained in the European Chemical Substances Information System (ESIS)[49], which contains basic information on the so-called Existing and Notified substances according to the former regulation on chemicals (Directive 67/548/EEC).[50]

As REACH aimed at improving the public knowledge on chemicals, the minimum result expected was an improvement in the dissemination of information on chemicals. The entries about substances are not dated, so there is no possibility of knowing when information was submitted or added, or updated; nor is there any way to know if and when a new substance has been registered (i.e. the date from which the substance is lawfully on the EU market).

48 Regulation 1367/2006 includes provisions for the application for the Aarhus Convention in the European Union.

49 Available at: http://esis.jrc.ec.europa.eu.

50 As an example, one can consult the information page on DEHP (Bis(2-ethylhexyl) phthalate, CAS number 117-81-7), a widely used plasticizer that is included in Annex XIV of REACH and will soon be subject to authorisation. The ESIS information sheet about DEHP includes: the identifiers of the substance, whether it is covered or not by other EU law, the classification, the risk phrases and the safety phrases and the danger symbols. In a separate dated searchable pdf, the IUCLID data sheet contains a set of non-confidential information such as company names, physico–chemical data, environmental fate and pathways, and toxicity and ecotoxicity information. It also includes the results of the risk assessment report compiled under the former EU Regulation on existing substances. The information is not intended for consumers, but it is easily accessible and the additional and more technical information can be downloaded separately.

Data in the technical dossier, which are comparable to those present in the ESIS database can be found but in order to do so it is necessary to click and scroll through several fields. In addition, information on safe use and descriptions of the uses of the substance can be found. Unfortunately, the information on uses provided is extremely generic[51] and information on exposure scenarios is missing thus no indication as to the situation in which a consumer may expect to be exposed to the substance is given. Furthermore, there is still no information on the name of the registrants (who have responsibility for the accuracy of the data provided) nor any indication of how much of each chemical is placed on the market by each registrant. We do not know whether the substance was subject to a CSA that was verified or whether that substance is a PBT or vPvB, nor is there any information on its endocrine disrupting properties or any other adverse effects. Further, there is no information about which assessment factors and reasoning have been used to derive DNELs[52] and PNECs[53].

Finally, there is no summary or glossary to explain what information is provided or guidance on how the dossier is structured. This means that tremendous effort is needed to extract the relevant information. For a consumer, the information makes little or no sense and it is badly presented. Even for an expert user, accessing the database is also a difficult task due to the lack of search tools and the inability to export the information (e.g. by substance, by hazardous property or by producing country) into an electronic data format allowing them to consult and analyse the information off-line. REACH establishes the obligation, under certain conditions[54], to notify the presence in consumer products of SVHC chemicals from the Candidate List.

The dissemination of information is particularly deficient. In March 2012[55], ECHA disseminated information regarding 203 notifications received between 1st June and 31st December 2011 in a report which contains little or no indication of where a consumer would realistically expect to find the SVHC in a product. More than half of the notifications concerned the four phthalates on the Candidate List. DEHP (88) and HBCDD (30) had the highest number of notifications. No information is provided about the notifier or the product. In the table disseminated, out of the 55 SVHCs that required notification, only 18 substances received at least one notification. Nine notifications[56] just indicate "no consumer use of articles" despite a notification being required whenever exposure to "humans or to the environment" cannot be excluded during the whole lifecycle[57].

More precise information on the use(s) of the substance is also a key element of the authorisation process, in particular, the identification of suitable alternatives. REACH Article 118 on access to information specifically states that precise use, function and information on application of a substance or preparation must be public during the authorisation process' public consultation[58].

51 The use description are derived from ECHA's "Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN)".

52 Derived No-Effect Levels, these are levels of exposure to the substance above which humans should not be exposed (REACH Annex I, 1.0.1).

53 Predicted No-Effect Concentration, these are the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur (REACH, Annex I, 3.0.1).

54 See Art. 7(2) of REACH.

55 See ECHA Press release of 5 March 2012.

56 i.e. Tris (20Chloroethyl)phosphate (2), 1-Methyl-2pyrrolidone (2), some refractory ceramic fibres (2), coal tar pitch (1), 2,4,-Dinitrotoluene (1); Diarsenic Pentaoxide (1) .

57 Recital 117 of REACH.

58 Art. 118(2b) states "without prejudice to Article 7(6) and Article 64(2)".

Classification and Labelling (C&L) Inventory

Any manufacturer or importer, or group of manufacturers or importers, who places on the market a substance subject to registration or that meet the criteria for classification as hazardous, must submit a notification of the identified C&L to ECHA. The C&L inventory is published on the ECHA website[59]. As in the case of registration dossiers, ECHA decided not to make public the identity of the notifiers. This causes two problems: users of chemicals have difficulties in identifying the most reliable notification and it creates a barrier to reaching an agreement among companies to harmonise the C&L. The published inventory contains hundreds of different C&L for the same substance[60] (even where a CLH is mandatory). According to Article 41 of the CLP Regulation, where the notification results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.

However, ECHA stated that it is working on a solution to allow notifying companies to get in contact with each other. Since ECHA received more than three million notifications covering more than 115,000 substances for the C&L Inventory, ECHA will have to ensure that the solution is workable.

59 http://echa.europa.eu/information-on-chemicals/cl-inventory (containing more than 100.000 substances), established Article 42 of the CLP Regulation

60 e.g. formaldehyde has 50 different C&L notifications, benzene 28, bisphenol A 35 and toluene 108.

Assessment against REACH objectives and ECHA's values

The dissemination portal is a cornerstone of REACH and there is a direct correlation between the protection of human health and of the environment and the empowerment that information gives to citizens in choosing between products containing certain chemicals and those that do not. Citizens' pressure can trigger companies to substitute hazardous chemicals in their products. According to recital 117 of REACH EU citizens should have access to information which would allow them to make informed decisions about their use of chemicals. Four years after the obligation to register chemicals came into force (June 2008), the dissemination website set up by ECHA is of little use to consumers, citizens and researchers. ECHA has made a large amount of data available, but this information is not user friendly, not easy to understand and, so far, incomplete. The database does not fulfill the basic requirements that can be derived from the provisions of REACH or from the EU Aarhus Regulation[61] that requires public institutions to "place the environmental information that they hold on databases and equip these with search aids and other forms of software designed to assist the public in locating the information they require."

ECHA spends over €10m per year on IT tools for the implementation of REACH[62]. However, this very large investment of resources, which has successfully supported industry in complying with REACH registration deadlines, has so far not helped to improve the design of the dissemination portal to support the interests of the public. Indeed, ECHA's multi-annual work plan for 2009-2011[63] barely mentioned dissemination. The possible underestimation of the importance of this issue has led to poor results in the design of its database and to the shortcomings that are seen today. Thus, it is our view that ECHA has failed raise the public awareness on the risk of chemicals and failed to promote substitution and innovation in the chemicals sector.

61 Regulation (EC) No 1367/2006 of 6 September 2006, OJEU L 264/13 of 25.9.2006.

62 See Annex III and IV of 2011 Workprogramme: about 12. 8 Millions are budgeted solely for IT. However the same document suggests that expenses relating to IT are higher since a figure of more than 20 Millions just for "IT applications hosting" and other IT related expenses of more than 1.7 Millions may not be encoded under the "IT coding".

63 See MAWP 2009-2011.

As for the Classification and Labelling Inventory, ECHA has managed the process of submission of a number of notifications well and it was much higher than expected. However, the database needs to be improved both in user friendliness and as regards the completeness and consistency of data provided. Further, ECHA should be more result-oriented when dealing with disclosure of data. There is no obligation to make public data about the notifiers in the C&L inventory, but it is also true that there can be no confidentiality issue around data which is already in the public domain through safety data sheets provided to professional users.

ECHA withholds a large amount of data on the uses and safety of chemicals, fails to explain why information is not disclosed and how ECHA's decisions are connected with information in the dissemination website. ECHA appears to have been mainly concerned that the data it holds is not made available to the public contrary to the wishes of registrants. Information provided in the dissemination website is anonymous and, despite ECHA's commitment to publish the names of the companies making registrations, such information is not yet available.[64]

64 ECHA announced that the information on the identity of the registrant will be made available in November 2012.

Recommendations[65]

In order to achieve its commitment to stimulate the safe and sustainable use of chemicals and to improve the quality of life of all citizens in Europe, the dissemination portal must be comprehensive and easy to understand. The basic rules for the compilation of safety data sheets should also apply to the database.[66]

For the period 2013-2015, ECHA should commit to enhancing its dissemination portal, to develop the concept of a "single point of access", to improve the format of the public database and to build the capability for more powerful searches on the properties and uses of chemicals.

In order to achieve ECHA's commitment to openness and transparency in its actions and decision-making, the database of chemicals needs to clearly indicate the dates on which the chemicals were registered, the existence of any pending confidentiality claims for data that do not appear in the relevant field, detailed information on the application and verification of the "notification of SVHC in articles" Article 7(2) obligation and the results of dossier and substance evaluation.[67] ECHA should therefore re-consider how dissemination of information generated through the notification of SVHC in articles obligation, the SVHC authorisation procedure phase or through other means could contribute to those objectives.

65 For more NGO positions on the issue please consult a joint NGO position paper on dissemination and on the scope of information under Art. 119(2) of REACH, in particular "other information contained in safety data sheets.

66 See Annex II of REACH.

67 The obligation to disseminate information on evaluation is provided in Article 77(2)(f).

ECHA should have a holistic approach to REACH in order to achieve its objective: generating, centralising and sharing information on use of chemicals of concern (subject to authorisation) and on their (precise) intended functions will considerably facilitate the identification of potential alternatives for chemical substitution for same uses, and therefore also support voluntary instruments such as the EU Ecolabel, EU Ecodesign or the Substitution Support Portal (SubsPort[68]). The needs for data generation should be considered already in relation to information requirements at the registration phase.

In regards to the **C&L inventory**: ECHA should publish the identity of C&L notifiers, in order to facilitate contact between companies to agree a common classification and labelling for the same substance. This would also help users to scrutinise the quality of the provided information. Impurities or composition information should also be published, as this will help producers and users to understand the possible reasons for divergences in C&L. The differences between different C&L and a comparison with the Annex VI mandatory classification according to the Harmonised Classification and Labelling (HCL) should be provided more clearly: It would be useful to link the submitted classification of the substance to the C&L section of the registration dossiers.

ECHA should organise a stakeholder consultation to explore possible avenues on how dissemination policy should be designed to enable those objectives to fully materialise and improve its policy on transparency concerning the safety of substances.[69] [70]

The databases will represent the public face of ECHA to the wider public, and by thoroughly fulfilling this task its success in becoming the world's leading regulatory authority on the safety of chemicals will be measured.

68 Kooperationsstelle (KOOP), Instituto Sindical de Trabajo Ambiente y Salud (ISTAS), ChemSec, Grontmij. Available at: http://www.subsport.eu

69 See Article 109 of REACH.

70 See recommendations under next section (section 3 on confidentiality claims).

Confidentiality claims

ECHA did not perform well in relation to confidentiality. It has to be more transparent and impartial in the way it deals with confidentiality claims. It should set a clear procedure and timing for the processing of confidentiality claims and provide explanations to the public on what information has been held confidential and why.

REACH provides the opportunity for registrants to request that certain information that is listed in Article 119(2) (e.g. tonnage bands, trade names of the substance, information in the safety data sheet) is not published in ECHA's dissemination website if it can be proved that such publication is potentially harmful for the registrant. In order to provide guidance on submitting confidentiality claims, ECHA prepared a Data Submission Manual[71] which gives good guidance on how to make a confidentiality claim and what kind of justifications are necessary. In the evaluation of both the information to be made public as well as of the claims for confidentiality submitted by registrants, ECHA has to take into account not only the general principles of transparency and openness included in the EU Treaties but also the applicability of the Aarhus Convention to data which it holds.

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

When chemical manufacturers and importers register a substance with ECHA they can indicate which information among that listed in Article 119(2) they want to have withheld from the public and have to submit the reason for their position. Controversy arose between ECHA and industry on one side and civil society on the other, around the interpretation of the content of Article 119(2)(d) which indicates that information on the safety data sheets which is not included under Article 119(1) (thus, under no circumstances could be claimed confidential) has to be published unless claimed confidential. ECHA's interpretation of this provision was that this information referred only to information on the "uses" and "uses advised against", thus completely omitting information on hazards such as the results of PBT assessment[72] and information on other adverse effects, such as global warming or endocrine disrupting potential[73], date of issue and revision date, or on the names of the registrants.

The dispute was resolved through a legal opinion of the European Commission which stated that all the information included in the Safety Data Sheet had to be made available to the public.[74] In an attempt to influence ECHA's Management Board, a letter was sent by chemical association CEFIC stating that "going beyond its remit exposes unnecessarily the ECHA Management Board and its individual members to tremendous and unprecedented liability risks".[75] ECHA finally announced in May 2011, after being sued by ClientEarth and ChemSec for not giving access to the names of companies that have registered substances in the SIN List, that it would publish the names of registrants. The names have not yet been published.

72 Paragraph 12.5 of Annex II.

73 Paragraph 12.6 of Annex II.

74 See letter from the Commission to the Chair of the Dissemination sub-group of the management board.

75 See Reuters Report of 11 May 2011.

Further, it is worth highlighting the fact that ECHA processes confidentiality claim reviews at an extremely slow pace. In March 2012, about half of the confidentiality claims assessments were finalised. However, nothing is known about the chemicals for which the confidentiality claims have been made or the outcome of the assessment. Further, ECHA started only recently with tonnage bands to partially indicate if the tonnage band was omitted because it had been claimed to be confidential. In all other cases, either ECHA omitted to publish the entire dossier or left certain fields completely empty so that it is impossible to know what information has been omitted.

Assessment against REACH objectives and ECHA's values

The generation and dissemination of information on substances is a key pillar of REACH. There is a direct correlation between extensive availability of information about substances and the protection of human health and the environment. High quality and extensive information empowers consumers (and everyone else in the supply chain) to make informed decisions, and pressure from citizens and downstream users can trigger business change by responsive industry players. Through its defensive approach to confidentiality, ECHA has failed to meet the goal of REACH to generate and make use of information on chemicals in order to guarantee a high level of protection of human health and of the environment. Furthermore, substitution and innovation in the chemicals sector has not been promoted.

ECHA's handling of confidentiality claims has not been open. Information has systematically been withheld from the public, e.g. as a result of a restricted interpretation applied to which parts of the SDS should be disseminated. Any challenge to confidentiality claims has been further hindered by lack of transparency on the part of ECHA as to what information is being withheld.

ECHA has been both excessively cautious in withholding industry information and dilatory when it is to be disseminated (e.g. the announcement in May 2012 that registrants' names would be published, but the date finally set has been delayed until November 2012). This undermines ECHA's efforts to demonstrate a reputation for impartiality and independence, and, to some extent, its stated value to meet deadlines.

As a consequence of ECHA's over-conservative interpretation of REACH and its lack of early engagement with relevant stakeholders, ECHA wasted a large amount of its resources in setting up an IT system that does not meet the requirements of REACH. This led to the restructuring of the IT tools for claiming the confidentiality of information and a considerable delay in the process. This also means expenditure of a considerable amount of taxpayers' money to correct poorly designed IT tools.

Recommendation

Steps need to be taken to reverse the default approach of ECHA and the chemical industry that information should, prima facie, be considered confidential. The way in which ECHA deals with the confidentiality of data is one major problem in the implementation of REACH.

We recommend that ECHA:

- Develops its transparency policy as provided by Article 109 of REACH including its policy on confidentiality claims. This would explain the legal framework applicable to chemicals data, ECHA's guiding principles and a step-by-step procedure for granting confidentiality.
- Sets clear examples of cases in which confidentiality of data can never be granted.
- Clearly links the data field of the information being claimed confidential with the status of assessment of the confidentiality claim (e.g. pending, under assessment, accepted).
- Operate strict timetables for processing confidentiality claims (e.g. maximum six months from the moment a claim is submitted).
- Make available information on which claims have been accepted and which not and the related justifications.

Access to documents requests

ECHA has largely ignored the regulation on access to (environmental) information and the consolidated jurisprudence of the European Court of Justice. In order to reverse this trend, ECHA should immediately develop procedures on access to information and include them in its transparency policy pursuant to Article 109 of REACH and incorporate the principles enshrined in the EU Treaties, in the Aarhus Convention and deriving from case law.

Recital 117 of REACH requires ECHA to "allow access to information in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information (1), Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (2) and with the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, to which the European Community is a party."

ECHA is therefore bound by the rules of Regulation (EC) 1049/2001 in giving access to the information it holds.[76] This means that it must give access to the information that it holds, with the exception of information that falls under Article 4 of the Regulation. According to the Aarhus Regulation[77], information on chemicals is environmental information and therefore, ECHA has an obligation to interpret any exception to its duty to disclose information in a restrictive manner and to disclose any information that concerns emissions into the environment[78]. In light of its overprotective treatment of industry-owned data, ECHA was taken to Court[79] by ClientEarth and ChemSec because ECHA refused to release information on the registrants of chemicals and on the quantities of hazardous chemicals placed on the market. Whilst on the one hand ECHA appears to accept that it has the obligation to publish such information, on the other hand it believes that it can do so whenever it decides to and with complete disregard for the time limits required by law.

Other instances of ECHA's approach should be noted. In May 2011, ClientEarth and the EEB requested access to a number of decisions on compliance checks and QOBLs. ECHA agreed to give partial access to these documents, which should, in any case, be public by default as they are decisions from a public institution and they validate the information on the substances that ECHA makes available to the public. However, ECHA then set its own timeline for granting access to the documents which were only provided to ClientEarth and the EEB after delays of up to six months. This approach does not comply with Regulation 1049/2001.

76 The information needs to be identifiable in any support (written, electronic, audio, etc).

77 Art. 2(1)(d)(ii) of Regulation 1367/2006 includes information on substances "affecting or likely to affect the elements of the environment".

78 Ibid Art. 6(1).

79 See Case T-245/11, Official Journal C 194 , 02/07/2011 P. 0020 - 0021.

In some cases, ECHA has also misled applicants seeking access to information. In one instance, ECHA's response to an applicant seeking information about nanomaterials registered under REACH included some amazing statements about REACH which appear to be completely invented. In a reply to the applicant's confirmatory application (ATD/101/2010), ECHA denied access to information contained in any Chemical Safety Report ("CSR") because "the legislator has considered that the publication of the CSR may potentially cause harmful effects which may be considered as a legal presumption that the CSR contains confidential information and its disclosure, either on the ECHA website or to a particular applicant, may in any case potentially cause commercial harmful effects to the registrant"[80]. This clearly reflects a fundamental misunderstanding of the existing legislation. Much of the information within the CSR has to be disseminated and only a limited amount of information is considered to potentially cause harm to the registrant if disclosed; this is subject to recognition of the position that, nevertheless, there may be an overriding public interest in disclosure.

80 See ECHA's responses in Annexes.

Further, EEB made an access to document request (ATD) on 30th March 2012[81] requesting all information on PBT/vPvB assessments available to ECHA, in particular in relation to the 11 PBT/vPvB registered substances subject to the "Registration Audit".[82] The ECHA response of 21 May[83] had found that a CSR had been submitted for only three substances (Anthracene oil, HBCCD, and Alkanes C10-C13,chloro or SCCP); the remaining being registered only as intermediates, where a CSR would not be required. However, despite the fact that information on the PBTness and vPvBness of substances is information on emissions and thus cannot be withheld for confidentiality reasons, [84] ECHA redacted some parts of the documents which were then only partly made available[85] after a confirmatory application was submitted. [86]

It is not clear on what basis the Registration Unit of ECHA redacted those parts of the document.

Assessment against REACH objectives and ECHA's values:

ECHA's performance on access to documents has been extremely poor. It has not followed REACH's mandate of providing greater access to information on chemicals to which citizens may be exposed and it has systematically failed to comply with EU regulations on access to environmental information.

81 Click here to access the assessment online

82 See final chapter.

83 See Annex for ECHA's responses.

84 See Article 6 of Regulation 1367/2006.

85 For HBCCD, under the "Summary and overall conclusions on PBT or vPvB properties" the following sentence was censored: "As the substance is essentially insoluble in water it is expected to rapidly partition to sediment and sludge, and is not expected to remain in the fresh-or estuarine water for longer than 40 days." The other sentence for Anthracene oil was: ""Environmental Toxicity Assessment" for Anthracene oil. "Single PAH present in Anthracene oil fulfil the T-criterion for PBT. This is not considered to be directly applicable to anthracene oil (AO) as such".

86 See Annex

Making information available has a crucial role in implementing environmental legislation and triggers a higher level of protection of the environment[87]. ECHA has taken positions which do not seem to be compatible with the general principles of the EU treaty, of the Aarhus Convention, of the Aarhus Regulation and of the Regulation on Access to Documents. Pursuant to these measures, institutions must be as open as possible and any exception to the general rule of disclosure of environmental information must be interpreted restrictively taking into account the overriding public interest in disclosure. Giving access to data that is not strictly confidential is crucial in order to make available information (e.g. to NGOs for monitoring purposes, for workers' protection and to researchers for scientific purposes). REACH indicates only four categories of information that are normally deemed to undermine the commercial interest of companies.[88] These provisions must be construed so as not to undermine overriding requirements for the disclosure of environmental information.

ECHA's approach has made access to documents requests a daunting task for civil society. ECHA appears to have reversed the general assumption that, in these circumstances, confidentiality is the exception and disclosure is the rule. These can be considered major shortcomings when considering ECHA as a transparent, independent and, overall, a public organisation.

ECHA's response to access to documents requests has also often not been consistent and has, in particular in the case of the ATD relating to PBT assessment mentioned above, given rise to concern that ECHA has redacted information which may be embarrassing or compromising to industry, but which is clearly not of a confidential nature. Further this case suggests that ECHA's Registration Unit is not aware of the fact that information on emissions into the environment cannot be held confidential, and confirms ECHA's overprotective attitude of hiding information from the public that sheds light on the properties of substances on the market.

Uncertainties around ECHA's compliance with the requirements for access to documents have led to significant time and resources being used by ECHA in processing access to document requests. ECHA has repeatedly failed to respect both the limits of the exceptions on access to information as well as the deadlines set in the legislation. Further, ECHA has been brought to court over its failure to provide acces to information that it has committed itself to disclose (i.e. the name of registrants). Much of the information sought by NGOs related to information that should have been disseminated in the first place, while instead of systematically disseminating information ECHA preferred to withhold it and examine whether, on a case by case basis, this information should be disclosed or not. Such practice surely used many of the resources that ECHA could have dedicated to other streams of work, rather than to examining documents and censoring parts that it considers to be potentially harmful for companies, if disclosed.

Recommendations

ECHA should review its procedures on access to documents and assess the information it holds in the following categories: information always to be disclosed; information to be disclosed under certain conditions; and information deemed to be confidential under certain conditions, unless exceptional conditions apply (e.g. precise use for substances under authorisation as provided by Article 118). These procedures, together with a review of consolidated case law of the European Courts should be included in ECHA's transparency policy according to Article 109 and discussed with all stakeholders.

87 Recital 2, Regulation 1367/2006.

88 See Article 118(2) of REACH.

ECHA's lack of ambition on compliance checks

ECHA has chosen to meet the lowest possible target in compliance checks. Further, it has restricted its powers by giving a limited interpretation of its power to ask companies to improve dossiers, particularly regarding risk management measures. Instead, ECHA requested voluntary improvement of the dossiers. ECHA must be diligent and its compliance check decisions should require companies to correct and put their dossiers in compliance. Further, ECHA should coordinate its efforts with enforcement authorities in case on non-compliance by companies.

According to Article 41 of REACH, ECHA can examine any registration in order to verify that it complies with the information requirements and with the rules on adaptation of standard information requirements, that the proposed risk management measures are adequate and that there is a justification for any separate submission. Decisions on dossier evaluation are adopted according to the procedure set out in Article 51 of REACH and set deadlines by which the registrant has to update its non-compliant dossier.

ECHA has the obligation to check compliance of at least 5% of registration dossiers per each tonnage band of registration (1-10, 10-100, 100-1000 and over 1000 tonnes)[89] and it has to take into account any information submitted by third parties on registered substances. The European Commission may increase, through a comitology decision, the percentage of dossiers to be checked by ECHA.

89 Priority must be given to dossiers submitted separately from the joint submissions; dossiers that deviate from the standard information requirements; substances that are in the Community Rolling Action Plan (CoRAP).

Under REACH, every year ECHA has an obligation to report its progress on evaluation.[90] In its latest progress report[91], ECHA highlights three main issues on dossier evaluation: **substance identity**, **the abuse of read-across** to waive data and the **poor quality of the Chemicals Safety Assessment (CSA)**.[92] In particular, on the latest, ECHA recommends registrants to: "[b]e thorough in completing your chemical safety assessment and document it in your chemical safety report. [...] Missing elements in the chemical safety report automatically lead to gaps in the advice and consequently affect the safe use". Thus ECHA appears to be admitting that non-complete dossiers have passed the completeness checking phase (see chapter 1.1 on this issue).

The report on ECHA's 2010 work also highlighted similar serious shortcomings in the dossiers checked for compliance.[93] The cumulative work on compliance check performed by ECHA as reported in the 2011 progress report is set out in Annex 3.[94]

90 See Art. 54 of REACH.

91 Evaluation under REACH Progress Report 2011.

92 The CSA has the purpose to assess and document that the risks arising from the substance manufactured or imported are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks. The CSA is documented in the Chemical Safety Report (CSR).

93 See Evaluation under REACH Progress Report 2010, page 3.

94 See Evaluation under REACH Progress Report 2011 (ECHA-12-R-02-EN), Annex 3.

Despite very serious problems in the compliance of the large majority of the dossiers taken into account for dossier evaluation, ECHA kept on referring to its dossier evaluation target to the least ambitious permitted by REACH:[95] 5% of the dossiers. Therefore, if it is true that there are serious shortcomings in the majority of the dossiers taken into account, the majority of substances will be used in the EU without sufficient data to prove that they are safe.

ECHA explained in its report on the operations of REACH and CLP[96] that "[t]o a certain extent, missing information elements that are used for the derivation of the risk characterisation and risk management can be addressed in a draft decision, but the actual risk management measures applied or recommended by the registrants cannot be addressed or corrected by requesting further information." This is a shocking conclusion. ECHA appears to be saying that the mandate to check the adequacy of the risk management measures, as provided by Article 41, cannot be implemented.

Instead, ECHA has decided to introduce a new instrument which has no legal value and which companies can completely ignore: quality observation letters: "A quality observation letter (QOBL) is sent to the registrant: when evaluating the dossiers the Agency may identify shortcomings that are not necessarily related to the lack of information. For example, **the risk management** measures proposed by the registrant may be inadequate if the proposed classification and labelling does not reflect the reported study results. In such cases, the Agency informs the registrant through a quality observation letter and asks for a revision of the dossier and submission of an updated version. Furthermore, it informs the Member States, which may take action if the registrant does not clarify the issue.[97] Thus, the QOBL letters have, in ECHA's view, the same goal as a decision but without any legal value.

95 See Art. 41(5).

96 See Evaluation under REACH Progress Report 2011 (ECHA-11-R-003-EN), page 27.

97 See Evaluation under REACH Progress Report 2010 (ECHA-12-R-02-EN), page 6.

On 8th June 2011, ClientEarth and the EEB made an access to documents request relating to all the QOBLs and compliance check decisions completed by that date[98].

An in-depth assessment of these documents is contained in a separate report with the Excel Worksheets.[99] This includes an indication of the main difficulties encountered in carrying out the assessment, general observations on ECHA's use of QOBL and decisions, their common structure and overall conclusions. For the 26 QOLs and decisions for which dossiers were available or searchable in the ECHA's website, we checked how ECHA had prioritised its examination and how it assessed dossiers, in particular, elements relating to classification and labelling, (eco)toxicity studies and risk management measures proposed.

All draft decisions, final decisions and QOBL approved by ECHA are kept secret. No draft decision has been published on ECHA's website to date and no information is available to the public regarding which substances have been checked, what conclusions have been reached or what data in the dissemination database is inadequate. The only public data on compliance checks is available on the page "Agreements on Compliance Check Draft Decisions" which presents the outcome o f five compliance checks without mentioning the substance affected or the company to which it is addressed.

Finally, ECHA has not provided any support to third parties to enable them to submit information on phase-in substances as provided in Article 41(6) of REACH. Such a tool would have been extremely beneficial in finding more information on registered substances and in filling the data gaps.

98 On 7th July 2011, ECHA granted partial access to documents and we were promised that we would receive, by different deadlines, certain type of documents. The reason given for the delay was that ECHA would need to retrieve manually confidential information for more than 100 documents "generating a high workload for ECHA at a time when we are concentrating our efforts in performing dossier evaluation work" . ClientEarth and EEB, therefore, submitted a confirmatory application and received 115 documents in 3 batchs after 4 months. Of these, 79 were QOBL and 36 were Decisions. The request is available here [weblink to ATD request]

99 The report is available here.

Assessment against REACH objectives and ECHA's values:

ECHA's approach in compliance checks fails to increase the level of protection for human health and the environment. ECHA interprets its role in compliance checks as only asking for more information. As a result, the adequacy of the risk management measures, which are a fundamental issue for guaranteeing that hazardous substances are used safely, cannot be improved. It appears from the in-depth assessment of QOBL that ECHA has overlooked a lot of important deficiencies in the assessment that should and could however have been addressed in a legally binding way.

The CSA and the CSR are key elements of REACH as they demonstrate how the substance can be used without risks. Risk management measures underpin one of the basic principles of REACH that "it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment."[100] An accurate CSR is the basic tool to understand whether this requirement is met and is a reference document for granting an authorisation[101] and for the preparation of a restriction proposal.[102] For the QOBL assessed, ECHA has never highlighted the need for priority risk management measures (such as collective measures, engineering measures, etc.) when the registrant has ignored them. For 15 dossiers (58%), only personal protection equipment measures are identified by the registrant as a risk management measure (RMM) and ECHA did not request additional measures to be included to be taken to ensure that the high protection goals are met. If ECHA allows a large number of substances to be on the market with a poor proof of their safety, decision-makers cannot rely on CSRs when making decisions, and substitution of hazardous substances will be slower, thus affecting innovation in more suitable alternative substances and technologies.

So far, ECHA gives limited information to the public on compliance checks and only upon request.[103] Names of registrants, substance names, list of substances being checked are regularly being withheld from the public view. Further, the dissemination website does not contain any indication that the data on the substances may not be reliable when ECHA has performed a compliance check to ensure that it is.

When performing compliance checks, ECHA appears to adopt a cautious approach to avoid interpretation of REACH that may be detrimental to industry. As a result, the reversal in the burden of proof which underpins REACH can be evaded. An indication of ECHA's lenient approach can be seen in the fact that only three appeals have been brought against ECHA's decisions on compliance check decisions and one of these has been rectified by the Executive Director.

ECHA has allowed the non-compliant registrants to update their deficient dossiers through a "spontaneous update". However, the time taken by ECHA to identify and follow up on the important shortcomings is paid for by European taxpayers. According to the Fees Regulation, any update of a dossier is normally subject to a fee to cover extra costs for the Agency. It was, therefore, not a resource efficient approach by ECHA to invite registrants to bypass the paying of the regular fees.

100 Art. 1(3) of REACH.

101 Art 60(2) of REACH requires the registrant to document in the CSR that the risk to human health or the environment from the use of the substance is "adequately controlled", which will be assessed at the authorisation phase for the relevant substance.

102 Art. 69(4) second indent.

103 Response to ATD request.

It may be questioned if the time-scale needed to request the registrant to address major shortcomings is adequate. This relates in particular to the compliance check on aniline[104], a substance identified as SVHC on the SIN List where at least 1½ years of non-compliance with REACH is tolerated by ECHA.

In general ECHA does not guarantee that, through its compliance checks, the information contained in a dossier is accurate and adequate, but only that it is complete. This may make it difficult for the public to have confidence in ECHA as an organisation working to make the REACH system work and ensure that chemicals hazards and risks are reported correctly.

ECHA has failed to prove that it is goal-oriented (i.e. safe use of chemicals) when carrying out compliance checks.

As ECHA cannot ensure, not even for the few dossiers it checks, that the substances are used in a safe manner, its commitment to the safe and sustainable use of chemicals can be questioned.

104 See separate report on Quality Observation Letters.

Recommendations

Compliance checks are an important part for the promotion of good registrations which form the basis for future decisions on the management of the risks presented by chemicals. ECHA needs to have a clear view on what it wants to achieve and has to be more assertive with industry. There is a need to explore the boundaries of ECHA's powers in compliance checks. ECHA suggests that such boundaries need to be further discussed with all stakeholders to be better defined.[105] However, ECHA has a powerful tool to determine the extent of its powers, namely REACH and its aims. We therefore recommend that ECHA considers the following approach when carrying out compliance checks:

Be transparent about the substances to be subject to compliance check: knowing in advance what substances are going to be subjected to compliance check would prompt companies to spontaneously update their dossiers and to have decisions more targeted to specific issues when a compliance check is opened. Further, it would allow third parties to submit targeted information to fill information gaps on the substances under evaluation, as happens for the CoRAP where contact details of the competent authority evaluating the substances under evaluation in 2012 have been made available.

Promote active support of third parties: REACH foresees that ECHA has to take into account the information submitted by third parties and by Member States when performing a compliance check and when selecting dossiers for compliance check. So far, there is no process by which way this information can be presented to ECHA. The Agency has never made a general call to submit information on substances.

105 See report on the Operation of REACH and CLP 2011 (ECHA-11-R-003-EN), page 27.

Make all decisions public: The outcome of dossier evaluation must be made immediately available to the public with the exclusion of CBI (provided that its exclusion must be explained). Both the name of the registrant and of the substance must be made public.

Praise good registrants: Although limited, a number of dossier evaluations end in no actions. This means that the dossiers are in compliance with REACH. It is important that the public and the stakeholders are aware of the substances for which the information is of good quality and who has provided it.

Reflect outcomes in the dissemination portal: The dissemination website contains information from registrants meaning it is not independently verified. However, when ECHA performs a compliance check and the dossier is successfully updated, the reliability of the information will have been validated. This information should also be available to the public. ECHA could consider a colour coding and highlight all updates in the data submitted (for more recommendations relating to the dissemination portal, please refer to Section 2.1) .

Seek Appeals, don't shy away from them: Compliance check decisions can be appealed and appeals are heard by the Board of Appeal[106]. However, so far, there have been few significant appeals. A low number of appeals - in a situation in which it is clear that the quality of the data is low - suggests that ECHA is being too soft and accommodating with industry. Through the jurisprudence of the Board of Appeal and, eventually, of the European Courts, many legal doubts on the interpretation of ECHA's powers could be resolved.

No more Quality Observation Letters: REACH is a complicated and comprehensive system. The interpretation of REACH should be based on the legal text and on the goals of the Regulation. QOBLs should be substituted by strong decisions that cover all observations on the dossier and require registrants to prove if their information is adequate to achieve compliance.

Report on outcomes of enforcement actions: When the quality of the dossier is poor, registrants are not in compliance with REACH. ECHA should, with the support of the Forum, monitor and report on enforcement actions on substances that have been the subject of a compliance check.

Be ambitious: The 5% target for compliance checks is low. As ECHA has announced[107] that it will also perform targeted compliance checks, it should aim at considerably increasing the number which it carries out. To ensure safe use of chemicals, all dossiers should be systematically checked for areas of concern, such as those relating to the CSR and critical environmental and human health endpoints.

106 REACH Arti cle 76 (h).

107 See Multi-Annual Work Plan 2013-2015, page 20.

CoRAP and substance evaluation

The annual evaluation rate of the CoRAP should be increased by a factor of three to cover a minimum of 95 substances per year, in order to reach the goal set by the Commission of evaluation of 950 substances by 2021. ECHA has undertaken useful coordination and prioritisation tasks. MSCA should have full access to the REACH IT database or be able to use the relevant IT tools in order to facilitate substance selection and do more engaged evaluation work.

Substance evaluation is the core process under REACH aimed at effectively verifying whether a substance constitutes a risk for human health or the environment. They are performed by Member States Competent Authorities (MSCAs) which may decide on further actions, such as authorisation or restrictions.[108] The first CoRAP was adopted on 29 February 2012 and MSCA have until 28 February 2013 (one year) to finalise their evaluation of those substances selected for consideration during that time-period. The CoRAP will be updated annually.

The original target was to have 950 substances evaluated by 2021[109], meaning an average of 95 substances per year which would be equivalent to evaluations of 3.5 substances per Member State per year. Workload is estimated at 75 working days per substance. Just listing a substance for the CoRAP may have, as a direct consequence, updating of a dossier by registrants, since they realise that the quality of its content will, ultimately, be checked in detail. However, lack of resources is frequently claimed by Member States as an impediment to achieving the goal of having a high number of substances evaluated.

The first CoRAP lists 90 substances. Member States indicated during consultation that they could handle only 36 substances for 2012, 23 for 2013 and 31 in 2014.[110] This is less than 1/3 than what is required to meet the objective of having 950 substances evaluated by 2021, far short of the 95 per year required average. The selection of the substances is mainly based on human health hazards (35%), environmental exposure (32%), environmental hazards (19%) and EDC properties (11%). Some also relate to suspected PBT/vPvB properties - an approach we welcome.

108 See Article 48 of REACH.

109 See http://chemicalwatch.com/8803/echa-publishes-list-of-91-substances-for-evaluation.

110 http://echa.europa.eu/documents/10162/13628/corap_2012_en.pdf

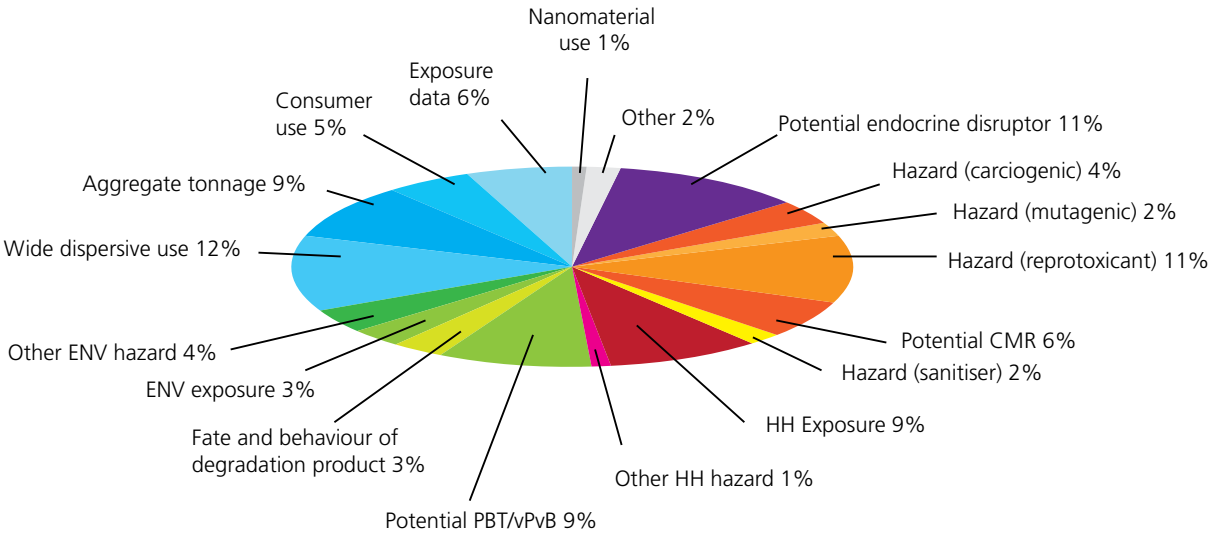

Figure 1: Ground of Concern leading to inclusion of substances in the preliminary draft CoRAP (both substances notified by MSCAs and proposed by ECHA).

Source: CARACAL doc 73/2011

According to a CARACAL document[111], the selection of candidate substances for the 2013 CoRAP update, a pre-selection based on ECHA IT applications and the consequent manual screening of dossiers, will identify candidate CoRAP substances. So far, eight Member States have indicated support for the screening exercise: Denmark, Estonia, France, Germany, Greece, the Netherlands, Sweden and the United Kingdom. Around 500 substances could be available for manual screening. According to ECHA,[112] it is anticipated that the Member States participating in the joint project will be able to manually screen at least 120 substances at the premises of their CAs. On average, the manual screening activities per substance would take one day (two days maximum). The critical issue is to identify the Member States that would carry out the evaluation of the candidate substances.

111 CARACAL doc 73/2011.
112 ibid .

Assessment against REACH objectives and ECHA's values

Substance evaluation is essential for assessing and guaranteeing whether the substance can be used without potential adverse effects for human health and the environment. ECHA has been quite reluctant to take a pro-active role in performing substance evaluation itself, referring instead to its self-limiting interpretation of REACH that ECHA's role is restricted to a coordination function and providing support for the prioritisation work for selection of candidates. According to Article 45 of REACH, ECHA has "to ensure that substances on the CoRAP are evaluated". In doing so, ECHA relies on the MSCA, which may appoint another body to act on their behalf. REACH does not preclude the possibility that this body is, in fact, ECHA. This view is supported by the fact that, according to Article 45(2), ECHA needs to make sure that all the substances on the CoRAP that have not been chosen by a MSCA are evaluated. Outsourcing could have been considered, but it seems that the REACH text leaves this possibility only to the discretion of Member States to appoint another body on their behalf. Any reluctance, be it by MSCAs or ECHA for more pro-active substance evaluationdoes not demonstrate resource-efficient and goal oriented attitude, since the need for subsequent actions (authorisations/ restrictions) could
have been identified earlier.

ECHA has been transparent in the selection process vis a vis external stakeholders. Useful information, such as the selection criteria and draft CoRAP, is published on the ECHA website.

Recommendations

ECHA could be more proactive in supporting substance evaluation by MSCAs. ECHA has direct access to the relevant data and tools needed to do this important exercise.
It should be considered if it is in line with the spirit and provisions of REACH that ECHA could conduct substance evaluations, if appointed by the MSCA as the body to act on their behalf. Outsourcing to independent auditors under the control of ECHA could also be considered. MSCAs should have full access to the REACH IT database or be able to use the relevant IT tools which ECHA has developed in order to facilitate substance selection and evaluation work.

Conclusions on more appropriate actions, such as submitting the substance to the authorisation or restriction procedure, could already be drawn in the prioritisation and selection phase. That would enable health and environmental protection objectives to materialise more quickly, without needing to wait the one year period for evaluation and, hence, saving significant amounts of Member States' resources.

The substance evaluations in 2012 would cost around 2.25 million EUR. It must be ensured that the evaluation costs incurred by ECHA and MSCAs are fully recovered from the producers of the substances concerned in order to implement "the polluter pays" principle. An amendment of the Fees Regulation in order to cope with the (financial) resource needs for the evaluation bodies is however in the hands of the European Commission.

Authorisation and Restrictions

Annex XV dossiers

ECHA has been more concerned about its internal capacity to handle the technical work it had been mandated to carry out according to REACH, rather than pursuing the high environmental and human health protection goals through substitution of SVHCs. In order to achieve the goals set by the Commission to include all known substances of very high concern in the Candidate List by 2020 and 136 substances by 2012, ECHA should rely on the REACH text to increase the efficiency of its nomination process.

Substances included in Annex XIV of REACH are subject to authorisation of their use in the EU. Before being included in Annex XIV, these substances (SVHC) are included in a Candidate List on the basis of their hazards. The White Paper that formed the basis of REACH estimated that 1,450 substances would eventually be included in the list of substances for authorisation. At the time at which this report was drafted, 14 substances were included in Annex XIV of REACH and 84 substances included in the Candidate List.[113]

At this pace, it will be more than 500 years until all SVHCs are removed from the European market.

At the time of the drafting of this report, 91 Annex XV[114 115] dossiers have been submitted for official recognition of that substance as a SVHC, five years after the coming into force of REACH. Out of these, 76 dossiers were submitted for the CMR properties of the substance concerned. According to Article 59(1) and (2), dossiers may be limited to an entry in part three of Annex VI of the CLP Regulation only. Indeed, this is because there is no doubt, for CMRs that have a harmonised classification, that they have the hazardous properties listed in Article 57(a)(b)(c) None of the Member States submitting Annex XV dossiers for the identification of SVHC used this possibility in light of a "gentlemen agreement" between all institutions concerned that a Risk Management Options (RMO) analysis would be performed also for CMRs.

Indeed, ECHA recommends Member States to also submit information on volumes, uses, releases and alternatives and risks because, only a reference to (Annex VI to the CLP Regulation) may not be enough for the purpose of priority setting. In addition, ECHA also recommends to avoid proposing CMRs that do not have a harmonised classification as the inclusion of the substance in the candidate list would be much easier. This approach makes the process very slow and burdensome. Further, if this approach was partially justified before the first registration deadline due to the lack of information on chemicals, it is not the case now. There are almost 5,000 substances registered with much of information being obtained on these substances which should be sufficient for the identification in the candidate list. [116]

113 Dating 28 September 2012.

114 A dossier for Cobalt dichloride was presented both by France and ECHA.

115 In addition, further 54 substances were proposed for identification as SVHCs.

116 See Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern, June 2007, page 14.

In March 2010, European Commissioners, Janez Potočnik and Antonio Tajani, made the following commitments to:[117]

- Get the Commission to drive the Candidate List process and put forward a greater number of known substances of very high concern (SVHCs) for inclusion in the List
- Have 136 SVHCs on the Candidate List by the end of 2012
- Draft a roadmap for the years after 2012, setting out a "longer-term vision"
- "Have all relevant currently known SVHCs included in the List by 2020"

Since the commitment from the Commissioners was announced, 55 chemicals have been included in the Candidate List and the Candidate List contains 84 substances. With a last minute move, the Commission required ECHA to present 37 Annex XV dossiers for CMR substances, these dossiers were submitted using the possibility to make a reference to Annex VI of the CLP. However a roadmap for inclusion of "all known SVHCs by 2020" has not been discussed yet.

Regarding the substances proposed for identification as SVHC or proposed for authorisation, it is interesting to highlight the most active actors in the Annex XV submissions.

117 See the Press Release From the European Commission of 25 March 2010 (Reference: IP/10/360).

118 37 of these dossiers were submitted without a risk management options analysis (RMO).

Country	Authorisation (CMR)	Authorisation (PBT/vPvB)	Authorisation (Equivalent concern)	Restrictions
Austria	7		1	
Belgium	3			
Denmark	3			5
ECHA/ EC	54 [118]	1		2
France	16	1		2
Germany	16	10	6	
Netherlands	8	1	2	
(Norway)	6			5
Slovakia	2			
Spain	1			
Sweden	4	1		3
UK		2		
Total	**120**	**16**	**9**	**17**

France and Germany have the biggest chemical industries in the EU (28,8% and 15,5% respectively)[119] and have submitted the highest number of dossiers. Austria, Denmark and Sweden, although account for a very small chemical industry have provided a significant input in the substitution process. The UK and most of all Italy, particularly stand out for the lack of effort to drive substitution through the restrictions and authorisation process. In particular Germany and Denmark have demonstrated to support REACH new approach to chemicals. Germany by proposing the first substances identified for their equivalent concern and Denmark for proposing a combined restriction of four phthalates. Active engagement in Annex XV submission should come in proportion with the size of the chemical market, therefore further efforts are needed from France and Germany and a commitment in REACH approach is needed from Italy, the UK and Belgium.

The Commission has failed in its role of initiator of restrictions especially by ignoring the possibility to use a fast track procedure (Article 68(2)) whilst avoiding a long and burdensome procedure when clear advantages for health and environment could be delivered. Further, the Commission has kept its promise on reaching the objective for 2012 in the last minute, without any planning and giving the impression that it has asked ECHA to write these dossiers only to fulfill a political promise. A wider approach and discussion on reaching its 2020 objectives should be formalised and a clear road map to achieve those goals should be delivered by the Commission in order to give certainty both to ECHA and to industry of what will be expected from them in the coming years. Effective substitution will not take place by making political statements about the need to speed up the Candidate Listing process without tasking ECHA to do the job or engaging in a meaningful dialogue with MSCA on how to achieve it.

119 The percentage refers to the sales by country in 2010. See CEFIC's "Facts and Figures 2011. The European chemical industry in a worldwide perspective, page 6.

Assessment against REACH objectives and ECHA's values

ECHA has taken a conservative approach on the issue of Annex XV dossiers. Although ECHA does not have the right of initiative in starting Annex XV dossiers, by setting low targets in its work programme it sends a clear signal to the other institutions concerned. Although ECHA has the responsibility to advise the Commission and Member States on issues relating to chemicals and it has a long term commitment to advance the safe and sustainable use of chemicals, it has not provided the necessary support in order to help the Commission to achieve its 2020 objective to include all known SVHCs in the Candidate List. On the contrary, ECHA's Executive Director said in February 2012 that the target set by the Commission for 2012 is "unlikely to be met".[120] ECHA appears to have intended to be resource-efficient by establishing Annex XV formats for its own sake and to streamline the process. However, these requirements which are not legally mandated, have, in practice, placed additional burden upon the process and have not brought any measurable advantage in the implementation of REACH. This has slowed down the SVHC candidate list nomination process, and, in this respect, ECHA has failed to act in a goal-oriented manner. Further it may now be questioned if Member States should provide all additional information that is useful for prioritisation already in the submission phase of Annex XV dossiers. ECHA should now hold enough information from the registration dossiers it should easily be able to extract and provide to Member States well in advance.

120 See "Candidate list target unlikely to be met, says Dancet" on ChemicalWatch of 3 February 2012 and " ECHA: EU's SVHC target 'unlikely to be met' in ENDS Europe of 6 February 2012.

Recommendations

The substitution of SVHCs is one of the most relevant outcomes of the REACH process. In the light of ECHA's commitment to the safe and sustainable use of chemicals, the phase-out of SVHCs should be treated as a priority issue and solutions must be proposed in order to reach the substitution deadline of 2020. Rather than adopting a defensive role "no capacity to handle" it should adopt a more goal-oriented and committed attitude towards achieving the substitution objective by 2020. ECHA should refrain from adopting procedures which make the substitution process more burdensome or which shift the burden of proof from industry to Member States. Instead ECHA, in its advisory role to the Commission and to Member States, should be proactive in suggesting and providing solutions on how to fulfill the policy promises to achieve the 2020 objectives. It is more a matter of priorities than capacity.

The Commission should be clear about the way it envisages the Candidate List and have a discussion with ECHA and Member States. The elaboration of the 'Substitution Roadmap' needs to start without further delay. A roadmap is needed in order to have a clear picture of the Commission's vision, to get priorities right and to set a clear timetable and actions for meeting the World Summit on Sustainable Development goal of minimising the adverse impacts of man-made chemicals on human health and the environment by 2020. Such a roadmap would also give certainty to companies which could plan their substitutions efforts. It should also result in a binding committing for the actors involved to realise the substitution goals by 2020.

All Member States should further contribute to the realisation of the substitution goal and set legal commitments with minimum Annex XV dossier submission turnover per year, as has been done by certain Member States. In that respect, 'effort sharing' must be proportionate to the importance to their chemical industry of placing on the market or exporting those (SVHC) substances.

Risk Management Options (RMO)

The RMO discussion is seen, in practice, as an impediment to rapid progress with SVHC listing and so far the results are disappointing. The listing of SVHCs needs considerable acceleration in order to trigger the process of substitution as intended by REACH. Contrary to current practice, the "indication of regulatory route to take" exercise should happen only during the prioritisation phase, where substances with high volumes, wide dispersive use or PBT/vPvB properties would normally be prioritised for listing within Annex XIV. All relevant substances meeting any of the properties of SVHC according to Article 57 should be officially recognised as such and be included in the Candidate List.

The risk assessment process under the pre-REACH regulation of chemicals was slow and resource-intensive process, which did not allow the system to work efficiently and effectively.[121] As a consequence, REACH recognised the need to do more to protect public health and the environment in accordance with the precautionary principle.[122] Thus, risk assessments have to be carried out by industry players in the registration process. In this phase, they have the chance to prove whether the substance can be used in a safe manner.

On 21-22 January 2009, ECHA organised a workshop with Member States and the Commission to discuss the "Candidate List and Authorisation as Risk Management Instruments". The workshop was prompted by experience of the first Candidate List listing and the "realisation that the processes are very complex and resource intensive". The discussion concerned the aim and scope of the authorisation process and involved an exchange of views on how its implementation could be rendered more efficient.

Although decisions on RMO are not foreseen by REACH, the key actors involved felt the need to get clarity on "the choice for either of the two" procedures for dealing with SVHC (authorisation or restriction). Once the substances meeting the properties for SVHC are officially listed, the prioritisation exercise would consider those substances relevant for authorisation or may de-prioritise substances where authorisation is less effective, such as: intermediates; uses not covered by REACH (such as pesticides and biocides); petroleum streams, and substances subject to restrictions. Another positive conclusion was to promote the grouping of substances with similar uses and chemical similarity.

As specified within REACH, the legal aspects of the interface between authorisation and the restriction process only become apparent once a substance is listed in Annex XIV. This is not the case when a substance is listed on the Candidate List, and, at this stage, the different RMOs are open to the initiator. Furthermore, it is clear from Article 58(6) that even if a substance is listed in Annex XIV, new restrictions to address the risks arising from the presence of that substance in articles may still be introduced.

121 White paper (COM(2001) 88 final), page 6.

122 See Recital 9 of REACH.

Assessment against REACH objectives and ECHA's values

The positive aspect of the workshop was the conclusion that the Candidate List has a purpose of its own: "in principle, all the substances proposed for, and finally included in the Candidate List should go to Annex XIV, there can, in practice, be other reasons for listing a substance in the Candidate List." The same considerations are valid for the debate on a "long" versus "short" Candidate List. However our view is that the whole RMO discussion has resulted in an impediment on Member States and the Commission to the submission of more Annex XV dossiers.

It appears to be a "chicken and egg" problem: practice has shown that Member States and Commission spend too much time analysing all the various RMOs, their impacts, costs to industry and so forth, or creating the perfect dossier to fulfill ECHA's recommendations but forget to do the first necessary step which is submitting an Annex XV dossier fit for official REACH inclusion in the Candidate List.

Recommendation

It definitely makes sense to consider how resources can be spent in the most efficient manner by discussing appropriate RMOs, provided that the objective of speeding up substitution is best served. So far, the results are disappointing and the processing of SVHC for inclusion in the Candidate List is far too slow, especially considering how effective the Candidate List has proved to be in the substitution of SVHCs.

In our view, the listing of SVHCs on the Candidate List should proceed without any delay, in order to trigger the process of substitution as intended by REACH. Further information, such as that necessary to defend the chemical during prioritisation, should be submitted at a later stage. Indeed the SIN List, the Member States[123] List and the ETUC List[124] all contain substances that should be included in the Candidate List as soon as possible.[125] It is our view that all substances which have any of the properties of SVHC according to Article 57 should be officially recognised as such and be listed in the Candidate List.

Therefore, prioritisation consideration should be left only after the process of identifying the substances in the candidate list. Indeed the candidate list is a preliminary step for the inclusion in Annex XIV, however there is no obligation to include the substance in Annex XIV if it is deemed that for some or all uses of some substances restriction may be a better regulatory option. This can only be done after identification in the candidate list.

Indeed, officially listing a substance to the Candidate List has the effect of generating information in the supply chain and providing information to consumers which may direct the decision makers towards a different regulatory option.[126] Finally, if substitution of SVHC is the final aim of REACH, ECHA should prioritise its resources to achieve this goal and dedicate less resources to activities that are not foreseen by REACH.

123 A list of pre-screened 478 SVHC for potential inclusion to the candidate list by an informal group of six EU Member States: NL, AT, DE, FR, SWE, DK.

124 See The Trade Unions Priority list.

125 See lists of priority chemicals in the Subsport database: http://www.subsport.eu/listoflists .

126 See Article 33 of REACH.

Agency independence and functioning of ECHA bodies

ECHA Management Board (MB)

ECHA's approach towards openness and transparency has been considerably improved thanks to the work of the Management Board Advisory Group on Dissemination. However, clear indicators are still missing to assess ECHA's performance on the key REACH objectives, such as driving substitution, generation of information and, generally, delivering a high level of environmental and human health protection. The Management Board should further steer ECHA to make REACH a success in delivering this key objective, but also to build public trust by recognising ECHA as the world leading chemicals Agency truly committed to well being.

The ECHA MB is the governing body of ECHA. Its powers are the appointment of, and exercising of disciplinary powers over, the Executive Director, appointment of the Chair and Members of the Board of Appeal and Committee Members. It has general responsibility for budgetary and planning matters (yearly work programme and multi-annual work programme). In addition, as a general task, the Board "shall adopt the internal rules and procedures of the Agency" (Article 78(3)).

The Board is composed of one representative from each EU Member State, three observers without voting rights (one each from Croatia, Iceland, and Norway), three representatives from the Commission and three members without voting rights appointed by the Commission to represent interested parties.[127] The European Parliament is also represented by two independent individuals[128]. The representatives of the European Parliament have voting rights but have not made much use of them so far.

Since a formal controversial vote is a rare exception in the Board, convincing arguments are all the more important. In a number of cases the public interest observers, although without voting rights, have been able to influence the work of the Board substantially; e.g. in the field of dissemination, awareness to potential "conflict of interest"-cases and, in general, providing support for a more determined approach in the implementation of REACH.

In particular, the approach of ECHA towards openness and transparency considerably improved with the creation of a Board Advisory Group on Dissemination. That group has managed to exert positive influence to counter ECHA's resistance towards fulfilling its obligations to disseminate data on chemicals. Tonnage bands of registered substances are now disseminated, as will be the name of the registrant and information relating to PBT /vPvB assessment. Further, a methodology for assessing CBI claims has been elaborated which will bring clarity to how ECHA will have to deal with processing those claims.

These positive developments were made possible through good cooperation between about a dozen Board members, nominated by Member States, and increasingly with the Executive Director and the ECHA staff.

127 Martin Führ (NGOs: EEB, ClientEarth, ChemSec, HEAL, WWF, Greenpeace, WECF), Hubert Mandery (CEFIC) and Gertraud Lauber (European Mine, Chemical and Energy Workers' Federation).

128 Former MEP Anne Laperrouze (ALDE group) took over from MEP Guido Sacconi (the S&D rapporteur for REACH). Following the resignation of EPP MEP Hartmut Nassauer, Christina Ruden was appointed as the second representative of the European Parliament in 2012.

However, in some areas, there are still serious concerns as to the full implementation of REACH. Public interest organisations involved in the monitoring of the implementation of REACH have voiced, both publicly and through their representative in the Board[129], a number of reservations about progress to date. Further, a letter addressed to ECHA from the European Parliament's Environment Committee on the mirroring similar concerns has made a considerable impact on recent discussions at the Board. The letter, based on an institutional agreement between European Parliament and European Commission, raises serious compliance concerns about registration dossiers and is worried that work on authorisations and restrictions is too slow. The European Parliament and Commission therefore called for a major strategic reflection and the articulation of the appropriate strategy which is necessary to restore public confidence in ECHA and ensure that REACH is not doomed to failure. That letter[130] supported the discussion in the Board that ECHA's complacent approach to industry in matters relating to dossier quality and compliance should be reviewed, especially given that ECHA itself recognises significant shortcomings in this area. Initially, ECHA's Secretariat was opposed to the option of withdrawing registration numbers in cases of severe non-compliance in data quality. However, due to pressure from the European Parliament and consensus by the Board that ECHA needs to do more, ECHA is now considering ways of taking a more goal-oriented approach in relation to REACH enforcement. The issue of bad quality of dossiers has, therefore, been reconsidered as high priority within the ECHA Multi Annual Work Programme (MAWP) clarifying that ECHA needs to "fulfil its role in the process of ensuring full compliance with information requirements pro-actively. The Agency is fully committed to use compliance check and other measures in a most effective and efficient way to improve the dossier quality". The option to withdraw the registration number in cases of continued non-compliance is explicitly mentioned even if it is likely that the approach on acting ex-post will concern only the worst of the worst dossiers, and will have limited impact. It is also agreed that ECHA should further develop its strategic approach to address dossier quality.

On the downside, the Board has taken the decision not to reopen the recruitment process for the nomination of the Executive Director. This is despite the fact that the European Ombudsman found, after a complaint from the EEB, that it could not verify whether or not the Commission had unduly and arbitrarily restricted the range of candidates for selection procedure of the ECHA Executive Director nor whether it had abused its discretion on the matter. This constitutes an instance of maladministration, and[131] the Board was informed about this bad precedent. Nevertheless, despite the European Ombudsman's decision, they chose a simple re-approval process. A more positive response could have been to open a regular and competitive recruitment procedure.

Assessment against REACH objectives and ECHA's values

The new approach and signals from ECHA to address the issue of bad quality dossiers, including the withdrawal of registration number are a welcome first move, even if taken reluctantly and without clear ambition. The positive role of the Board in steering ECHA towards a commitment in ensuring full compliance with REACH is a positive step. Further the Board had a decisive role in driving ECHA to disseminating more and better information.

However ECHA still lacks a comprehensive strategy and the work plans do not state what are the overall objective of ECHA's work that are being set for each time period. The Board can and should do more to ensure ECHA becomes more goal-oriented and delivers on protecting human health and environment.

129 For the Trade Unions at that time through Tony Musu (ETUC).

130 _

131 Decision of the European Ombudsman closing his inquiry into complaint 696/2008/(WP)OV against the European Commission.

Recommendations:

The Board members need to continue with their approach of good cooperation in the spirit of delivering on the REACH objectives with full commitment to the benefit of all EU citizens. Recent developments show that the Board is pointing ECHA in the right direction, and demonstrating the importance of considering the bigger picture of the rationale for REACH, rather than limiting itself to implementing specific provisions of REACH where ECHA has a role.

The Board should use its powers of approval of ECHA's work plan and budget to direct the work of the Agency in achieving qualitative objectives, not only quantitative ones. The development of a strategic approach setting out an ambitious vision, timeline and the concrete means by which ECHA will deliver on the REACH goals is particularly needed. Here the Board should fulfill its steering and governing role. Lessons can be learned from the first registration deadline and a courageous approach adopted before the upcoming 2013 registration deadline in order to block market access to substances for which incomplete data is submitted (e.g. dossiers above 10 tonnes without DNELs or PNECs should be immediately rejected as incomplete).

We are not alone in our views. For example, we echo the findings of the Commission study on ECHA's review[132], which recommends clear indicators to assess ECHA's performance on the key REACH objectives, such as driving substitution, generation of information and, generally, delivering a high level of environmental and human health protection. It is important to enable an assessment - through measurable indicators - on how and to what extent ECHA has contributed to realising those key objectives of REACH (and CLP). That information should be included in the Multi-Annual Work Programme and general reports in the future.

Since ECHA aspires to become "the world's leading regulatory authority on the safety of chemicals", the Board members should make sure that its strategic objectives and concrete actions are indeed "driving forces" towards the achievement of the ambitious objectives laid down by REACH, which ECHA needs to deliver.

132 See page 7.

Member State Committee (MSC)

The MSC has done a good job in considering all the available information for the first official "equivalent concern" EDC nomination. All available information should, indeed, be considered and the benefit of the doubt, as regards availability of data, should be weighted in favour of human health and environmental protection. The MSC has demonstrated that it can resist political pressure from certain Member States and industry in the prioritisation process for adding Candidate List SVHC to the Authorisation List. However it should be more goal oriented in requesting registrants to generate information to fill the knowledge gap on substances.

The MSC is involved in the REACH evaluation and authorisation processes. It is responsible for the formal identification of SVHC nominations as well as providing opinions on the prioritisation process for listing SVHC on the Authorisation List (Article 58(3)). In relation to dossier evaluation, the MSC needs to agree on amendments proposed to testing proposals (Article 40.3) and compliance checks (Article 51). On substance evaluation, the MSC provides an opinion on the CoRAP and settles possible divergences in relation to the responsibility to carry out the evaluation of a substance in the CoRAP (Article 45(3)).

According to the REACH text, the MSC takes decisions on those matters by consensus, needing to "reach a unanimous agreement". Consequently, the MSC has a particular role and responsibility in the implementation of the key mechanisms of REACH. It is composed by one member appointed by each Member State, who may be accompanied by advisers on scientific, technical or regulatory matters.

Our assessment of the MSC will focus mainly on its role relating to the formal listing of SVHC on the Candidate List and prioritisation on the Authorisation List (Annex XIV).

Hexabromocyclododecane (HBCDD) is, so far, the only formally recognised PBT listed on the SVHC authorisation list (Annex XIV).[133] Authorisation applications may, therefore, only be granted following socio-economic analysis which will need to be submitted, at the latest, by 21 February 2014. It was, therefore, expected that the socio-economic discussion would be raised in the consultation process. The dossier was submitted by Sweden on 30 June 2008. During the public consultation on the draft recommendation and draft annex XIV entries for HBCDD, the polystyrene industry (a downstream user of this substance) objected to the prioritisation of HBCDD on the grounds that no suitable alternatives would exist and by reference to socio-economic concerns.[134] A further 6 Member States[135] had raised concerns and stated that the restriction procedure would be more appropriate to address the risks of HBCDD from textiles, that there may be difficulties in substitution and therefore, would give rise to "relocation of the production outside the EU, [with] negative consequences for the EU economy". Those Member States have developed arguments based on socio-economic benefits against prioritisation (e.g. that the benefits of use of HBCDD would outweigh risks). They conclude that for those reasons, the substance should not be prioritised.

133 Available here.

134 Minutes of the 8th Meeting of the Member State Committee (MSC-8) 18-20 May 2009 (page 6).

135 Minutes of the 8th Meeting of the Member State Committee (MSC-8) 18-20 May 2009 (page 9).

However, the MSC secretariat and the rapporteur rightly found that any matter relating to alternatives and the assessment of socio-economic effects might only be considered at the authorisation application phase. The MSC chair has properly decided not to accept these concerns, stating that the matters are "related to other issues than those which can be considered for the prioritisation step of the procedure to include a substance in Annex XIV on the basis of Article 58(3)."[136] The ECHA MSC chair has concluded that the MSC should refrain from using political argument or economic considerations (e.g. impact on SMEs) which are irrelevant for the prioritisation phase, and only sound evidence against the official REACH criteria would be used.

Example 2: How MSC dealt with the first "equivalent concern" SVHC nomination

On 29th November 2009, Germany had submitted an Annex XV dossier for the first time, based on Article 57(f), because of the endocrine disrupting properties of 4-tert-octylphenol. The dossier triggered long discussions in the MSC because it also meant setting a precedent for how to identify an endocrine disrupting SVHC.

The MSC agreed that the substance can affect the endocrine system of organisms in the environment, since these cases were well documented in the Annex XV dossier. Since that substance may exert endocrine disrupting estrogenic activity in fish, it was therefore considered as an endocrine disrupter in the environment. Some MSC members had initially preferred to defer any decision on the basis that there would be no EU-wide agreed definition of either endocrine disrupting chemicals or of the criteria to be used to assess endocrine disrupting properties.

136 Minutes of the 8th Meeting of the Member State Committee (MSC-8) 18-20 May 2009 (page 9).

The ECHA Secretariat went ahead, but insisted that there needs to be evidence of the endocrine mode-of-action mediated toxicity of a substance in order to reach a conclusion on human health-related hazards. The MSC therefore concluded that there "was not a firm conclusion on potential human health relevant adverse effects". For identifying a substance of "equivalent concern", the ECHA Secretariat has made clear that the mode-of-action - i.e. endocrine disruption - needs to be established and a case needs to be made that effects on human health or the environment are severe. This is where the discretionary powers of MSC members come into play, since the REACH text is not clear on where the line should be drawn.

Based on the above reasons, the identification basis was amended and 4-tert-octylphenol was identified as an equivalent concern SVHC because it has endocrine disrupting properties for which "there is scientific evidence of probable serious effects to the environment". However, the MSC has rejected the conclusion that there are also probable serious effects for human health.

Regarding the MSC role on substance evaluation, the consideration on compliance checks decisions apply partially to the MSC. Further, the review didn't look into detail on the MSC behaviour on requesting information to be generated, however it is evident that there are clear obstacles in the MSC towards the generation of information through animal testing. Further, it is of special concern the amount of sessions in the MSC that take place without the presence of observers due to the possible mentioning of information that may be of confidential nature. Closed session usually happen without a thorough legal justification.

Regarding the MSC role on substance evaluation, the consideration on compliance check decisions apply partially to the MSC. Further, the review did not look into detail on the MSC behaviour on requesting information to be generated, however it is evident that there are clear obstacles in the MSC towards the generation of information through animal testing. Further, it is of special concern the amount of sessions in the MSC that take place without the presence of observers due to the possible mentioning of information that may be of confidential nature. Closed session usually happen without a thorough legal justification.

Assessment against REACH objectives and against ECHA's values

In dealing with SVHCs inclusions, we have noted that the MSC has so far **taken decisions which are, overall, in line with the spirit of the REACH protection objectives.** REACH requires members of the MSC to make the identification of SVHC subject to careful attention and in accordance with the precautionary principle. However, discussions in the MSC tend to be drawn into the "paralysis by analysis" dilemma of the past where, before deciding to take action on substances that cause considerable harm, absolute proof of meeting the SVHC properties needs to be provided as well as designed steps taken to generate more information on the use of those substances. This tends to greatly slow the processes. However, in most cases this defensive attitude is raised by a minority of Member States, which have mostly been lobbied by their industry stakeholder groups or have not accepted the paradigm shift inherent in REACH.

ECHA's MSC has also resisted the pressure to delay a decision on the inclusion recommendation as well as any call to further gather and assess information on volume, uses and potential risks or await formally established EDC criteria before taking the substance forward. The MSC made it clear that uncertainties would not disappear if more time was taken for the decision and **showed commitment to well being** by taking action on the basis of information at hand.

On the fundamental question of "to be prioritised, or not to be prioritised", the MSC provided a sensible answer that is **goal-oriented** in fulfilling the substitution objectives under REACH, and the discussion about prioritisation was initiated quite early.[137] The revised document on ECHA's general approach for prioritisation of SVHC for inclusion in Annex XIV has the merit of constituting a tool for improving the efficacy and transparency of the prioritisation approach. It allows an understanding of how all steps in the prioritisation process have been undertaken and makes sure it is adequately documented and justified. **Experience so far has shown that the process is transparent and justifications are provided.**

137 In this respect, it is worth noting that Germany has submitted a very useful paper elaborated by the German Federal Environment Agency proposing an interim strategy to prioritise SVHC according to environmental risk criteria of REACH, which has triggered discussion relating to SVHC identification and prioritisation approaches. (see German Proposal for an interim strategy to identify and prioritise SVHC according to environmental risk criteria of REACH dated 10 June 2009).

ECHA rightly recognises that meeting only one of the three criteria[138] is, in principle, sufficient to prioritise a substance for inclusion in Annex XIV. At the MSC-21 meeting of 7-9th December 2011[139], ECHA also clarified (in relation to the Cobalt II salts inclusion) that the purpose of the scoring system is only to facilitate discussion, and it does not provide precise reflection of reality.

Further, the fact that MSC has recognised and addressed the problem of inter-changeability of groups of very similar chemicals by adopting a "grouping approach" is also a positive approach to driving effective substitution. However, it needs to be noted that the ECHA (MSC) Secretariat was reluctant to address the issue of grouping and deferred discussion on this topic to the CARACAL meetings. It is thanks to the insistence of some MSC members that proposals addressing group of substances in the prioritisation process have been finally addressed.[140]

Finally, the MSC has demonstrated a positive and supporting attitude towards stakeholder participation. NGOs have so far always been able to intervene and contribute to the discussion in meetings. At its 24th meeting on 6-8th June 2012, the MSC agreed to accept an overall NGO representation of up to five NGO observers at any given meeting. The EEB, ClientEarth and Chemsec have been recognised as new observers to future MSC meetings, together with WWF, Greenpeace and HEAL. However, too many agenda items are discussed in closed sessions and often the decisions seem to be arbitrary, so although **the MSC has been generally open it should be more consistent in its transparency policy**.

138 i.e. PBT or vPvB properties or wide dispersive use or high volumes.

139 See minutes of MSC 12 meeting of 9-10 June 2010 (MSC/M.012/2010 Final).

140 See minutes of MSC 12 meeting of 9-10 June 2010 (MSC/M.012/2010 Final , page 6).

Recommendations

The MSC should continue to resist political pressures from certain members and industry relating to the identification and prioritisation of SVHC and rigorously follow the REACH legal text, which states
"[t]o ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and, possibly, to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention.[141]

It needs to make decisions on the identification of SVHC based on the available information at hand. In case of doubt, it should not delay action through requesting further testing or generation of information whilst accepting the risk to cause further potential harm to human health and the environment. In the case of SVHC, this means that it should be sufficient to base decisions on screening data regarding certain properties, in line with the precautionary principle. According to REACH, the burden of proof should be on industry to generate more solid evidence in the event that it considers that the decisions taken by Member States are "too protective " in a particular case.

It should also be kept in mind that adding a certain chemical to the Candidate List will only trigger limited legal effects. In most cases, this means driving innovation within the whole supply chain, which may deliver results faster than the generation of new information on the properties of a given substance, which in turn may only lead to further discussions about remaining scientific uncertainties. It needs to be remembered that the impacts of decisions that turn out to be "overprotective" to the detriment of certain industry players may always be subsequently rectified, whereas damage done to human health or the environment by hazardous substances are often irreversible and may not be remedied by economic compensation.

In the interests of more transparency, opinions of the individual members that rejected the inclusion of a SVHC (minority positions) to the Candidate List or the prioritisation of a Candidate List SVHC to Annex XIV, should always be made publicly available in order to make them accountable to the public and future generations. This approach is already taken in relation to opinions on prioritisation.

141 Recital 69 of REACH.

Risk Assessment Committee (RAC) and Committee for Socio-economic Analysis (SEAC)

The Risk Assessment Committee (RAC) and the Committee for Socio-economic Analysis (SEAC) are the two scientific committees of ECHA. The main function of the RAC is to prepare the opinion of ECHA on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling. The SEAC prepares opinions on applications for authorisation and on proposals for restrictions or can provide opinions on socio-economic issues in relation to substances on request of the Executive Director. Each Member States nominates a representative, but the members are (or should be) independent. Member States that nominated them cannot give any instruction to a member of these committees.[142] Both committees should take decisions on the basis of the available information. REACH's approach to decision-making is, unlike the past, not analytic. Under REACH, when risk from a substance cannot be excluded, regulatory risk management measures should be applied. Observers are also invited to RAC and SEAC meetings.

142 See Article 85(7).

The Risk Assessment Committee

RAC members should base their opinions on available scientific evidence and always adopt a precautionary approach in its decision-making. Based on REACH's approach, the RAC should define whether risk can be excluded and not whether a risk is sufficiently proved. The burden of proof lays on the producers of a substance, not on the institutions. However the RAC does not appear to have understood the basic shift that REACH brought to the regulation of chemicals. An example can be seen by reading the RAC opinion against the proposal for restriction of four classified phthalates (DEHP, DBP, BBP, and DIBP) in articles.[143]

In spite of the fact that all four phthalates are SVHCs, based on their classification as reproductive toxicants category 1B and RAC recognised that "there is concern for reproductive and developmental disorders in the general population, because of combined exposure to these phthalates during the whole lifetime, both in a cumulative way", in its final (fourth) opinion RAC surprisingly does not support a restriction. In the opinion of the RAC, uncertainty or safety factors[144] are overestimated and in this sense its approach has been quite controversial.[145] Thus, despite recognising the widespread presence and exposure to these chemicals, the RAC concluded that there is no risk worth addressing.

143 Opinion on an Annex XV dossier proposing restrictions on four phthalates (ECHA/RAC/RES-O-0000001412-86-07/F).

144 Is a measure index on the differences between individuals due to genetics or other factors since the hazard may be higher for particular groups, called susceptible populations. It is also used to account for the largely unknown effects of animal to human extrapolations, increased variability in humans, or missing data.

145 The 10 fold safety factor is thought to be a 'conservative' judgment, meaning it is on the safe side. However RAC, in many cases, consider 10 fold and even lower factors were considered as "too conservative" or even not needed. The more uncertainties are found, the higher uncertainty factors should be applied (minimum of 10) as a more protective approach. Furthermore, when developmental and reproductive effects are expected, a 10-16 fold safety factor is needed (even an extra factor) in order to protect infants and children. However no extra factor was considered at all by RAC.

In particular, the RAC questioned low-dose effects and adverse effects from combined exposure to several chemicals[146,147,148] which are underestimated in the RAC opinion. Even though the amount of the four phthalates in use might be decreasing, there will still be exposure that could result in adverse combination effects at low doses.[149]

RAC's justification for there being no need for the restriction is based on "the risk to be addressed, taking into account future market trends and the effects of other Community legislation and risk management measures on exposure in the foreseeable future". Given that the RAC accepts that the Danish dossier may have over-estimated or under-estimated some current exposure routes, the RAC conclusion is not robust. Further the RAC has pre-empted with this view the authorisation procedure on the very same phthalates, since it assumes that the authorisation requirement will lower the use, "hence there is no risk". RAC also asserts "substitution to other plasticisers than the four phthalates has been going on for the last 10-15 years. The substitution process is expected to continue in the future". RAC's opinion on phthalates is at odds with REACH.

146 Silva E, Rajapakse N, Kortenkamp, A 2002 Something from "nothing": eight weak estrogenic chemicals combined at concentrations below NOECs produce significant mixture effects. Environ Sci Technol 36:1751–1756.

147 Benachour N, Moslemi S, Sipahutar H, Seralini GE 2007 Cytotoxic effects and aromatase inhibition by xenobiotic endocrine disrupters alone and in combination. Toxicol Appl Pharmacol 222:129–140.

148 Rajapakse N, Silva E, Kortenkamp A 2002 Combining xenoestrogens at levels below individual no-observed-effect concentrations dramatically enhances steroid hormone activity. Environ Health Perspect 110:917–921.

149 In addition, a recent report by the Swedish Society for Nature Conservation ("Home sweet home? – dusty surprises under the bed") shows that citizens are exposed to a wide range of substances from the dust in our homes. The findings showed that the total level of phthalates were in some countries found to be higher than the level which public authorities today consider to be safe, if the combination effects are considered.

Socio-Economic Assessment Committee (SEAC)

Like the RAC, the SEAC is often stuck in the fine details. Although SEAC should decide basing itself only on available information (i.e. information included in the dossiers they receive and information received from public consultations), its members often deem necessary to search for more and more information outside what is made available to them. Further, SEAC's approach on socio economic benefits (of restrictions) is largely in the direction of quantitative analysis. These are highly uncertain on health and ecological impacts. Difficulties arose when realising that a socio-economic analysis (SEA) might be difficult under REACH because of lack of information on exposure routes and response functions and valuation of data. Various methods for quantification of health and ecological impacts exist in the context of SEA but results very much depend on the scoping of the assessment, benefit transfers and how to deal with uncertainties. This is where the impacts of choices made by members of the SEAC are most likely
to affect the goals of REACH.

The SEAC Secretariat has been very keen to promote marginal abatement cost-curves (MAC curves) which have strong limitations. In particular, they often overestimate costs, as the industrial stakeholders most likely to respond to consultations will tend to be those that consider themselves most likely to be adversely affected (amongst other reasons). In addition they tend to not recognize the wider benefits of actions and they only provide half of the cost-benefit equation. Further it is not clear on how these curves should be used in practice.

In addition, as regards various risk management options, it was agreed to focus on the following three criteria: effectiveness (proportionality), practicality and monitorability.[150] Each of those criteria gives considerable discretion to SEAC, which may affect the balancing of public and private interests in assessing the socio-economic factors justifying the regulation of the marketing and use of a substance.

150 See minutes of SEAC 3 (SEAC/M/03/2009 Final).

During the first five years of REACH the SEAC had very little work to do since the Commission and Member States submitted a very limited number of proposals for restrictions. However, the SEAC's approach is evident in some cases where it did not consider fully the benefits of restrictions in relation to human health or environmental protection concern the opinions on the following restriction proposals. Although it made no difference for the final outcome when discussing the **dimethylfumarate (DMFu) restriction**, the SEAC did not take into account the benefits of the restriction on workers protection. However, as a general rule, all effects arising from a proposal should be factored into the analysis. In **mercury in measuring devices**, restriction dossier porosimeters have been excluded from the restriction although emissions from this source may be bigger than from all other combined uses (mainly on the grounds that there is "high uncertainty in the technical feasibility of alternatives"). **In the restriction of Phenylmercury compounds dossier**, it was considered that the cost-benefit assessment (CBA) should exclude non-EU effects of the restriction, although REACH should be applied in a non-discriminatory manner regardless of whether substances are traded on the internal market or internationally (Recital 3) and aims to fulfill the SAICM[151] objectives.

Finally, as for the RAC opinion, the SEAC draft opinion on the restriction of four phthalates[152] does not seem to be consistent with REACH's high level of protection objectives. The draft opinion largely bases its conclusions on RAC's opinion instead of focusing solely on the socio-economic benefits of the possible restriction. It is particularly striking that the SEAC bases its negative opinion on the "ongoing trend of decrease in use of phthalates without taking into account that the inclusion of the substances in Annex XIV for authorisations has no impact whatsoever on the marketing of these substances through the import of articles but it only affects the use of the substance". This means that any article containing the four phthalates could enter without restrictions in the EU (with the exception of articles where restrictions already exist). Finally, SEAC uses the uncertainties of the baseline scenarios as a justification for inaction.

Assessment against REACH objectives and ECHA's values

Regarding the substance of the work of the RAC and SEAC, it has to be pointed out that the reversal in the burden of proof that REACH has promoted was often ignored. Although REACH is underpinned by the precautionary principle that guarantees action even if some cause and effect relationships are not fully established scientifically, the approach of the scientific committees so far has been to adopt opinions only when "strong evidence" is available. Experience in participating in SEAC and RAC has shown that, in the balance in evaluating data has been weighted in favour of industry interests to the detriment of the REACH protection objectives.

In most cases, uncertainties about technical feasibility or costs of alternatives serve as a pretext for not acting on known hazardous substances of concern, meaning that the REACH objectives of substitution and innovation will not materialise. There has been criticism within SEAC that data brought before them in order to provide for an informed opinion was often limited.

In particular the approach of RAC and SEAC on substance restriction proposals has been slow and not protective for human health and the environment. As shown in the phthalates restriction opinions, "the reversal of the burden of proof" and the high environmental and human health protection objectives of REACH seem not to be accepted or understood by ECHA's scientific committees. They should advise on whether there is a need for restriction based on the best available data at this time, and not suspend action until new data is available. This approach is at odds with the REACH spirit and paradigm shift. Such approach benefits those who continue to profit from the marketing and use of SVHC, especially those imported in the EU. However this will not support frontrunner companies that have invested resources in order to be ahead in substitution of hazardous chemicals.

Based on the above it is therefore legitimate to question whether all members are motivated and committed to well being.

151 Strategic Approach to International Chemical Management adopted on 6th February 2006 in Dubai, implementing the 2020 global goals of minimisation of significant adverse effects on human health and the environment.

152 Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on four phthalates.

In relation to transparency and openness in decision-making, NGOs participation in these meetings has not always been easy, particularly in the RAC where many more discussions of specific substances have taken place. However, we welcome the fact that ECHA enables the participation of NGOs at meetings in Helsinki by covering the travel and accommodation costs. In relation to decision-making processes, improvements have been made. Initially, observers were not even allowed to comment on the minutes of the meetings of the RAC, particularly when the discussions focused on data that was considered to potentially be of commercial interest. Indeed, "confidential" documents and closed meeting sessions have hindered the effective participation of NGOs in committee meetings.

It is worth noting that the SEAC has not experienced any problems as a result of holding open sessions thus far. The intention to hold closed sessions in the future, in particular in the assessment of authorisation applications, would not only undermine the transparency commitments of ECHA but also put into question a working approach which functioned well in the past.

Recommendations

The Committees should follow the spirit (and letter) of REACH in considering the available information when forming their opinion. Slow and too analytical processes are the reasons REACH was deemed necessary. Uncertainties should not work in the favour of the chemical industry; citizens are not guinea pigs and the "wait and see" approach will not benefit human health and the environment. This means that members of the committees need to be more courageous in their decisions when they deal with uncertainties or assumptions. It is thus urgent that both these committees reconsider their approach to forming their opinions, especially as they will soon have a major increase in workload when, based on new information and of a higher number of substances in Annex XIV, they will have to process a large number of requests for authorisation and a higher number of restriction proposals.

SEAC, RAC and the ECHA staff supporting them need to metabolise the shift that REACH brought and to rethink the role of these scientific committees in the context of REACH. Further, it must be taken into account that the impacts of restriction decisions and authorisations that turn out to be "overprotective" to the detriment of certain industry may always be rectified later on, whereas damage done to human health or the environment by hazardous substances are often irreversible and may not be remedied by economic compensations. However, there are hundreds of examples of decisions taken too late and almost no examples of decisions being overprotective.[153]

In order to change the approach of the scientific committees it would be perhaps useful to reformulate the questions that are responding. The RAC should assess whether risks can be excluded from the marketing and use of a substance, while SEAC should assess also from a qualitative perspective, whether the continued use of an SVHC outweighs the benefits of its restriction.

153 See Late lessons from early warnings: the precautionary principle 1896–2000, European Environmental Agency, 2001.

ECHA FORUM

The Forum for Exchange of Information on Enforcement is the first experiment of its kind for enforcement authorities that coordinate their efforts in achieving REACH's goals. The Forum has positively established its work and carried out compliance projects. However, it lacks a vision of what it would like to achieve with its coordinated enforcement strategy. Finally, the Forum has not been reactive to two main problems concerning REACH registration: the registration of substances as "intermediates" without proof that "strictly controlled conditions" are met, and the lack of registration of a large number of chemicals classified as CMRs.

REACH created the Forum for Exchange of Information on Enforcement in order to give a formal framework to the existing enforcement network. The aim of the Forum is to coordinate enforcement activities across the European Union. The Forum, which is a body of ECHA, is composed of enforcement experts from Member States. A further five members can be chosen for their expertise and co-opted to the Forum. The Forum has various functions in relation to REACH enforcement strategies and practice[154].

The Forum has initiated three projects to check the implementation of certain provisions of REACH: En-Force-1, focusing on pre-registration obligations and safety data sheets compliance; the REACH En-Force-2, focusing on downstream users' obligations; and a third project (in preparation) which will focus on the relation with customs authorities. Further, the Forum has compiled some useful guidance on inspections and checklists for inspectors when performing an onsite inspection.

In the case of intermediates, ECHA has highlighted that a large number of substances were registered as intermediates without following the legal texts which provides for a simplified registration obligation when a substance is an intermediate used under "strictly controlled conditions". As highlighted in the section on intermediates both the interpretation of the definition of "intermediate" and the interpretation of how to apply "strictly controlled conditions" were disputed by industry associations. Due to the constraints in the legal text that do not allow dossier evaluation for intermediates, only enforcement actions could correct eventual breaches of REACH.

The Forum has not reacted to this exceptional threat at the registration phase with a coordinated action and reporting of results in a timely manner. However, a pilot project is being carried out as a follow up of ECHA's Article 36 letters and the outcome should be known by the end of 2013.

A further issue concerns missing registrations of hundreds of CMRs. In the case of missing CMRs, ECHA prepared a report on the fact that only 406 CMR out of the 1116 substances with a harmonised classification have been registered.[155] However, the large number of non-registered CMRs is a cause of concern which should have been addressed by the Forum as a matter of priority, in coordination with the ECHA Secretariat. After all, not registering a substance is one of the breaches that bring the highest penalties under REACH.[156] In 2012 ChemSec issued a report documenting that a number of non-registered CMRs were still on the Swedish market in the years before the first registration deadline.[157]

154 See Article 77 (4).

155 This figure, is subject to limitations in the research performed by ECHA. See, "CMR substances from Annex VI of the CLP Regulation registered under REACH and notified under CLP – a first screening" (ECHA-12-R-01-EN), page 12.

156 Reference to Milieu Report, 2010.

157 http://www.chemsec.org/images/stories/2012/news/SIN_List_CMRs_not_registered_with_ECHA_compared_with_Swedish_Product_Register_data.pdf.

Assessment against REACH objectives and ECHA's values

Altogether, the experience of the Forum has been positive as it is creating harmonised implementation experiences, which are particularly helpful for smaller countries that have less resources and experience in the enforcement of chemicals legislation. Such action has a positive effect in guaranteeing a uniform treatment of companies in the enforcement of certain key provisions of REACH. However, the Forum is mainly focusing on the compliance with specific REACH provisions without aiming at achieving the general objective of the Regulation to protect citizens and the environment from chemicals of concern.

The Forum so far has **acted in an independent way** and the professionalism and experience of its members make it **trustworthy in its decision-making**. However, the Forum has a **serious problem with the transparency** of its proceedings. So far no stakeholder has been invited to the meetings of the Forum, except for yearly stakeholder open sessions in which stakeholders are invited to give input to the work of the Forum, but without the Forum having consequently to address any issues raised.

Despite the **positive experience from the work of the Forum in terms of harmonization of inspections, exchange of information, and testing compliance on specific REACH obligations**, the Forum has not been reactive to the unexpected challenges that the REACH implementation has brought to the system. The above mentioned examples (intermediates and not registered CMRs) are particularly worth highlighting.

Finally, the Forum, limiting itself to mere compliance to basic provisions of REACH, does not directly stimulate the safe and sustainable use of chemicals through its coordinated enforcement actions.

Recommendation

The coordination role of the Forum is essential in guaranteeing that regulations are enforced in a harmonised way and that the objective of REACH is pursued in a uniform way. Therefore, although considering that the experience, so far, has been positive, we recommend that the Forum should:

- **Become more transparent:** discussions over enforcement strategies, checklists for inspectors and general principles of enforcement rarely raise concerns of confidentiality. Stakeholders should be able to participate and give input to the work of the Forum.
- **Be reactive:** NGOs have highlighted specific shortcomings in the implementation of REACH such as non-compliance with the obligation to communicate information on SVHCs in the supply chain and examples of CMRs not registered but likely to be still on the market. The Forum should try to respond to these concerns with coordinated enforcement actions.
- **Look at the larger picture:** The Forum as an ECHA body is committed to stimulate the safe and sustainable use of chemicals. It should therefore seek, together with its compliance programmes, to identify strategic provisions that would ensure that hazardous chemicals are used and marketed in a safe way, in particular, chemicals used in consumer products.

Board of Appeal

ECHA's Board of Appeal would be a very useful and effective independent body to resolve issues on the implementation of REACH by ECHA. The Agency should take greater advantage of the existence of the Board of Appeal and seek to develop an "internal jurisprudence" on REACH instead of applying cautious interpretations of REACH which tend to undermine the achievement of REACH goals and data generation. ECHA should set minimum targets for appeals in order to show commitment to a new courageous role in the implementation of REACH.

REACH established a Board of Appeal within ECHA to guarantee processing of appeals for any natural or legal person affected by decisions taken by the Agency. The Board of Appeal is part of ECHA, but it takes decisions independently. The Board of Appeal consists of a Chairman and two other members who are appointed by the Management Board together with alternate members. The following decisions are subject to an appeal:

- Exemptions from the general obligation to register for PPRD
- Rejections of registrations under completeness check
- Sharing of existing data in the case of registered substances
- Sharing of data involving tests
- Examination of testing proposals
- Compliance check of registrations

Although several issues around dossier quality have been highlighted by ECHA, the number of appeals against ECHA's decisions has been very low. Only 11 appeals have been submitted to the Board. Out of the 11 appeals, no decision was taken in six cases, following either withdrawal by the appellant (in two cases) and rectification of the decision under appeal by the Executive Director (in four cases)[158]. Only two decisions have been taken so far with the remaining three pending.

However limited, the jurisprudence of the Board of Appeal has:

- Defined the power of the Board to raise new grounds for the possible annulment of the contested decision in application of Article 93(3) which provides for the power of the Board to "exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action".[159]
- Highlighted ECHA's breaches of the principles of good administrative behaviour, particularly in relation to updating ECHA's procedures, FAQ documents and providing clear, accurate and precise communications.[160]
- Clarified ECHA's obligation to reject registrations when a fee is not paid within the required deadline.[161]

158 The Executive Director has the power of rectifying a contested decision pursuant to Art. 83(2)(m) after consulting with the chair of the Board of Appeal.

159 See case A-001-2010, paragraphs 1.2, pages 8-9.

160 Ibid. paragraphs 3.1.2, 3.1.3, 3.1.4.

161 See Case A-004-2011, page 11.

Surely, after five years of REACH, it would have been useful to have had decisions on the interpretation of ECHA's powers regarding rejection of incomplete dossier registrations, or to the limit of ECHA's power to address insufficient risk management measures in the registration dossiers and on other crucial provisions for the implementation of REACH. It appears, also through the practice of rectifications of contested decisions, that appeals are perceived by ECHA as a failure rather than a signal that ECHA is actually acting in order to achieve a high level of protection of the environment and of human health and, thus, seeking to define the limits of its powers to achieve the goals of the REACH.

Assessment against REACH objectives and ECHA's values

The Board of Appeal has not yet issued decisions that have an impact on the fulfillment of REACH's objectives. It will be crucial to interpret the procedural elements of REACH in the light of its basic principles.

Transparency: Every appeal is public as are final decisions, as prescribed by the rules of procedure.

Independence: Ensuring the independence of the Board of Appeal is a big challenge. The Board is a part of ECHA and must be independent from it but, at the same time, the members of the Board are part of ECHA's staff and work in the same building. In addition, appeals are likely to be brought mainly by companies, since the rules for access to the European Courts also apply to the Board of Appeal[162] so a considerable amount of pressure can be exercised on its members.

Trustworthiness: So far the Board's decisions are of high legal quality and take into account all aspects of REACH as well as the jurisprudence of the European Courts. Their outcome establishes great confidence in the work of the Board of Appeal.

162 See Article 92 of REACH.

Recommendation

The Board of Appeal can be a key actor in the development and implementation of a highly ambitious policy on safe and sustainable use of chemicals. The Board has no influence over the number of appeals brought to them. Therefore, these recommendations are addressed to ECHA's Secretariat and the Executive Director:

- Be courageous - do not try to avoid appeals (in particular on rejected registrations failing completeness checks and con compliance check decisions).
- Make use of the power to rectify contested decisions under appeal only in exceptional circumstances recognising that decisions of the Board of Appeal can clarify many substantial and procedural issues on the functioning of ECHA.
- Take active measures to promote the Board's independence (e.g. organise workshops with stakeholders, consider a different location for the Board of Appeal).
- Support the Board of Appeal by increasing its staff and resources.

ECHA's independence and conflicts of interest

REACH seeks to phase out hundreds of chemicals from the market that bring large profits to the chemicals industry - one of the most influential commercial sectors in the EU. ECHA should be extremely careful in its recruitment process and have clear and transparent policies for hiring former industry representatives and, particularly, ex-lobbyists. Financial and cultural biases in the implementation of REACH are difficult to reverse and ECHA has done little to demonstrate its commitment to independence.

REACH places an obligation on ECHA to be independent from vested interests in order to guarantee the confidence of other EU institutions, Member States, the general public and interested parties.[163] For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, as well as transparency and efficiency. For this reason, a number of declarations of interests have to be made.[164]

When dealing with the chemicals industry, regulatory independence is extremely important. In 2001 CEFIC, the main lobby of the chemical industry, addressed a letter to MEPs saying, against all scientific evidence, that "there is little direct evidence of widespread ill health or ecosystem damage being caused by the use of man-made chemicals".[165] The obstruction tactics and the alarmism from the chemical industry did lead to the "watering-down" of REACH, which nevertheless remains a powerful tool. It was likely that with the creation of ECHA, the practice of revolving doors would be continued[166] in ECHA. However, ECHA did not set up a strong and transparent policy on how to deal with conflicts of interest.

Despite requesting a declaration of interests from its future employees, it is not clear to what extent this declaration influences the recruitment process.[167] In particular, some high level ECHA staff have been identified as coming straight from industry lobbying positions and being responsible for taking decisions on chemicals, which may have an impact on the chemicals' market life. Problems have been identified, such as the selection of members of ECHA's committees, where long-standing industry representatives were appointed to an ECHA Committee.[168,169] However this is a shared responsibility of Member States, which have pre-selected their candidate for nomination, and the ECHA Management Board who has finally appointed them based on the list of nominees,
in the absence of an adequate conflict of interest policy.

After an access to documents request from which ClientEarth and Friends of the Earth Europe obtained the declarations of interest of two high level members of ECHA's staff,[170] ECHA's Director of Regulatory Affairs sent a lette r explaining that the procedure to evaluate chemicals in ECHA is performed in such a way that the involvement of the Director for Evaluation and of Heads of the Evaluation Unit only arises in the final steps of the dossier evaluation process. Further, when final discussions are held before the draft decision is finalised, staff members that may have a conflict of interest do not participate to those discussions. This explanation is difficult to accept and comprehend and it is not clear how it would be possible for a staff member of ECHA to perform any activity if they have been active lobbyists for the entire chemicals industry for several years, thus giving, for any activity, the perception of a conflict of interest.

163 Recital 95.

164 See Articles 83, 84, 87, 88 and 90.

165 Perroy, A. 2001. Director-General, European Chemical Industry Council (CEFIC). Letter to MEPs, 12th November 2001. In Caulkin, S. & Collins, J. 2003.The Private Life of Public Affairs. Green Alliance,August 2003.

166 See examples of this practice during the REACH negotiation in Greenpeace's 2006 publication "Toxic Lobby", page 13.

167 See "ECHA Guidance on conflicts of interest and invitations and gifts, as well as declarations of commitment, confidentiality and interests (Decision of the Interim Executive Director ED/01/2007)."

168 See ECHA Guidance on conflicts of interest and invitations and gifts, as well as declarations of commitment, confidentiality and interests (Decision of the Interim Executive Director ED/01/2007).

169 See CV of SEAC member Z. Slezak and his comments to the inclusion of two phtalates in the candidate list.

170 See declarations of interests in Annex VII.

However, ECHA has realised the flaws in addressing potential conflicts of interest and has approved a new "Policy for Managing potential Conflicts of Interests"[171]. The policy establishes an Ethical Committee with a consultative function within ECHA. The Committee is composed of three members, one of whom is external to ECHA and has consultative functions on potential conflicts of interests. For the moment, the Committee is not yet functioning and no rules for addressing conflicts of interests have yet been established.

Assessment against REACH objectives and ECHA's values

Having an interest in ECHA's scope of work does not automatically mean that there is a conflict of interest. However, potential conflicts of interest have to be taken very seriously, not only when they involve financial interest, but where there is an intellectual bias that needs to be avoided. ECHA has implemented a rigorous system of declarations of interest and systematically makes public the declarations of interest of Committee Members and of the Executive Director, thus showing a sufficient level of transparency by making these declarations public. However, ECHA has failed to put in place a system that avoids infiltration by representatives of vested interests. This contributes to the perception that ECHA is somewhat biased in favour of industry and that its decisions are strongly influenced by industry representatives. [172]

171 See Document MB/45/2011 final.

172 See Final Report the Review of the European Chemicals Agency, (PWC) page 6.

Recommendations:

Corporate influence in the regulation of chemicals is not only a risk, but a reality. Despite the presence of few innovative companies who invest in cleaner production processes and prioritise the substitution of dangerous chemicals, the priority for chemicals manufacturers and downstream users is to profit from chemicals, despite their potential negative effect on human health and on the environment. ECHA should bear this in mind and implement strategies to minimise corporate influence:

- **Lobbyists:** of private interest representatives of industry affected by REACH should not be allowed to become part of ECHA' staff where potential conflict of interest may arise without a cooling off period of at least five years.
- **Establish registers** of staff leaving ECHA. ECHA's former staff should not be allowed to represent industry in their relations with ECHA for the five year period following the end of their appointment in order to disincentive former staff to take advantage of their network at ECHA.
- **Ethical committee:** it should have both a reactive role when civil society denounces possible cases of conflicts of interest and an active role by discussing the appointment of any ECHA staff and members of committees who have strong links with the chemical industry. Further, the functioning and composition of the ethical committee which will act on request of the Executive Director and which have two out of three members that are internal to ECHA, should be reviewed within one year of its appointment.
- **Be transparent:** the names and titles of all ECHA staff should be made public together with the declaration of interests of all Directors and Heads of Unit. If ECHA thinks that their experience with the chemical industry does not impair their public interest role in working with ECHA, the public should know the justifications.

Annexes

Below is a list of documents which can be accessed online (click to open).

I. Registration Audit

II. Assessment of QOBLs 2009-2011

III. Compliance check decision

IV. Response to access to document request 1, 2 and 3

V. Second response to access to document request

VI. Registered SVHC dossiers audit spreadsheet

VII. Declaration of interests

EUROPEAN
ENVIRONMENTAL
BUREAU