EUROPEAN ENVIRONMENTAL BUREAU

A Roadmap to Revitalise REACH

REACH AUTHORISATION PROCESS
A Critical Assessment

Authors: Dolores Romano and Tatiana Santos
Project coordinator: Tatiana Santos
Editors: Pieter de Pous and Philippa Nuttall Jones

The authors would like to thank: Tony Musu, Ninja Reineke, Lisette van Vliet, Ken Huestebeck, Vito Buonsante and Julian Schenten

EUROPEAN ENVIRONMENTAL BUREAU

The European Environmental Bureau is the environmental voice of European citizens, standing for environmental justice, sustainable development and participatory democracy. We seek to ensure a healthy environment and rich biodiversity throughout the European Union and beyond.

Boulevard de Waterloo 34
B-1000 Brussels, BELGIUM

Tel +32 2 289 1090 | Fax +32 2 289 1099
eeb@eeb.org | www.eeb.org

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EXECUTIVE SUMMARY

Since the Regulation concerning

the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was approved in 2006, substantial progress in the management of chemical substances has been achieved in Europe. Although many substances of high concern are still produced and used in the EU, companies and other stakeholders now have a better knowledge of them and their risks, thereby improving risk management measures and increasing substitution.

Despite these advances, much more effort is needed to move towards a cleaner and greener production and use of chemicals and to achieve the commitment elucidated in the Seventh Environmental Action Programme (7EAP) of developing by 2018 an EU strategy for a non-toxic environment. One part of the REACH regulation vital to achieving these aims is the authorisation process, introduced to ensure the substitution of substances of very high concern (SVHC) by safer alternatives.

Authorisation recognises that our society does not want substances that are identified as being of very high concern; under REACH, only in exceptional circumstances, when a benefit for society is proved to outweigh the risks and there is no other possible alternative, may continued use of a SVHC be granted. Nevertheless, to date, all authorisations applied for have either been granted by the Commission or are recommended by ECHA to be granted—even applications that did not meet basic legal requirements such as demonstrating adequate control of the risks or that benefits outweighed the risks, and/or where safer alternatives are in fact already available in the market.

Authorisation shifts the burden of proof so that it is now the operator's responsibility to demonstrate that dangerous substances are either necessary for the benefit of society (and there are no alternatives) or are adequately controlled, if they aim to use, manufacture or import an SVHC (listed in Annex XIV). Even applications that did not meet basic legal requirements such as demonstrating adequate control of the risks or that benefits outweighed the risks, and/or where safer alternatives are in fact already available in the market. The European Commission stopped the inclusion of SVHC in Annex XIV in August 2014 and has focussed its efforts on "simplifying and streamlining" the applications for REACH authorisation process in line with its "better regulation" agenda. However, these efforts have led the process to become more burdensome and ineffective since they add new steps and demand duplicated information.

The committees of the European Chemical Agency (ECHA), which are responsible for overseeing the process, have been granting all authorisations by default, while the Commission is allowing the committees to develop important political and social opinions such as providing conclusions on the proportionality of an authorisation when the risk to society is not adequately controlled in the guise of technical arguments which the Commission simply then rubber-stamps.

The EEB has been following closely the process, actively participating in it as far as we have been allowed. This report offers a critical assessment on the implementation of the authorisation chapter in relation to its aims as established by the REACH Regulation and provides proposals to improve the process.

MAIN CONCLUSIONS

Authorisation has started to deliver! Although authorisation is a very 'young' process, we can already identify many positive impacts: the Candidate List is an important driver to encourage companies to replace SVHC with safer alternatives; applications for authorisation have not been submitted by the "sunset date" for half of the substances included in Annex XIV, meaning that they are no longer on the market in the EU (unless introduced through imported articles); public consultations are showing the technical and economic feasibility of safer alternatives in the supply chain; substitution plans are foreseen for several uses, which will result in the use of safer alternatives; and the risk management of chemicals is improving as a result of the application process, as companies attempt to prove adequate control of the risks from SVHC.

The implementation of authorisation by the Commission and ECHA is preventing REACH from reaching its ultimate goal of protecting people from dangerous substances.

The decision by the Commission and ECHA to grant (or recommend) all applications for authorisation by default, even when safer alternatives are known to be available or when the analysis of alternatives is inadequate, undermines the authorisation process, supports a "business-as-usual" approach by which authorisations become permits to pollute, and creates an economic disadvantage for companies that have invested in safer alternatives.

ECHA's risk assessment and socio economic analysis committees (RAC and SEAC) need to improve their assessments. In particular, SEAC's narrow interpretation of technical and economic feasibility means that alternatives appear as unsuitable, even if they are available. Furthermore, SEAC's methodology for socio-economic assessment systematically overestimates the benefits for applicants and underestimates the costs for society as a whole for the continued uses of the SVHC. RAC should take all available science into account when delivering its opinion, including low dose effects of certain chemicals and the combined exposure to several SVHC in the same use.

The Commission should focus on achieving substitution, the main goal of the authorisation process, as well as on improving its implementation as a whole by making it more efficient. Instead of favouring certain sectors, namely those that lobby hardest, and making it easier and cheaper for companies producing and using obsolete chemicals using SVHC to get authorisations, improvements should be targeted at fulfilling the goals set by REACH: making it simpler for Member States to nominate substances for the SVHC Candidate List; getting all SVHC recommended by ECHA in Annex XIV; and supporting more rigorous decisions on substitution.

EEB RECOMMENDATIONS

To the Commission:

- Facilitate the process of including substances in both the Candidate and Authorisation Lists to better contribute to the overall goal of the authorisation process, which is to assure that SVHC are replaced by safer alternatives.
- Give a clear mandate to ECHA to give favourable opinions only for specific, well documented and well justified applications and to reject applications for broad uses of SVHC at the conformity check stage.
- Reject granting authorisations for uses for which safer alternatives are already available in the European market and broad use applications not previously rejected by ECHA, including authorisations for the use of DEHP in raw and recycled PVC, HBCDD in FR EPS, and lead chromate pigments.

To ECHA:

- Apply the burden of proof placed by REACH on applicants for authorisation. RAC and SEAC should not be redoing, rewriting or revising applications.
- Reject, at the conformity check stage, applications not complying with REACH information requirements, such as applications for broad uses, missing fundamental information on exposure scenarios, alternatives and/or socio-economic assessments. A review of the conformity check procedure is critically needed as ECHA considers it only a completeness check.
- Encourage third parties' contributions to the public consultations on alternatives.
- Improve the technical quality and scope of RAC's and SEAC's assessments.
- SEAC should improve socio-economic assessments by including all costs for society as well as the profits for competitors producing alternatives. A better balance between costs for the applicant and external costs associated with SVHC is needed.

To Member State Competent Authorities:

- Speed up the inclusion of SVHC in the Candidate List and demand the speeding up of the inclusion of SVHC in the Authorisation List.
- Commit to a minimum number of proposals of SVHC in the Candidate List. Member States with limited resources could make use of Article 59 to submit proposals of SVHC with a harmonised classification while Member States with greater resources could focus on substances of equivalent level of concern under Article 57(f) such as EDCs.
- Vote against the granting of authorisations to applications that did not fulfil the criteria established by the REACH legal text, for example when broad uses are applied for or when alternatives are shown to be available during consultations.

To Members of the European Parliament

- Demand that the Commission speeds up the inclusion of SVHC in the Candidate and the Authorisation lists.
- Follow up and review the procedures and outcomes of the Commission's and ECHA's work regarding the authorisation of SVHC.
- Demand the Commission follows the requirements established in the REACH Regulation when deciding on granting authorisations and oppose authorisation decisions otherwise.

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FOREWORD

Since Europe's flagship chemicals legislation, the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), was approved in 2006, substantial progress in the management of chemical substances has been achieved in Europe.

The registration of chemicals under REACH, despite shortcomings in the process, is giving rise to better knowledge of the chemicals used in Europe. Although many substances of high concern are still produced and used in the EU, companies now have a better understanding of them and their risks, thereby improving risk management measures and increasing substitution.

However, this should only be the beginning of the story. Despite these advances, much more effort is needed to move towards cleaner and greener production and use of chemicals and to achieve the commitment in the Seventh Environmental Action Programme (7EAP) of developing by 2018 an EU strategy for a non-toxic environment.

One part of the REACH regulation that is vital to achieving these aims is the authorisation process that was introduced to hasten the substitution of substances of very high concern with safer alternatives.

Authorisation recognises that consumers should be protected from these substances in the products they buy and that these chemicals should be phased out. The only exception to this is in genuinely exceptional circumstances where alternatives are not available or the costs to society are too great. Furthermore, under this process, the burden of proof is on operators to demonstrate that hazardous substances are necessary for the benefit of society.

This all sounds very good in theory.

But in practice the process is not working so well - too few substances are being put forward for authorisation, meaning that too few hazardous substances are being phased out, putting human health and the environment at risk. This report underlines these flaws and sets out a clear path for reform showing how the authorisation procedure can be made fully fit for purpose. Even more worrying, earlier initiatives to simplify and streamline the process as part of the Commission's Better Regulation agenda have made the process less effective.

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The Commission missed a golden opportunity to boost the chemicals regulation when it announced its Work Programme for 2016 in November. We hope the EU executive will take the findings of this report forward without delay. Although all parties have a key role to play, it is the European Commission which should ensure that European citizens and the environment receive the best possible protection from dangerous chemicals.

Our intention with this report is to defend the REACH Authorisation process as the main regulatory tool to protect human health and environment from exposure to harmful chemicals as well as to contribute to make the process to be really effective in achieving the REACH protection goal.

Jeremy Wates
Secretary General

1. INTRODUCTION

1.1. Introduction to the report

Since the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was approved in 2006, substantial progress in the management of chemical substances has been achieved in Europe. The registration of chemicals under REACH, despite shortcomings in the process, is giving rise to better knowledge of the chemicals used in Europe. Although many substances of high concern are still produced and used in the EU, companies now have a better understanding of them and their risks, thereby improving risk management measures and increasing substitution.

Many companies have moved to safer alternatives and are using systematic tools for evaluating their chemicals.[1] These include SUBSPORT[2], a database that compiles hundreds of substitution case studies, and the OECD substitution tool box[3]. This trend needs to continue so that companies that are lagging behind also start moving to safer alternatives, meaning that all companies become toxics-free. But much more needs to be done in order to achieve both the objectives of REACH and the commitment elucidated in the Seventh Environmental Action Programme (7EAP) of developing by 2018 an EU strategy for a non-toxic environment.[4]

One part of the REACH regulation that is vital to achieving these aims is the authorisation process that was introduced to hasten the substitution of substances of high concern with safer alternatives. Authorisation recognises that our society does not want substances that are identified as being of very high concern; only in exceptional circumstances, when a benefit for society is proved to outweigh the risks or no substitute exists, may continued use be exceptionally granted.

Authorisation is intended to improve the former situation, where any substance could be marketed until public authorities demonstrated that a specific use of a substance posed an unacceptable risk to human health or the environment (the so-called restriction process). Authorisation shifts the burden of proof so that it is now the operator's responsibility to demonstrate that dangerous/hazardous substances are either necessary for the benefit of society or adequately controlled.[5] Under the authorisation process, companies aiming to use, manufacture or import a substance of very high concern (listed in Annex XIV of the Regulation) have to apply for an authorisation. This means that once a chemical is added to Annex XIV, only the uses of the chemical for which a company has applied for and been granted authorisation will be allowed in the EU. All other uses must end after a specific date.

Authorisation is therefore the main legal instrument the EU has to eliminate the most hazardous substances from our workplaces, goods and environment.

The REACH authorisation chapter has been running for more than seven years and the committees of the European Chemical Agency (ECHA), which are responsible for overseeing the process, have already delivered 44 opinions on applications for

1 ECHA Newsletter includes case stories of companies that have changed to safer alternatives. *http://newsletter.echa.europa.eu/*

2 SUBSPORT Substitution Support Portal *http://www.subsport.eu/*

3 *http://www.oecdsaatoolbox.org/*

4 EEB, CHEM Trust, Friends of the Earth and Zero Waste Europe. The Circular Economy and REACH: an essential partnership. *http://www.eeb.org/index.cfm/library/the-circular-economy-and-reach-an-essential-partnership/*

5 Will we reach our chemical goals? Newsletter # 70 metamorphosis, European Environmental Bureau, December 2013: *http://www.eeb.org/?LinkServID=CADFCE19-5056-B741-DBA130A08A0A11D0&showMeta=0&aa*

Photo: MMU Library Services

authorisation. NGOs have been following closely the process, participating in it as far as they have been allowed. This report intends to offer a critical assessment, from an NGO perspective, on the authorisation chapter in relation to its aims as established by the REACH Regulation. The report also intends to provide proposals to improve the process.

1.2. REACH Authorisation process

This chapter describes in brief the details of the REACH authorisation process in theory, including its steps, timelines and stakeholders involved.

The ultimate aim of the authorisation process as stated by the legal text (see annex I) is to assure that substances of very high concern (SVHC) are progressively replaced by safer alternative substances or technologies where these are economically and technically viable {Art.55}.

To achieve this, SVHC are divided into two groups, and both groups are subject to authorisation on a case-by-case basis, but under different criteria. For the first group, substances where 'safe thresholds' of use or exposure can be established, the applicant has to demonstrate that the risks related to the use of the substance concerned are "adequately controlled" in order to obtain an authorisation.

For the second group of substances, where safe thresholds of use or exposure cannot be established, an authorisation may nonetheless be granted if:

— the socio-economic benefits outweigh the risks to human health or the environment arising from the use of the substance; and

— there are no suitable alternative substances or technologies.

SVHC that are not granted an authorisation cannot be marketed directly in the EU after the established sunset date. However, they can still enter the EU market through imported articles.

This is not the only limitation of the authorisation process, it is also flawed by the exclusion of:

— risks arising from hazard properties other than those in Annex XIV;

— risks arising from the manufacturing process of a substance;

— risks from substances used as intermediates in the manufacture of other chemicals;

— risks from certain uses, including research and development (R&D), medicinal products, food and feeding stuffs, cosmetics, food contact materials, medical devices, biocides, pesticides, certain fuels, use in mixtures below certain concentration limits.

In order to minimise the number of articles containing SVHC being imported into the EU, REACH establishes that after the sunset date, ECHA shall prepare restriction proposals if it considers that the risks from these substances are not being adequately controlled.

The authorisation process comprises the following steps:

1. SVHC identified
2. SVHC prioritised (and officially listed) for the authorisation process
3. Companies apply for authorisation
4. ECHA committees give opinions
5. Final decision by the European Commission after consultation of Member States

Step 1: Identification of substances of very high concern and inclusion in the Candidate List

The first step of the authorisation process is to identify those chemicals whose intrinsic properties and potential to damage health and the environment are so significant that their use, presence or discharge into the environment should be avoided. REACH Article 57 lists the hazardous properties agreed to denote the substances of very high concern:

— carcinogenic, mutagenic or toxic to reproduction (CMR) classified in category 1A or 1B according to 1272/2008 Regulation;

— persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances according to the criteria in Annex XIII of the REACH Regulation; and

— substances identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to humans or the environment of an equivalent level of concern as those above, for example endocrine disruptors.

Substances of very high concern are identified by a process involving proposals from Member State Competent Authorities or ECHA (on behalf of the European Commission) and decisions taken by the ECHA Member State Committee. Member States prepare a dossier – known as an "Annex XV dossier" – to propose a substance, and interested parties can comment during a public consultation. Subsequently the Member State Committee decides whether the substance should be subject to authorisation and, if so, puts it on the so called "Candidate List".

The Member State Committee must unanimously agree for a proposed substance to be officially recognised as a SVHC. If there is disagreement, the European Commission decides by Comitology procedure including Member State representatives).[6]

6 An explanation on how the Comitology procedures work can be found at the EU Commissions website: *http://ec.europa.eu/transparency/regcomitology/index.cfm?do=implementing.home#2*

The Agency publishes and updates the Candidate List every six months.[7]

When substances are listed as being of very high concern, companies subsequently have to comply with certain legal obligations, such as:

- Providing workers and consumers (the latter on request) sufficient information to allow the safe use of articles which contain substances on the Candidate List in a concentration above 0.1% (w/w) {Art. 33)}.
- Within the supply chain, providing the recipient of the substance with a safety data sheet {Art. 31(1)}.
- Producers or importers of articles also have to notify ECHA if their article contains a substance on the Candidate List in quantities totalling over one tonne per producer or importer per year and above a concentration of 0.1% (w/w) {Art. 7(2)}.

Therefore, one of the added values of the Candidate List is the "right to know," which enable EU citizens to find out which SVHC are present in the consumer products they purchase, to make informed choices and to avoid products containing harmful chemicals, so creating pressure on industry to develop safer products. The Candidate List is therefore an important tool to accomplish REACH's aim of ensuring a high level of protection of human health and the environment and promoting substitution.

The Candidate List can be found at: *http://echa.europa.eu/web/guest/candidate-list-table*

Step 2: Prioritisation of substances in the Candidate List and inclusion in Annex XIV (Authorisation list)

In principle, all substances included in the Candidate List will eventually be subject to the authorisation process {Art. 59(1)}. The REACH law lays out a procedure to prioritise which candidate substances go first through the authorisation process (listing on Annex XIV). Priority should normally be given to substances that are persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), those that have wide dispersive uses or that are produced in high volumes. The Agency should submit substance recommendations to the Commission at least every second year {Art. 58(3)} after consultation of Member States.

Interested parties can submit comments during this procedure. The Commission then decides by comitology:

- whether or not a substance recommended by the Agency will be subject to authorisation;
- which uses of the substances included in Annex XIV will not need authorisation (e.g. because sufficient controls established by other legislation are already in place);
- the "sunset date" by when a substance can no longer be used without authorisation.

The Authorisation list can be found at: *http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list*

Step 3: Applications for Authorisation

Manufacturers, importers or downstream users wanting to continue marketing, importing or using a substance included in Annex XIV (Authorisation List) should apply for authorisation at the latest 18 months before the sunset date.

Applications for authorisation are read and assessed by two committees in ECHA – the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC). These committees are made up of experts nominated by Member States and chaired by the ECHA Secretariat staff. The Agency's committees have 10 months to give their draft opinions after receiving an application.

An application must specify both the identity of the SVHC and the specific use(s) for which authorisation is sought. Therefore, a single company may submit separate applications for different uses of the same substance. Each application shall be assessed individually by RAC and SEAC.

7 *http://echa.europa.eu/web/guest/candidate-list-table*

The application must include the following documents {Art. 62(4)}:

- Chemical safety report (CSR)
- Analysis of alternatives (AoA)
- Substitution plan (where suitable alternatives are available)

And may include the following documents {Art. 62(5)}:

- Socio-economic analysis
- Justification for not considering certain risks

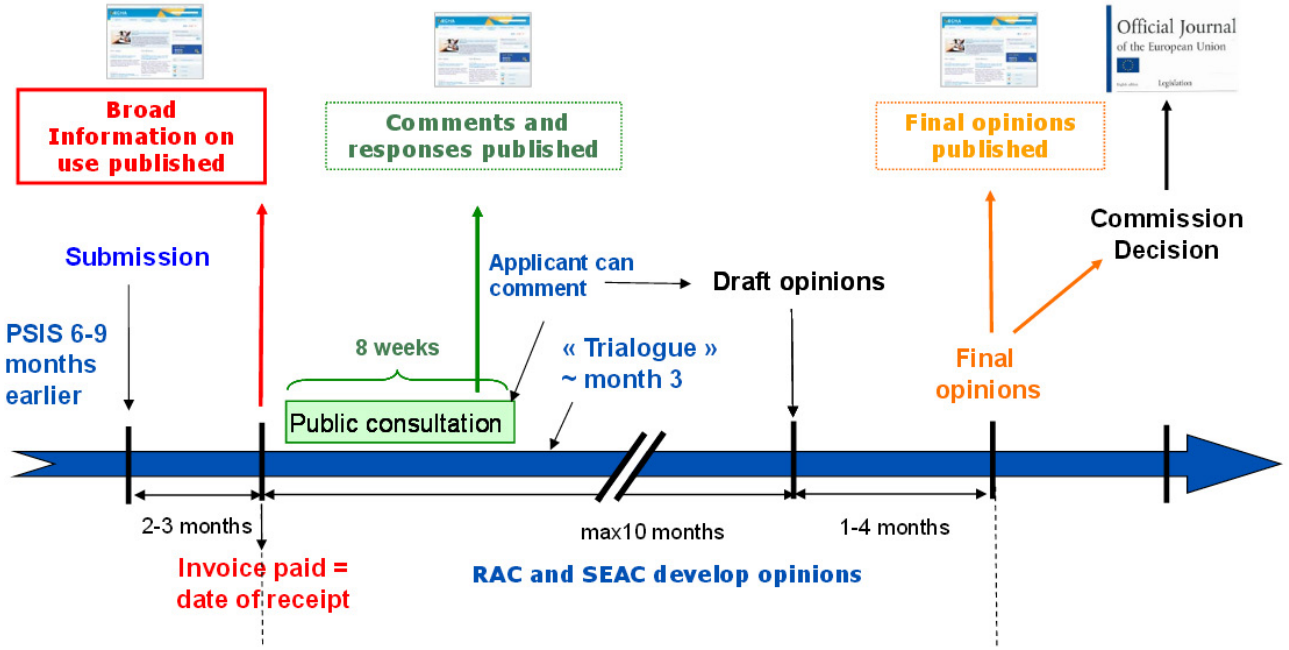
Applicants must pay a fee to ECHA when the process officially starts. The amount depends on the size of the company, and the number of uses and exposure scenarios.

Step 4: RAC and SEAC opinions

ECHA must provide expert opinions for all applications via its Risk Assessment Committee and its Socio-Economic Analysis Committee.

REACH text {Art. 64(4)} states that the draft opinions shall include an assessment of the risk to human health and/or the environment arising from the use(s) of the SVHC as described in the application and from possible alternatives (if relevant) by the Committee for Risk Assessment (RAC) and an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the SVHC as described in the application and of any third party contributions submitted through the public consultation by the Committee for Socio-economic Analysis (SEAC).

Diagram 1: timelines of the REACH authorisation process



Source: ECHA

Step 5: Granting of authorisations by the European Commission

According to the legal text, authorisations may be granted if the applicant can demonstrate that risks from the use of a safe-threshold substance are adequately controlled, even where there is a safer alternative substance or technology.

If a risk is not adequately controlled, an authorisation may still be granted if the company can prove that the socio-economic benefits outweigh the risks and that there are no suitable alternative substances or technologies.

For the second group of substances, the “adequate control route” cannot be used if it is not possible to determine safe exposure levels (thresholds) or if the substances have persistent and bioaccumulative properties.

All authorisations will be reviewed after a certain time-limit (so called review period), which is set on a case-by-case basis. However, authorisation may be reviewed at any time if {Art. 61(a)}:

(a) the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or

(b) new information on possible substitutes becomes available. Although it doesn’t establish who shall check this and the process for such a review.

Besides, authorisations shall normally be subject to conditions, including monitoring {Art. 60(8)}.

2. PROGRESS OF THE AUTHORISATION PROCESS

2.1. Identification of SVHC and establishment of the Candidate List

The responsibility for proposing substances to be included in the Candidate List lies with the Member States Competent Authorities and ECHA (on behalf of the European Commission).

As foreseen in the legal text, all substances identified as meeting the criteria for authorisation should be included in a Candidate List for eventual inclusion in the authorisation procedure. {Recital 77, article 59}.

To date, it is still not clear how many substances have the hazardous properties that qualify them for the 'substances of very high concern' designation. This is, in part because of the poor quality of data submitted by industry during the registration phase. This uncertainty makes it difficult to evaluate the real progress or lack thereof of the current list of SVHC.

The EU White Paper "Strategy for a future Chemicals Policy" estimated that 1,400 substances (5% of the substances registered in the EU market) had hazardous properties giving rise to very high concern and should therefore be progressively phased out and substituted with safer alternatives via authorisation.[8]

However, the estimation of 1,400 substances of very high concern is underestimated since it did not take into account substances with equivalent level of concern properties, such as endocrine disrupting chemicals (EDCs), PBT/vPvB-like substances and certain neurotoxicants or sensitisers.

For example, the priority list of chemicals developed within the EU-Strategy for Endocrine Disruptors identified in 2011 includes 118 substances with evidence of endocrine-disrupting activity that were not considered in the White Paper.[9]

Moreover, ECHA's database of notified substances includes 3,950 substances with a self or a harmonised classification in the EU as carcinogen, mutagen and/ or reprotoxicant category 1,[10] while the White Paper "only" considered 1,350 CMR substances.[11]

In principle, REACH Article 59(3) allows the currently existing 1,148 CMRs category 1 to be fast-tracked onto the Candidate List with an abbreviated dossier. However, neither a Member State nor ECHA has made use of this possibility so far.

In contrast with the high numbers of potential SVHC, only 163 substances have been included in the Candidate List to date (see annex II) and, for the most part, the pace of substances placed on the list has been very slow.

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8 Commission of the European Communities. White Paper Strategy for a future Chemicals Policy. COM(2001) 88 final. Brussels, 27.2.2001. *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF*

9 *http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#priority_list*

10 C&L Inventory. Consulted August 26th, 2015. *http://echa.europa.eu/information-on-chemicals/cl-inventory-database?p_p_id=clinventory_WAR_clinventoryportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&_clinventory_WAR_clinventoryportlet_searching=true&_clinventory_WAR_clinventoryportlet_jspPage=%2Fhtml%2Fview.jsp*

11 850 CMR substances that where identified when the White Paper was drafted plus another 500 additional CMRs expected to be identified in the future

As a response to concerns raised by NGOs[12] and some Members of the European Parliament in 2010, the then Industry Commissioner Antonio Tajani and Environment Commissioner Janez Potočnik announced that in line with their ambition to make the substitution of SVHC a reality, "the inclusion of new substances in the Candidate List should be accelerated, and that all relevant currently known SVHC should be on the list by the end of 2020".[13]

After this political commitment was made, it took nearly another three years for the Commission, ECHA and Member States to agree on the "SVHC Roadmap to 2020" (February 2013), which laid out a work plan to identify and include all relevant, currently known SVHC in the Candidate List by the end of 2020. This Roadmap includes a new process called the Risk Management Option Analysis (RMOA) for each substance. This is a screening process for deciding on the most appropriate regulatory or alternative action to be taken for each substance, that is, whether Candidate Listing and authorisation are warranted from the point of view of the proposing Member State rather than any other risk management option, including those outside the scope of REACH (e.g. workplace threshold levels) or even no action. This RMOA screening process is not from the REACH legal text, but a subsequent procedural development. The objective stated in the Roadmap is to screen 440 substances by 2020, around 55 substances per year.

Many Member States find the RMOA process very helpful to look at which way forward is the best. However, as annex II shows, the roadmap has not sped up the inclusion of substances in the Candidate List in the years 2013-2015. On the contrary, as feared by NGOs,[14] the RMOA exercise has slowed down the process, working in practice as a bottleneck to the SVHC listing process. Only 24 substances have been included since its approval two years ago. This is the equivalent to 12 substances per year, compared to 29 substances included in 2010, 28 in 2011 and 67 in 2012.

The whole screening exercise of the roadmap is also behind schedule, as it has been completed for only 32 substances, the equivalent to 16 substances per year despite the 55 that were foreseen by the roadmap, as annex III shows.

And the RMOA process is not just slow but it is also not delivering what was politically committed to (and what REACH says). In fact, the 2020 roadmap is actually not being applied. In our view, not all substances that have undergone an RMOA and ended up being 'parked' meet the roadmap criteria for no regulatory action.[15]

As annex IV shows, only 13 countries have submitted a proposal for including a SVHC in the Candidate List. ECHA and Germany have carried most of the effort, though France, the Netherlands, Austria and Sweden have also contributed more than 10 dossiers each. The chemical industry in Germany, France and the Netherlands plays a substantial economic role (see annex V), but these countries have nonetheless greatly contributed to the authorisation process.

However, most Member States, including several with a strong chemicals industry, such as Italy or Ireland, are not contributing at all to the process, while others, like the UK and Spain, are only contributing marginally.

Several Member States claim that they do not have the resources to prepare an Annex XV dossier, but they could have used the less burdensome fast-track listing option given by Article 59(3) mentioned above. ECHA should prepare an Annex XV dossier using this fast-track option in order to encourage Member States to follow.

The Candidate List contribution to innovation

Many studies, including those listed below, show that the Candidate List is the main driver of innovation in the chemicals sector.

An evaluation by the European Commission of the impact of the REACH regulation on the innovativeness of the EU chemical industry states that "*the Candidate List is currently creating the greatest deal of innovative activity (with the SIN list, and more recently, possibly the CoRAP).*"[16]

A report on how stronger laws help bring safer chemicals to market by the US NGO the Centre for Environmental Law (CIEL) shows how publicly available patent records reveal how the inclusion of four phthalates on the Candidate List sparked the invention of alternatives for certain uses of these substances. The report highlights a noticeable acceleration in the filing of patents, and thus the pace of invention, beginning around 1999, coinciding with the adoption of stricter rules[17] and accelerating again in 2006, when REACH was adopted.[18]

Downstream users from many different sectors have also identified the Candidate List as an important driver for innovation and substitution. For example, the high street clothing behemoth H&M said:

"When substances are listed on the REACH Candidate List, the demand for more innovation and finding better alternatives

12 Joint NGO letter to European Commissioners Potočnik and Tajani on REACH. 11 March, 2010. *http://wwf.panda.org/?190485/Joint-NGO-letter-to-European-Commissioners-Potonik-and-Tajani-on-REACH*

13 Roadmap on Substances of Very High Concern. European Commission, February 2013: *http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT* and *http://europa.eu/rapid/press-release_MEMO-11-864_en.htm?locale=en*

14 *Commission Workshop "Implementation of SVHCs Roadmap and communication" - 28 November 2013 - Brussels*. Presentation by the NGOs: *http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/svhc-santos_en.pdf*

15 Ibid 13

16 Centre for Strategy and Evaluation Services. Interim Evaluation: Impact of the REACH regulation on the innovativeness of EU chemical industry. Sevenoaks: CESS, June 2012. *http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf*

17 Such as EU temporary ban on six phthalates (DINP, DNOP, DEHP, DIDP, BBP, and DBP) above a certain concentration in toys and childcare products intended to be put in the mouth by children less than three years old.

18 Baskut Tunkat. Driving Innovation. How stronger laws help bring safer chemicals to market. Center for International Environmental Law (CIEL), 2013. *http://www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf*

increases, which fuels the production of alternatives and finally increases the availability and decreases the prices for these alternatives. This process is fortunate for our business since we often are frontrunners, paying higher prices for the alternatives in the beginning and are committed to phase out substances of very high concern."[19]

All chemicals that meet the Article 57 criteria of being a substance of very high concern should urgently be included in the Candidate List without undergoing through the RMOA process.

EEB recommendation:

The fact the Candidate List only contains 163 substances is a missed opportunity for health and the environment and for the European Commission's growth and jobs agenda given that the list is one of the main drivers for substitution, and hence innovative chemicals and technologies, in the EU.

The process for including substances of very high concern in the Candidate List should be swift, but the process has been made over-costly and over-burdensome for Member States through the introduction of the RMOA. By front-loading the process with demands for use and exposure information that legally belongs only to the prioritisation step, the RMOA process is dissuading Member States from preparing dossiers.

RMOAs not only hamper the substitution goal and the precautionary principle, but also deny the "right to know" to EU citizens. Hence, SVHC listing serves an important independent function from the authorisation procedure per se and this is one of the main reasons why we argue that all chemicals that meet the Article 57 criteria of being a substance of very high concern should urgently be included in the Candidate List without undergoing through the RMOA process.

ECHA, wealthier countries and those with the most significant chemical industries should contribute the most to the authorisation process. More experienced Member States and ECHA should help other countries to prepare Annex XV dossiers. The priority lists developed by civil society organisations such as the SIN List[20] and the Trade Union Priority List[21], are a good starting point to identify SVHC and speed up the Candidate Listing process without need of RMOAs.

In short, the whole process of including substances in the Candidate List should be simplified and streamlined.

19 Chemsec. Disfavouring companies that produce or use alternatives restricts EU innovation potential. *http://www.chemsec.org/images/Disfavouring_companies_quotes.pdf*

20 SIN (Substitute It Now!) List. ChemSec. *http://chemsec.org/what-we-do/sin-list*

21 ETUC: *https://www.etuc.org/trade-union-priority-list*

2.2 Prioritisation process of SVHC to the "Authorisation List".

The REACH legal text {Article 58(3)} establishes that ECHA must make, at least each second year, recommendations to the Commission for the inclusion of substances in the Authorisation List (REACH Annex XIV). As part of ECHA's process to formulate the recommendation, the Member State Committee renders an opinion on the substances proposed by the ECHA Secretariat, but it is the European Commission that takes the final decision.

The Member State Committee (MSC) has set up its own methodology to prioritise SVHC for Annex XIV based on the three criteria defined in Article 58(3). This article leaves open the possibility of including additional criteria -for example, the MSC grants higher priority to endocrine disrupting chemicals, but other criteria are not considered. The prioritisation of SVHC linked to recognised occupational diseases, for instance, would minimise the incidence of these diseases and the inherent costs for society, as proposed in the Trade Union Priority List for REACH authorisation.[22]

To date, ECHA has made six recommendations (in 2009, 2010, 2011, 2013, 2014 and 2015) for the inclusion of 58 substances in the Authorisation List (Annex XIV). However, only 31 substances have so far been included in Annex XIV by the European Commission. The figures are particularly low for substances with PBT/vPvB properties -today only two substances with PBT/vPvB properties are included in Annex XIV. Since August 2014 no new substances have been included in the list as a result of a moratorium unilaterally imposed by the Commission due, according to DG GROW, to complaints from some industry stakeholders (mainly the chromate industry) that authorisation is expensive, burdensome, unpredictable and complex.[23,24] The Commission intends to maintain the moratorium until the authorisation process is streamlined and simplified (see section 2.8)[25] in order to "reduce the burdens for industry".[26]

During a conference organised by ECHA and the Commission to get feedback on the functioning of the application for the

22 Ibid 21

23 Streamlining and simplifications of the authorisation process for some specific cases. Doc. CA/81/2014, European Commission. Available at: *www.chemicalwatch.com/downloads/CA_81_2014_streamlining_and_simplifications_of_authorisation.pdf*

24 Opening remarks by European Commission at Conference on "Lessons learnt on Applications for Authorisation", ECHA, February 2015: *http://echa.europa.eu/documents/10162/21825501/afa_201502_2_berend_en.pdf*

25 Updates to Annex XIV will wait. Chemical Watch: *https://chemicalwatch.com/22092/eu-commission-focuses-on-authorisation-simplification*

26 *REACH authorisation: Public consultation on streamlining and simplification of the REACH authorisation application procedure for applications concerning uses of substances in low volumes and on a one-time extension of transitional arrangements for uses of substances in legacy spare parts*. European Commission: *http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081*

authorisation process,[27] participants, including industry, agreed that the authorisation process was, in general, working. ECHA's Executive Director Geert Dancet explained that overall application costs had fallen by 30% in the relatively short period since the authorisation process began with the inclusion of the first substances in the Authorisation List in 2011, and called on the Commission to resume its preparations for including recommended substances on the Authorisation List.

The Commission has also decided to take socio-economic elements into account before taking decisions on future Annex XIV updates.[28] For that purpose, the Commission asked ECHA to include an additional public consultation on each draft recommendation of new Annex XIV substances to gather socio-economic data before the application phase. Although this public consultation is not foreseen in the legal text, taking into account all benefits and costs of new legislation is becoming common practice in EU legislative process.[29]

Since February 2014, the Commission has already received two recommendations from ECHA totalling 20 priority substances that should be included in Annex XIV. These recommendations are yet to be considered by the Commission. This is de facto "freezing" of the REACH authorisation process.

In a response to an EEB letter,[30] Commissioners Bieńkowska and Vella confirmed that "the Commission will resume the preparatory work to start again adding SVHC to the Authorisation list once ECHA will have submitted the forthcoming sixth recommendation on priority substances".[31] ECHA did send its recommendation during the summer of 2015 as expected. However, by November 2015, the Commission has not yet resumed its work.

Another issue to tackle is the fact that during the prioritisation process, ECHA does not consider all substances that were not prioritised during previous recommendations and remain in the Candidate List.

EEB recommendation:

The MSC should consider all remaining SVHC in the Candidate List for each new recommendation for SVHC prioritisation. Moreover, it should take into consideration other factors, such as data on occupational diseases linked to SVHC as an additional criterion for SVHC prioritisation in Annex XIV.

NGOs join Mr Dancet in requesting an end to the moratorium. We believe that the process should continue without further delay as it is undermining the progress of REACH.

The public consultation to gather socio-economic data before inclusion in Annex XIV is problematic because it will influence the final recommendation, which is contrary to the spirit and text of REACH. The intention of the Regulation is to phase out SVHC, whether or not there are currently alternatives. The incentive for developing alternatives will be severely damaged if the current situation influences whether a substance is prioritised for authorisation.

Socio-economic aspects are already considered in the later phase of authorisation (in opinions from committees on the applications) and in the RMOA (which was also not foreseen in REACH). Furthermore, such a consultation cannot gather enough useful data on alternatives because the scope is too general and it is not possible to know which specific uses will be applied for later. Moreover, the legal text allocates the responsibility for compiling information on alternatives in the applicants for authorisation.

All these additional steps to the prioritisation process are making it more uncertain, complex and burdensome and undermine efforts to shift the burden of proof.

Better guidance to applicants for authorisation is needed.

27 Conference on "Lessons learnt on Applications for Authorisation". Helsinki, 10-11 February 2015. *http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/conference-on-lessons-learned-on-applications-for-authorisation*

28 Ibid 24

29 see European Commission, Impact Assessment Guidelines, SEC(2009) 92

30 European NGOs call on the European Commission to lift the de facto moratorium on processing Substances of Very High Concern for authorisation under REACH. May 2015. Available at: *http://www.eeb.org/index.cfm/library/letter-ngos-ask-european-commission-to-lift-de-facto-moratorium-on-processing-svhc-for-authorisation-under-reach/*

31 European Commission letter. Commissioners Bieńkowska and Vella letter to the EEB. 15 July 2015. Ref. Ares (2015)2491671

2.3. Applications for authorisation

In this chapter we will examine different elements of the applications, including the number of applications received for each SVHC in Annex XIV, the scope of the applications, the information provided by applicants and the conformity check.

To date, the application deadline for 15 out of the 31 substances currently included in the Authorisation List has already expired. ECHA has only received submissions for seven substances (see annexes VI and VII). Therefore, already half of listed SVHC (eight substances) are currently not allowed on the market in Europe because no-one has asked for permission to use them and the assigned sunset date has passed. MDA, Musk xylene, DIBP, BBP, Lead chromate, Diarsenic pentaoxide, TCEP and 2,4-DNT are no longer permitted to be placed on the EU market and used.

ECHA has received 28 applications from 44 applicants and for 56 uses of seven SVHCs.

In cases of pending applications (such as DEHP in PVC items) production still continues until a decision is taken. There is no deadline for the European Commission to take a decision.

EEB recommendation:

For half of the substances under the REACH authorisation regime, no application for specific use was received. This means that these substances of very high concern are no longer used in the EU and are likely to have been substituted with alternatives.

However, in order to adequately evaluate the real impact of REACH on the removal of these SVHC from the marketplace we need to know more about the weight of these substances in the European marketplace before their inclusion in the Candidate and Authorisation Lists. It is equally important to know whether these substances continue to be both manufactured in the EU for export outside the EU and whether they are imported through articles as neither the manufacturing nor the import processes are in the scope of REACH authorisation. We welcome ECHA's proposal to try to analyse this.[32]

Delayed decisions by the European Commission (such as on DEHP in PVC items) are undermining the protection of health and environment as continued exposure to SVHC is allowed with no deadlines.

Scope of the applications

Although many of the submitted applications are use specific, applications for very broad uses of SVHC involving thousands of tonnes and potentially hundreds of downstream users have been submitted by chemical manufacturers as annex VII shows. This is the case for applications for the use of DEHP in raw and recycled PVC, HBCDD in flame retarded expanded polystyrene (EPS) and lead chromates in paints. In these cases, applicants provided very broad descriptions of uses that were not documented by corresponding exposure scenarios and exposure assessments. As a result, ECHA could not clearly understand the risks from the continued use of the substances.

For example, RAC's opinion on the application for authorisation (AfA) for the use of DEHP to manufacture recycled PVC articles states: "*... that the presented exposure assessment for the worker population is not representative for this application for authorisation. This is because the application covers several process technologies…, process categories … and many worker settings within each process category. The authorisation is also requested for application across all EU Member States and EEA countries.*"[33] The same is true of the analyses of alternatives for DEHP, which did not correspond to the broad use applied for, including all downstream users involved. As a consequence, the scope of the authorisations applied for is so broad and unclear that they result in what are, in essence, requests for general authorisations for an industrial sector rather than use-specific authorisations.

During RAC's 28th meeting, ECHA's Secretariat stated that "*neither ECHA nor the committees are in a legal position to reject broad scope uses at the conformity check stage*".[34]

EEB recommendation:

We maintain that broad scope applications do not conform to the requirements of Article 62 (as required by Article 60(7)) and should be rejected at the conformity check stage. While REACH allows applications for several uses, these uses need to be well defined and the exposures documented and well described. Adequate control in accordance with REACH Annex I can only be demonstrated for specific uses.

Information provided by applicants

Before submitting their documents, applicants receive in-depth advice from ECHA's Secretariat on how to prepare the application. However, experience has shown that the submitted applications are very different, both in the quantity and quality of the information provided. In some cases, extremely long applications were received (up to 2,000 pages) with too much irrelevant and futile information, according to the committees.[35] In general, the information from use-specific applications is much more complete than from broad use applications. In many cases, applicants actually using the SVHC did not provide any

32 *http://www.saferalternatives.org/assets/media/documents/Matti_Vainio.pdf*

33 Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC). Opinion on an Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP) use: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles ECHA/RAC/SEAC Opinion. *http://echa.europa.eu/documents/10162/8d9ee7ac-19cf-4b1a-ab1c-d8026b614d7a*

34 Minutes of the 28th Meeting of the Committee for Risk Assessment (RAC-28) *http://echa.europa.eu/documents/10162/13579/rac_meeting_28_minutes_final_en.pdf*

35 Chair of SEAC presentation at Conference on "Lessons learnt on Applications for Authorisation". Slide 9: *http://echa.europa.eu/documents/10162/21825501/afa_201502_10_oberg_en.pdf*

real exposure data from the uses applied for, not even from their own facilities, but only modelled estimations.

Both RAC and SEAC have asked applicants for further information in almost all applications during the opinion development, after the application was deemed in conformity. For example, during the discussion of the AfA for the use of DBP in a specialty paint for the manufacture of motors for rockets and tactical missiles: "*The RAC asked the rapporteurs and the ECHA Secretariat to request the applicant for measurement data (for other substances used in the process), a better illustrated explanation of the process, the volume of the substance used at one time and the frequency of the activity*".[36] In another example, during the discussion of the first draft opinion on the AfA for two uses of diarsenic trioxide submitted by Linxens France: "*the Chairman concluded that there is need for further scrutiny concerning the risk estimates via dermal exposure. The rapporteurs and the Secretariat proposed to refer the issue back to the applicant and request the applicant for further clarifications on the duration of activities and for recalculations concerning dermal exposure to provide the RAC with a more realistic estimate*".[37]

In some cases, applicants have subsequently sent information not requested by the Committees in order to complete their applications. SEAC has also used additional information not submitted either by the applicant or by third parties during the public consultation or under request in order to develop their opinions.

REACH text {Article 64(3)} allows additional information to be requested by the committees **only** before they make a judgement on the conformity of the application with the requirements of Article 62. Further information from the applicant can be requested only by the SEAC only in relation to possible alternative substances or technologies. However, both RAC and SEAC have requested information (not related to alternatives) from applicants that they deemed important, much later, after the conformity check phase.

36 Ibid 34

37 Minutes of the 29th Meeting of the Committee for Risk Assessment (RAC-29) 2-6 June 2014. *http://echa.europa.eu/documents/10162/13579/rac_29_minutes_en.pdf*

Even ECHA's document on RAC and SEAC's common approach on developing opinions on applications for authorisation states that: "it is the responsibility of the applicant to demonstrate that the risks are adequately controlled and/or the benefits of continued use outweigh the remaining risks.... RAC and SEAC should be reticent to gather additional information or data, other than specified in Article 64(1) and 64(3)".[38]

Yet, instead of simply putting the onus back on the companies, when the issue was discussed during the 28th RAC meeting, "ECHA suggested and the Committee agrees to take a pragmatic approach for the moment on a case -by -case basis. Hence, the Committee should consider whether the information [that it presumably wants to request] is critical for the concrete application for authorisation".[39]

EEB recommendation:

Applicants for authorisation should improve the quality and transparency of their applications. More efforts are needed to achieve fit-for-purpose applications with the right amount of relevant information.

We consider that the RAC should avoid requesting and accepting further information from applicants once an application has been deemed in conformity, or not, and SEAC should limit its request to information on alternatives. The Commission, when deciding whether to grant an authorisation, should not take into account the information provided to RAC or SEAC (except relevant information on alternatives) after the conformity check.

REACH is designed to avoid the delay game of the past, where industry drip-fed information. Scientific committees as well as decision makers should learn to give opinions and take decisions on the basis of the available information in order to finally shift the burden of proof fully onto the operators.

RAC has to give opinions on the risks as described in the application and not in general – meaning that RAC cannot make an opinion if the description is flawed.

38 ECHA. Common approach of RAC and SEAC in opinion development on applications for authorisation. Twentieth meeting of the committee for risk assessment. 06-09 March 2012 fourteenth meeting of the committee for socio-economic analysis 13-15 March 2012. *https://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf*

39 Ibid 34

Conformity check

REACH text {Article 64(3)} establishes that the committees must check that an application includes all relevant information specified in Article 62 and, if necessary, request that the applicant supplies additional information to bring the application into conformity.

A review of the conformity check procedure is critically needed.

In several cases (e.g. DEHP for raw and recycled PVC, lead chromate paints or HBCDD) the information provided was significantly incomplete. For example, several applications submitted lacked the basic information on exposure that is needed by RAC to develop its opinion. In other cases, the technical and economic feasibility of alternatives could not be confirmed by SEAC due to poor descriptions of the socio-economic implications or limited surveys of downstream users that failed to provide relevant data. In other cases (e.g. trichloroethylene[40]), the applications were so incomplete that some committee members wondered if it was a draft rather than a "real" application. However, the ECHA Secretariat informed the committees that it was difficult to reject an application, even in these poor conditions, because once the application fee had been paid, the Agency's committees are obliged to give their draft opinions within 10 months of receipt of the application by ECHA. As the fee is paid before the conformity check, this de facto means that ECHA considers all applications to conform to requirements. In the end, the application quality was so poor that the committees recommended authorisation for only 26 months.

EEB recommendation:

We maintain that the interpretation currently used by ECHA that all applications are in conformity once the fee has been paid and all fields required in Article 62 are filled in by the applicant contradicts the REACH text Article 64(3). ECHA treats the conformity check process as a bureaucratic step or a completeness check, just verifying if the required documents are provided, but not the content of them. As mentioned above, this situation overloads the committees with unnecessary work. The burden of proof and information provision should be carried by the applicant not on the committees. A review of the conformity check procedure is critically needed.

40 Application by Chimcomplex S.A. Borzesti: *http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1655/del/50/col/synonymDynamicField_302/type/asc/pre/2/view*

2.4. Public consultation on alternatives

Transparency

As part of the authorisation process, REACH Article 64(2) establishes that *the Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information…with a deadline by which information on alternative substances or technologies may be submitted by interested third parties*.

In order to comply with this requirement, ECHA has established a public consultation process, allowing third parties to provide information during an eight-week period.

ECHA publishes the information from the alternatives assessment, the exposure scenario and the socio-economic assessment, that applicants consider not confidential. But ECHA does not check the confidentiality claims made by the applicants. ECHA argues that REACH does not include legal provisions to approve or reject confidentiality claims in the authorisation process.[41] Moreover, ECHA has stated in various fora that the Agency does not have the resources to do so in the very short time-frame in which it must process the application dossiers (i.e. within 10 months). As a consequence, the Agency does not publish any information claimed by the applicant to be confidential but "encourages applicants to be as open as possible".[42]

Several applicants have deemed parts of their applications confidential. The most striking cases until now have been the applications for the use of DEHP in PVC. These applications claimed the complete chemical safety assessment (CSA) to be confidential and provided minimal information on exposure scenarios and socio-economic costs. This means that basic information such as the population exposed and the production volumes are hidden from the public. Seventy per cent of the content of the applications for the uses of DEHP in raw PVC and 90% of the content of the applications for the uses of DEHP in recycled PVC formulations and articles was considered confidential.

The information provided during the public consultation of several applications therefore failed to provide a clear understanding on why and how the SVHC were used. As a result, third parties were unable to understand whether the alternatives were economically and technically feasible for the applicant, and this hindered both stakeholders' meaningful and effective participation in the authorisation process and consequently the committees' capacity to achieve an opinion taking into account third parties contributions as foreseen in the legal text.

Following NGO complaints,[43] ECHA has decided to publish the information provided by the applicants, blanking out the paragraphs with confidentiality claims and advises applicants

41 ECHA answer letter to EEB D(2014)0147 MV/ca, 7/02/2014

42 *https://chemicalwatch.com/17702/ngos-accuse-echa-of-failing-on-authorisation*

43 NGO Letter to Mr Geert Dancet, Executive Director, ECHA.16 December 2013. *http://www.eeb.org/?LinkServID=D3B592E6-5056-B741-DB4B95B097C2D86F&showMeta=0&aa*

not to claim as confidential certain key information. According to ECHA, about 90% of the information contained in the new application dossiers is now available to interested parties in the public consultations.[44] However, ECHA still leaves it up to the applicants to decide which information is or is not confidential, without assessing any of these claims.

EEB recommendation:

Although ECHA has made substantial progress in this area, we consider that all information provided during the authorisation process should be made publicly available. We believe this should be the case as the information refers to substances of very high concern that have been prioritised by Member States, ECHA agency officials and the Commission because they are widely dispersed, produced in high volumes or PBT substances. To ensure that the public is properly informed, assessments of confidentiality claims should be much stricter than for registered substances. In our view ECHA wrongly applies a more lax confidentiality policy for SVHC under authorisation than for substances under registration.

Information on alternatives

Many third parties participate in the public consultations on alternatives, not only NGOs, but also companies, associations, researchers and government authorities have provided information on alternative substances, materials and processes. This is true in particular for applications for broad uses or upstream applications, where both manufacturers of alternatives, as well as downstream users are demonstrating the availability of alternatives.

For example, during the public consultation on the use of DEHP in PVC articles 11 organisations submitted comments.

During the public consultation on the use of lead chromate pigments, dozens of clients of the applicants provided comments supporting the authorisation. On the other hand, several organisations provided information on alternatives, including NGOs (EEB, ChemSec), manufacturers (British Coatings Federation, BASF, Verband der Mineralfarbenindustrie e. V., ETAD) and insurance companies (Allgemeine Unfallversicherungsanstalt Austria).

Organisations providing comments during the public consultation on the applications for the continued use of DEHP in PVC formulations and articles.

Comments supporting the authorisation

Japan Plasticizer Industry Association (JPIA)
ACEA - European Automobile Manufacturers Association

Comments providing information on alternatives

Toxics Use Reduction institute (TURI)
Exxon Mobil Petroleum and Chemical BVBA
Lowell Center for Sustainable Production at the University of Massachusetts, Lowell
ChemSec
Allgemeine Unfallversicherungsanatalt, Austria
Health and Environment Alliance (HEAL)
CHEM Trust
BUND
European Environmental Bureau (EEB)

However, the information provided by interested third parties seems to have been barely considered by the SEAC committee as valid. This may indicate that SEAC in actual practice tends to consider that it is up to the applicant to judge the suitability of the alternatives.

EEB recommendation:

Many companies (especially downstream users) are not aware of these public consultations and of their importance and do not understand the benefits of contributing. Non-chemical alternative companies may not even be aware of REACH.

In one example the European paints and coatings industry (Cepe) shows that there are plenty of available alternatives to leaded paints that are widely used in the EU. In fact, the trade body argues that several global paint producers, including AkzoNobel, BASF and Jotun, have banned lead pigments from all of their formulations worldwide, making the committees' opinion [recommending authorisation based on lack of alternatives] a "huge surprise" to them.[45] They assumed that if EU companies were not manufacturing leaded paints, SEAC would never support the use of lead chromates in paints. These companies were not aware that SEAC only considers the information that is submitted by the applicant and contributors to the public consultation. ECHA should encourage and incentivise third parties' participation in the REACH authorisation process to assure that SVHCs that have safer alternatives are not used.

SEAC should neutrally judge the validity of the information on alternatives provided by third parties.

44 Opening remarks by Mr Geert Dancet, Executive Director, ECHA. Conference on the lessons learnt of applications for authorisation. 10 February 2015, ECHA, Helsinki. *http://echa.europa.eu/documents/10162/21825501/afa_201502_1_dancet_en.pdf*

45 Chemical Watch: EU paint associations oppose lead pigments authorisation. *https://chemicalwatch.com/23102/eu-paint-associations-oppose-lead-pigments-authorisation*

Trialogues

The ECHA Secretariat, together with the RAC and SEAC rapporteurs for the application dossiers, hold meetings (trialogues), when relevant, with applicants, observers and stakeholders who have provided comments during the public consultation. During these meetings, applicants respond to questions from RAC, SEAC and also from stakeholders and third parties who have contributed to the public consultation. Among others, the applicants have to answer questions about their failure to use available alternatives and, in some cases, have the opportunity to discuss with competitors why they consider the alternatives as unsuitable.

The information on alternatives from the public consultation creates pressure on the applicants to demonstrate why they are not substituting and also influences RAC's and SEAC's opinion development.

EEB recommendation:

We believe that trialogues are useful and that the public consultation is providing new information on alternatives that has not been considered by applicants and is showing the feasibility and availability of safer alternatives to the SVHC that are being considered for authorisation. However, to make full use of the trialogues -and the public consultations, it is crucial that third parties receive better information than at present about the use applied for.

2.5. RAC opinion development

REACH legal text Article 64(4)(a) states that the Committee for Risk Assessment draft opinions should include the following elements: *an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives.*

Determination if the SVHC is a threshold substance

According to REACH, RAC should first determine for which substances of very high concern it is possible, or not, to determine a threshold in accordance with REACH section 6.4 of Annex I.

In the case of a threshold substance, RAC should then proceed to assess if the applicant demonstrates that the risk to human health and the environment from the use(s) applied for is adequately controlled.

In the case of a non-threshold substance, RAC should give an opinion on the appropriateness and effectiveness of the proposed risk management measures (RMM) in attaining the exposure levels given in the applicant's exposure assessment and ensure that the exposure levels are as low as technically and practically possible.

However, in some cases RAC has not performed the first step of assessing whether certain chemicals are or not threshold substances.

This was the case of reprotoxicants with an endocrine mode of action (DEHP, BBP and DBP). RAC directly assumed reprotoxicants to be threshold substances by default. According to the chair of RAC *"it should be recognised that the threshold approach is, as such, scientifically accepted for reprotoxic substances in the context of human health risk assessment"*.[46] However, reprotoxicity can be caused by many different modes of action, some may

46 ECHA reply to EEB letter regarding RAC derivation of DNEL for EDC substances, in particular BBP. D(2013)5155_Reply to EEB comments, Helsinki. 04/09/2013

be dose related and others not, such as endocrine-mediated effects.

This is the case for DEHP, BBP and DBP; for which RAC acknowledged that their reprotoxicity is mediated by an endocrine mode of action, but claimed that it is nevertheless appropriate to establish a reference DNEL, thereby treating them as threshold substances.

Due to the importance of, for example, the timing of exposure, mixture toxicity and non-linear dose response relationships, uncertainties in a risk assessment make it very doubtful that safe thresholds can be derived with sufficient certainty for endocrine disrupting substances. Furthermore, the Commission has concluded that: "it may be difficult (albeit not impossible) to determine a safe threshold with reasonable certainty for endocrine disruptors." According to the Commission, it is up to the REACH registrant to demonstrate that a threshold exists, and the ECHA Risk Assessment Committee to examine the validity of the assessment and decide if it exists or not.[47]

However, given the Commission's delay of over two years with its REACH review on whether EDCs should be excluded from Article 58(2) (adequate control route), RAC had already established DNELs by the time the Commission's conclusions were made. How RAC will treat other similar substances in the future remains to be seen.[48]

47 Endocrine Disruptors REACH Review. CA/25/2014. European Commission. Available at: *www.chemicalwatch.com/downloads/36_CA_25_2014_REACH_review_for_EDs.pdf*

48 Chemical Watch, EU Commission says industry should demonstrate EDC thresholds. *https://chemicalwatch.com/20070/eu-commission-says-industry-should-demonstrate-edc-thresholds*

EEB recommendation:

Before setting a derived no-effect level (DNEL), RAC should ascertain if the SVHC is, indeed, a threshold substance. In our view, the added uncertainties in a risk assessment for EDCs necessitate treating them as non-threshold substances, the same as PBT/vPvB or carcinogens and mutagens.[49]

Therefore we expect that RAC first critically evaluates whether a safe DNEL can be set for the substance in question, taking all available science into account instead of assuming that all reprotoxicants (and maybe other endpoints) have a threshold by default. This has no scientific basis in our view, particularly after the Commission's review of EDCs in the REACH authorisation process mentioned above.

Available information for RAC to give its opinions

Although it has been a challenging exercise for RAC to deliver opinions on many applications given the insufficient information provided, the committee should base its opinions on the information submitted in authorisation applications.

In several cases the uncertainties regarding the information provided have been so high that RAC has not been able to deliver an opinion.

For example RAC's opinion on the uses of HBCDD for flame retarded expanded polystyrene (FR EPS) states:

"*RAC considers that, based on the information provided by the applicant, the uncertainties in the exposure assessment are too high to conclude on the remaining risk of the use applied for. RAC considers that the emissions to the environment for this use have not been adequately described in the application. As a consequence, RAC was unable to evaluate the appropriateness and effectiveness of implemented and proposed operational conditions and risk management measures in reducing the risks.*"[50]

As mentioned previously, RAC asks applicants for further information when needed, however, in many cases, the committee develops its opinion without being able to check the reliability of the information provided. In other words, RAC is 'trusting by default' the information provided by the applicant.

49 see e.g. *http://www.chemtrust.org.uk/wp-content/uploads/CHEM-Trust-Briefing-on-REACH-EDC-review-FINAL.pdf*

50 Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC). Opinion on an Application for Authorisation for Hexabromocyclododecane (HBCDD), alpha -hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane. Use: Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications. ECHA/RAC/SEAC:AFA-O-0000004949-56-12/D *http://echa.europa.eu/documents/10162/0144eda8-0377-4cc6-aa94-c0de9a5a9456*

For example, during its opinion development on the uses of DEHP in raw PVC, RAC decided to base its risk assessment of consumers on the exposure values given by the applicants: 9 µg/kg/day for adults and 10 µg/kg/day for children. According to the applicant, these data come from the preliminary results of the DEMOCOPHES project for the 90th percentile. However, as highlighted by Danish RAC members in their Minority statement, "*We haven't been able to find any reference to these values. The published Layman's Report does not mention these figures and they can't be reliable calculated from the figures in that report. This makes the calculations and assumptions non-transparent for the RAC*".[51]

EEB recommendation:

We consider that RAC should not accept at face value information provided by applicants that has not been adequately referenced and documented. RAC should act as a neutral judge. We see a contradiction in the information RAC demands when assessing industry applications for authorisation versus restriction dossiers by Member States.[52] With restriction dossiers, RAC is extremely demanding. For example, it has rejected academic scientific publications supporting the proposal, even though they have been peer-reviewed and analysed by governmental agencies during preparation for the Annex XV dossiers. On the other hand, when assessing industry applications for authorisation, RAC is very lax and accepts at face value the information received without this being of scientific standard or peer reviewed. To date, RAC has not rejected any application for insufficient information.

Health and environmental adverse effects

REACH Article 62(4)(d) states that applications shall include, unless already submitted as part of the registration, a chemical safety report in accordance with Annex I. This report must cover the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV.

Almost all authorisation applicants have included a new chemical safety assessment (CSA) instead of using the chemical safety report (CSR) that was submitted when the SVHC was registered. This may be in order to save the costs of buying the information from registrants or to avoid the poor quality of the CSR submitted during the registration process.

The REACH legal text states that applications should only include adverse effects arising from the intrinsic properties of the SVHC specified in Annex XIV. Therefore, even though a SVHC may have different adverse properties, only the one(s) included in Annex XIV will be considered. Hence, for example, a SVHC may be PBT and a reprotoxicant, but only the reprotoxic effects to humans may be addressed if only its reprotoxic classification was used when including the substance in the Candidate List.

However, to only consider the intrinsic property(ies) used for inclusion in the Candidate List when assessing the risks of the use of a substance is like putting blinkers on a horse. Although it is known that the use(s) of the SVHC may have risks related to its other intrinsic properties, the authorisation process does not look at them.

Therefore, due to this deficiency in the legal text, the opinions regarding the level of control of the risks are partial and misleading.

This was the case with the applications for the uses of DEHP and DBP, where only reprotoxic human health effects were considered, disregarding the environment effects highlighted back in 2008 by the EU risk assessment report (RAR) on DEHP.[53]

Applications for the uses of HBCDD offer a different example of the partiality of the risk assessments carried out under the authorisation process. HBCDD was included in the Candidate List for being a PBT, although it has a harmonised classification as toxic to reproduction category 2 and toxic via lactation.

RAC accepted the applicants' point of view that only the environmental effects should be considered as it was included in Annex XIV as PBT. And since the substance was not "officially" classified as reprotoxicant (under the CLP Regulation) when the substance was included in the Candidate List, reprotoxicity was not mentioned in the rationale for its Candidate List inclusion. As a result, RAC considered that the human health effects should not be assessed.

Therefore, all health risks to workers manufacturing and handling HBCDD from flame retarded expanded polystyrene (FR EPS), as well as the risks to consumers and to the general population exposed through the environment, were not assessed in the industry's application.

EEB recommendation:

The CSA of the applications for authorisation only include an assessment of the risks from the SVHC properties for which the substance was included on the Candidate List. Although it is known that the use(s) of the SVHC may have risks related to its other intrinsic properties, the authorisation process does not look at them. As a result, partial and misleading risks assessments are yielding proposals to grant authorisations for the continued use of very high concern substances which have wide dispersive uses, high production volumes and/or high persistence and bioaccumulation in the environment, and hence pose 'ignored' risks. We consider that all intrinsically hazardous properties of the SVHC should be considered when deciding to permit the continued or new use of such substances. This requirement should be introduced by the Commission.

51 Minority position statement by Frank Jensen (RAC) and Peter Hammer Sørensen (RAC) on: The Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP 2a)(DH001632-63) *http://echa.europa.eu/documents/10162/24bd42de-7abc-4d02-9d4c-eb609044c7eb*

52 E.g. see opinions of RAC and SEAC on the phthalate applications for authorisation and the DK restriction proposal

53 JRC. bis (2-ethylhexyl) phthalate (DEHP) CAS No: 117-81-7 EINECS No: 204-211-0 Summary Risk Assessment Report. Ispra: European Chemicals Bureau, 2008.

Exposure assessment

Although applicants receive detailed advice from ECHA staff during pre-submission meetings, all broad scope applications and many applications for specific uses lack adequate descriptions of exposure scenarios. This situation makes it very time consuming and difficult for RAC to deliver its opinions and is making ECHA staff waste its time.

Other limitations in submitted exposure assessments to date include:

- the use of modelling data instead of monitoring data for specific uses. In other cases, bibliographic data was presented instead of real exposure scenarios. Not even applicants that currently use the SVHC presented real exposure data to prove that the SVHC is adequately controlled.

- not considering the combined exposure to several SVHC in the same use, even when they have very well known synergic adverse effects. For example, if two SVHC (e.g. DEHP and DBP) are used in the same task (even in the same use applied for), at the same production sites, by the same workers, applicants and/or RAC do not consider the real exposure situation, this is, that workers are exposed to both SVHC, and only assess if the single exposure to each one of the substances is below the reference DNEL.

For example during the opinion development of the applications for DEHP and DBP in ceramic sheets and printing pastes for the production of capacitors and lambda sensor elements, the applicant presented two applications, one for DEHP and one for DBP, and actually calculated the risk of the combined exposure to both substances in both applications. However RAC decided not to take account of the combined exposure and only considered workers' exposure to one of the substances in each application. This resulted in favourable opinions on the capacity to achieve adequate control. This treatment side-stepped a previous RAC decision adopted during its 28th Meeting on how to deal with combined exposures: "The Committee examined two possible scenarios. The first, when two different but similar substances grouped in one application for the same use are evaluated… RAC agreed that it should give an opinion for each combination of substance and use in the application... However, RAC can evaluate combined exposures, and if combined RCRs are above one, the Committee could recommend further conditions.[54]

- not considering that workers are also exposed to SVHC in their professional and in their private lives. When calculating workers' exposure, applicants do not add the extra exposure that workers have to SVHC also as citizens outside of work. RAC has not been consistent among applications and in some cases has included the extra exposure and in others not (e.g. DEHP and BBP in ceramic sheets).

- considering that worker protection measures, as well as waste management and abatement techniques (waste management schemes, landfills, incinerators) suggested by the applicants will be 100% effective in protecting workers and reducing inputs to the environment.

A positive outcome of the authorisation process is that some companies applying for specific uses of a SVHC are improving their risk management measures so they can demonstrate the ability to adequately control risks or to show that their measures effectively reduce risk. For example, information from several applications has shown that companies using carcinogens (e.g. trichloroethylene, diarsenic trioxide) and not complying with legal requirements under occupational health and safety regulations (for example not monitoring and biomonitoring exposure), began to do so when they decided to apply for an authorisation. Other examples include the implementation of different pollution abatement techniques.

EEB recommendation:

RAC exposure assessments have several limitations that should be improved in order to deliver more accurate and consistent opinions. Given that authorisation gives permission to continue using a substance of very high concern in a specific, use dependent situation it should be a prerequisite that real emission data and very specific use and exposure scenarios in the application constitute a convincing case.

54 Ibid 34

© photo: Michelle Griffiths

Analysis of alternatives

In their alternatives assessments, applicants only include information on the official classification (in the CLP Regulation[55]) of the different substances in order to compare them with the SVHC property listings although there are many other adverse effects without official classification such as endocrine disruption or certain types of neurotoxicity. Therefore, alternatives assessments provided by applicants are of very limited relevance. They do not include in-depth information on the toxicological and ecotoxicological properties of the SVHC and its alternatives.

During its opinion development, RAC has only carried out a rough analysis of the risks of alternatives based on the information provided by applicants.

RAC has not carried out any detailed assessment of the risks of the alternatives as it considers that it only has to do so for non-threshold substances following the socio-economic authorisation route and for applications where SEAC has considered that suitable alternatives are available for the applicants. For all submitted applications, SEAC has considered that there do not appear to be suitable alternatives for the applicant.

EEB recommendation:

The analyses of alternatives should follow an established methodology that takes into account: i) the toxicological and ecotoxicological properties of the SVHC; ii) possible alternatives; iii) data gaps and iv) assessment of alternative materials, technologies and processes. The OECD has published a compilation of alternatives assessment methods and frameworks that can support applicants and RAC to improve alternatives assessments.[56]

RAC Opinions

Opinion development has been a challenging exercise for RAC given the insufficient quality of the chemical safety assessments in many applications.

Instead of openly rejecting very poor applications, RAC has preferred to propose a short review period. This can be seen in the opinions where very high uncertainties and inconsistencies are highlighted by SEAC and yet neither committee has recommended a rejection.

RAC is responsible for assessing whether applicants have demonstrated that the risks arising from the use(s) of the SVHC are adequately controlled or if the proposed operational conditions and risk management measures (OC and RMM) are effective. However, what this committee is actually doing is assessing if it would be possible for the applicants to adequately control the risks if OC and RMM are implemented and redoing the applicants' assessments when they are not properly done. For example, in the AfA of the use of DBP in ceramic sheets and printing pastes, RAC considered that the applicants' assessments of combined exposure of workers were implausible and worked out its own calculations for what it considered more plausible exposure scenarios.[57]

We question if RAC's role is to give advice on how adequate control may be achieved instead of assessing if the applicants have actually demonstrated that they can adequately control the SVHC's risks.

RAC has delivered positive opinions for almost all applications, although it has considered that adequate control was not demonstrated in several cases (e.g. for DEHP in PVC uses), and has been unable to evaluate in other cases (e.g. HBCDD) the appropriateness and effectiveness of the implemented and proposed operational conditions and risk management measures in reducing the risks.

EEB recommendation:

Applications lacking the required information should be rejected during the conformity check instead of spending RAC's and ECHA Secretariat's limited resources trying to bring the applications up to minimum conditions and receive an authorisation.

We question if RAC's role is to give advice on how adequate control may be achieved instead of assessing if the applicants have actually demonstrated that they can adequately control the SVHC's risks.

It is widely accepted that REACH was purposely designed to put the burden of proof regarding meeting the requirements for authorisation on the applicant in both the adequate control route and the socio-economic route. Therefore, the applicant bears both the procedural burden of providing evidence and the substantive burden of proof. Accordingly, RAC (and SEAC) should give a negative opinion if the applicant fails to clear up reasonable doubts. Instead of proposing short review periods, RAC (and SEAC) should follow the REACH legal text and give negative opinions to those applications that do not meet the legal requirements for granting authorisation.

55 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

56 OECD Substitution and Alternatives Assessment Toolbox (SAAT) *http://www.oecdsaatoolbox.org/*

57 Application for Authorisation for Dibutyl phthalate (DBP) for industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements *http://echa.europa.eu/documents/10162/81ccd18d-b392-4297-aed8-2c05dc656d21*

2.6. SEAC opinion development

SEAC's role is to assess if the applicant has demonstrated that all the requirements for an authorisation are fulfilled with regard to:

- the availability, suitability and technical feasibility of alternatives;
- the socio-economic benefits arising from its use outweigh the risk to human health or the environment.

Available information on which SEAC gives its opinions and information flow

Unfortunately, SEAC has accepted certain applications as conforming to requirements and has even recommended an authorisation to be granted when no analysis of alternatives was provided despite being required in REACH Article 62(4)(e).

This is the case for the applications submitted by DCC Maastricht B.V. for lead chromates pigments in paints. In the analysis of alternatives documents provided, the applicant explains that "at the formulation stage PY.34 and PR.104 have no function, hence no analysis of alternatives can (or needs) to be made." SEAC accepted the applicants' explanation since "at the formulation stage no meaningful analysis can be completed as it is in the end use the value and importance of the pigments can be differentiated".[58] However, the legal text is clear that a request for authorisation shall specify for which use the authorisation is sought AND include an analysis of the alternatives in all cases. If it is in the end use the value and importance, then the analysis of alternatives should be made for this end use.

Instead of proposing short review periods, RAC (and SEAC) should follow the REACH legal text and give negative opinions to those applications that do not meet the legal requirements for granting authorisation.

Another example of an application where an analysis of alternatives is lacking is that by Linxens France SA for diarsenic trioxide. The applicant split its application in two parts (formulation of diarsenic trioxide powder into a mixture and liquid formulation for use in an industrial electrolytic process). For the company, it would not make sense to obtain one use authorised without the other one also being authorised. However, in the first use, the applicant did not submit an analysis of alternatives arguing that: "*At the formulation stage the substance has no function so no analysis of alternatives can (or needs) to be made, it is simply a separate step that requires its own exposure scenario. The reader is referred to the full analysis of alternatives for the second use that describes the industrial use of the preparation*". SEAC (again) accepted this lack of analysis of alternatives by stating that: "diarsenic trioxide does not have any functionality at the formulation stage"[59] disregarding the legal text requirements.

In other cases where the application is lacking very basic information, SEAC (along the same lines as RAC) reduces the review periods it suggested instead of giving a negative opinion. SEAC has never rendered a negative opinion so far.

Another example is the application for trichloroethylene (use No 12). The technical and economic feasibility of alternatives are poorly described and the survey of downstream users is very limited. In its opinion SEAC states "*SEAC does not find the descriptions and comparison of alternatives considered by the applicant sufficiently detailed and wide enough in their scope, such that questions remain about the scope of alternatives considered as well as the extent to which alternatives have had their technical and economic feasibility adequately assessed from the perspective of the downstream users*".[60] Instead of suggesting a rejection of the application, SEAC is recommending a shorter authorisation period of 26 months.

Several other applications have lacked the necessary information for SEAC to adequately deliver its opinions. In these cases, instead of rejecting the authorisation, SEAC has looked itself for data and carried out its own assessments.

This is the case, for example, of the opinion development on the applications of several uses of DEHP for the manufacture of PVC products and articles. In these cases, RAC considered that the applicant did not demonstrate adequate control for all the uses applied for and could not calculate the remaining risks due to the lack of adequate exposure information. Further, SEAC considered that the health impact analysis provided by the applicant was not adequate. But crucially, instead of giving a negative opinion as the applicant did not fulfil the criteria, SEAC decided to carry out its own estimations of both the health impacts caused by the continued use of this SVHC and their related

58 Applications of DCC Maastricht B.V. OR for Lead sulfochromate yellow (C.I. Pigment Yellow 34) and Lead chromate molybdate sulphate red (C.I. Pigment Red 104) for the use number 1 of Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use. Application numbers: 0012-01 and 0012-02. Detailed information available at: ***http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1627/term*** and ***http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1628/term***

59 Application of Linxens France SA for diarsenic trioxide for the use: Formulation of diarsenic trioxide powder into a mixture. Liquid formulation for use in an industrial electrolytic process. Application number: 0011-01. Detailed information available at: ***http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1625/term***

60 Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Opinion on an Application for Authorisation for Trichloroethylene Industrial use of trichloroethylene (TCE) as a solvent as a degreasing agent in closed systems. ECHA/RAC/SEAC: AFA-O-0000006175-75-01/D. Consolidated version. Date: 15 July 2015 ***http://echa.europa.eu/documents/10162/bb35cbbf-60cf-46bd-967f-073400bf0490***

costs, in order to demonstrate that the benefits for the applicant overweighed the risks to the population.[61]

EEB recommendation:

REACH triggers applicants for authorisation to submit an analysis of alternatives (Article 62(4)(e)). ECHA should not, therefore, accept applications without an analysis of alternatives and SEAC should reject them. SEAC should also reject any information that has not been adequately referenced and documented instead of merely reducing the review period it recommends. Likewise, SEAC should not complete this information on the applicant's behalf. As RAC, SEAC has to give opinions on the information as described in the application and not in general – meaning that SEAC cannot make an opinion if the description is flawed.

Analysis of Alternatives

In general, applicants are only considering "drop-in" substitutions (i.e. the replacement of one chemical substance by another chemical substance) as possible alternatives. In most cases, applicants do not consider alternative materials, technologies or processes. SEAC does not consider if each individual use applied for can be substituted, but rather looks to see if the substance can be substituted (e.g. lead chromates' and phthalates' broad uses applied for).

For all submitted applications, SEAC has considered that there do not appear to be suitable alternatives for the applicant.

SEAC's role is to assess if the applicant has considered all available information on alternatives in its application and whether it has demonstrated that there are no technically and economically feasible alternatives for the use(s) for which they applied.

SEAC had a very intense discussion on how to evaluate feasibility since there is no definition in the REACH legal text on what feasible means.[62] Leading English dictionaries give the literal meaning of feasible as "able to be made, done, or achieved"[63] and the literal meaning is exactly the same in other language versions of the Regulation.[64] Hence, the literal standard provided by REACH is whether an alternative exists for the use in question and whether the alternative serves the function needed in the technical sense.

EEB recommendation:

In order to guarantee that all suitable alternatives can be addressed, the analysis of alternatives must clearly and comprehensively define the ultimate function of the mixture, article or process where the SVHC is used in addition to the narrow function of the substance in the product. A broad and comprehensive definition of the use would ensure that both specific information on the technical function of the substance as well as a good understanding of the end use and service-life of the substances are provided.

It is extremely important to clarify the scope of an analysis of alternatives, which should be much broader than evaluations of drop-in substitutes.

Non drop-in alternatives as well as alternatives to downstream uses should be better considered by SEAC.

Technical feasibility

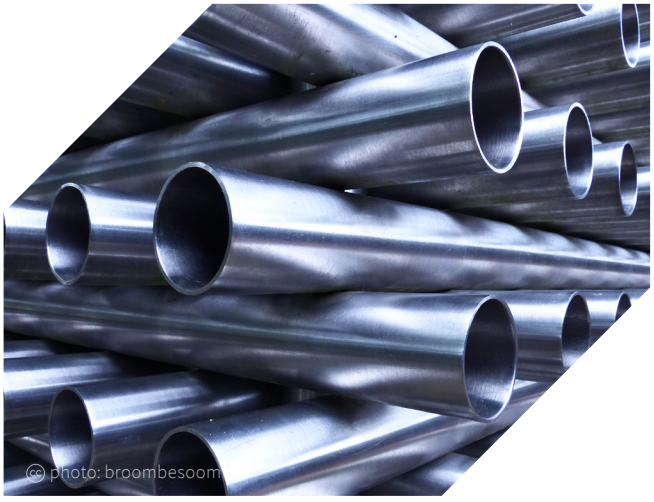
An alternative should be considered to be technically feasible when the applicant or third parties through the public consultation or under a SEAC request justify that alternative substances, materials, technologies or processes are available in the marketplace for the use(s) applied for. The definition of use(s) is therefore key to evaluate alternatives, and applicants have to

61 Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC). Opinion on an Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP) for industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, small household items (<10cm) that can be swallowed by children, clothing intended to be worn against the bare skin; also toys, cosmetics and food contact material (restricted under other EU regulation)] ECHA/RAC/Opinion N° AFA-O-0000004280-84-13/D ECHA/SEAC/Opinion N° AFA-O-0000004280-84-13/D Consolidated version 22 October 2014.

62 ECHA, "How the Committee for Socio-Economic Analysis will evaluate economic feasibility in applications for authorisation", 2013, SEAC/18/2013/03. Available at: *https://echa.europa.eu/documents/10162/13580/seac_authorisations_economic_feasibility_evaluation_en.pdf*

63 See *http://dictionary.cambridge.org/dictionary/british/feasible*; cf. also *http://www.merriam-webster.com/dictionary/feasible* and *http://www.collinsdictionary.com/dictionary/english/feasible?showCookiePolicy=true*.

64 e.g. In French "faisabilité" means "[q]u'on peut faire; possible, realisable", cf. *http://www.larousse.fr/dictionnaires/francais/faisable/32715*; in Spanish « viable » means "Dicho de un asunto: Que, por sus circunstancias, tiene probabilidades de poderse llevar a cabo", *http://lema.rae.es/drae/?val=viable*; in German "Durchführbarkeit" is synonymous with "ausführbar, machbar, möglich, praktikabel, realisierbar, zu machen",*http://www.duden.de/rechtschreibung/durchfuehrbar*; in Dutch "haalbar" means "te bereiken of verkrijgen",*http://www.vandale.nl/opzoeken?pattern=haalbaar&lang=nn#.VQhc_E3wsdU*.



provide detailed information on the precise functions or tasks performed by the Annex XIV substance.

Applicants use, in general, a narrow definition of the precise function of the SVHC in their identification of alternatives that leads mainly to the identification of drop-in chemicals as feasible replacements for the SVHC. Narrow use(s) definitions lead to an unreasonable narrow view of alternatives and therefore the applicants do not properly address the technical, economic, and social impacts of alternative materials, technologies and processes. This is the case, in particular, of applicants of authorisations for broad uses.

Applications submitted by manufacturers and importers are, of course, tailored to their interests, that is, to continue producing and marketing these SVHC, and do not consider adequately available alternatives for downstream users.

For example, this is the case of the application for the use of HBCDD that was (intentionally) split by the applicant into two uses; the manufacture of flame-retarded (FR) unexpanded polystyrene beads and in the expansion of these beads into expanded polystyrene (EPS), and formation of the polystyrene into articles. The applicants excluded any alternative that is not a simple drop-in substitute for HBCDD in the process for manufacturing EPS. The applicants define the function of HBCDD as "a flame retardant in EPS" and state that this specific function means that other insulation materials do not need to be considered, i.e., they are not alternatives to HBCDD, although the applications cover a wide range of uses such as, flat and pitched roof insulation, floor/slab insulation, interior wall insulation with gypsum board, insulated concrete forms and sound insulation in floating floors. While this is sensible from the point of view of the manufacturer, it does not give a complete picture of the alternatives available to HBCDD or to FR-EPS.

Applicants use, in general, a narrow definition of the precise function of the SVHC in their identification of alternatives that leads mainly to the identification of drop-in chemicals as feasible replacements for the SVHC. Narrow use(s) definitions lead to an unreasonable narrow view of alternatives and therefore the applicants do not properly address the technical, economic, and social impacts of alternative materials, technologies and processes.

While HBCDD's narrowly defined function is to flame-retarded EPS, the purpose of flame retarding EPS is to provide fire-resistant building material (primarily for insulation, but with other functions, as described above). During the public consultation, information on many other means of achieving these same essential functions was submitted, including alternative substances, materials (mineral wool, PUR, XPS, natural materials such as wool, cork, etc.) and improvements in building design. However, SEAC accepted in this and in other applications the narrow definition of essential functions used by the applicants that result in an inappropriately narrow alternatives assessment.

The appropriate scope of an analysis of alternatives must include all possible substances, materials, and techniques which could be used to "remove the need for the Annex XIV substance function altogether" as advised by ECHA.[65] According to the "Guidance on the preparation of an application for authorisation", *"an alternative is not necessarily a drop-in replacement, it could also be a technique (e.g. a process, procedure, device, or modification in end product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in production, process or product that removes the need for the Annex XIV substance function altogether."* [37]

SEAC opinions also lack consistency regarding technical feasibility. For example, in its opinion on the application for the use of DEHP for the manufacture of raw PVC articles it considers that

65 Submission of information on alternatives by interested third parties for the public consultations on alternatives for Applications for Authorisation. ECHA -13-G-02-EN, March 2013. Available at: *http://echa.europa.eu/documents/10162/13555/instructions_third_parties_afa_en.pdf*

alternative materials are technically feasible for downstream users manufacturing PVC articles (e.g. for rubber boots, garden articles, etc.). However, in its opinion on the application for the use of DEHP for the manufacture of the same articles with recycled PVC, SEAC considers that no technically feasible alternatives are available, not even raw PVC!

EEB recommendation:

SEAC should set clear and consistent criteria for assessing technical feasibility and not only rely on applicants' declarations of non-technical feasibility. This would add predictability to the process. If a "similar" company (with similar size, production processes and products) produces, imports or uses an alternative, this should be a clear sign that alternatives are technically feasible.

SEAC should assess the technical feasibility for the use applied for, including the downstream uses of the upstream applications. If alternatives are available for the downstream users or there are similar downstream users using alternatives, these should be considered technically feasible by SEAC.

Economic feasibility

According to the guidance on the preparation of an application for authorisation "one criterion for an alternative to be economically feasible is whether the net present value of the revenues minus costs is positive".[66] In other words, the issue is that using the alternative should result in generating gross profit. The guidance document does not identify any other compulsory criterion and, therefore, we contend that in fact this is the only applicable standard. This guidance creates legitimate expectations both to applicants and to third parties, as it is "also intended to be used by third parties that may have information on alternative[s; emphasis added]".[67]

Unfortunately ECHA's view is not in line with the SEAC's guidance on how to evaluate economic feasibility:

"*Economic feasibility does not equate to an individual firm's ability to afford to pay for any increases in net cost which might be associated with an alternative substance or technique" because of "the principle of equal treatment of applicants in similar situations". The committee "does not consider that it would be appropriate to set some non-zero threshold below which any increase in costs associated with an alternative would be judged economically feasible for the applicant to adopt" as "there are no agreed criteria for what a reasonable threshold should be*".[68]

Although SEAC's instructions recognise the need for "clear principles, which can provide guidance", they merely reject affordability and a non-zero threshold as a standard, and do not provide any conclusions or a reliable standard of their own.

In line with the inconclusiveness of its paper, SEAC has avoided giving a clear definition of economic feasibility in its opinions.

Although SEAC's paper states that it is not possible to establish a threshold zero, in practice SEAC's focus on net costs for the applicant seems to indicate that it is inclined to deny feasibility if the switch to the alternative would entail higher costs. This was the case in its opinion on the application for authorisation for the industrial use of diarsenic trioxide as a processing aid in gold electroplating.[69]

However, SEAC has occasionally used the willingness of the applicant to bear the additional costs of an alternative as what seems to be a corrective to its apparent standard of no additional costs. This was the case in its opinion on the application for the authorisation of HBCDD in the formulation of FR EPS.[70]

The standard provided for by the Regulation is not whether the applicant wants to use the alternative but whether he can. SEAC's approach has important negative consequences:

- Applicants tend to exaggerate the cost to say that there are no suitable alternatives.
- Progressive replacement of SVHC with safer alternatives is delayed (with the consequent higher costs for human health and/or environment).
- It reduces incentives for innovation (that cause market loss for companies using safer alternatives).

It seems that ECHA sets the measure of economic feasibility as 'if you apply for authorisation it is because it is not economically feasible to apply an alternative' - which is placing the horse before the cart.

SEAC has avoided giving a clear definition of economic feasibility in its opinions.

SEAC opinions are also lacking consistency, clarity and predictability, and therefore are discouraging potential suppliers of alternatives to participate in the authorisation process.

When assessing the economic feasibility of alternatives, applicants in general tend to only consider the cost of implementation of the safer substances, but not the cost savings related to

66 ECHA, "Guidance on the preparation of an application for authorisation", 2011, ECHA-11-G-01-EN, *https://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf.* p. 75; partly repeated on p. 77.

67 Ibid.66, p. 1.

68 ECHA, "How the Committee for Socio-Economic Analysis will evaluate economic feasibility in applications for authorisation", 2013, SEAC/18/2013/03. Available at: *https://echa.europa.eu/documents/10162/13580/seac_authorisations_economic_feasibility_evaluation_en.pdf*

69 ECHA, Opinion on an Application for Authorisation for [... i]ndustrial use of diarsenic trioxide as processing aid in gold electroplating", ECHA/RAC/SEAC AFA-O-0000004619-65-12/D, p. 12. *http://echa.europa.eu/documents/10162/5353a295-34cf-431c-8346-91dd867454a5*

70 ECHA, Opinions on applications for Authorisation for HBCDD in the formulation of FR EPS, ECHA/RAC/SEAC: AFA-O-0000004949-56-11/D, p. 19 and in the manufacture FR EPS, AFA-O-0000004949-56-12/D, p. 19. *http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1602/term*

avoiding the use of the SVHC as described in ECHA's guidance on the preparation of socio-economic analysis as part of an application for authorisation (e.g. costs related to worker protection expenses, monitoring of emissions, disposal costs, etc).[71]

Furthermore, in applications for broad uses submitted by manufacturers/importers for formulations of the SVHC they manufacture/import and also for broad downstream uses of these formulations, economic feasibility is generally assessed only from the manufacturers' perspective, not for the (broad) use applied for. However, as the application also covers downstream uses, the economic feasibility for the companies using these SVHC should also be assessed.[72]

EEB recommendation:

SEAC should review its apparent interpretation of economic feasibility, using higher net costs as a yardstick and leaving "economic feasibility" with hardly any meaning, as no business in its right mind would ever apply for authorisation if the (safer) alternative was also cheaper. There is a need for "economic feasibility" to be defined beyond 'not more expensive' considering that feasible means 'possible'.

Likewise the use of the "willingness" of the applicant to use the alternative as a standard for economic feasibility should be reviewed.

Detailed observations on SEAC's work on authorisations have been described already by NGOs in a paper presented at CARACAL's March 2015 meeting.[73]

SEAC should also consider costs beyond implementation, in particular on the cost savings related to avoiding the use of the SVHC.

Likewise in the technical feasibility section, the fact that "similar" companies, including downstream users are using alternatives without a major impact in their competitiveness or that even gained market shares because of that, should be used as an indicator of economic feasibility.

Socio-economic Assessment

SEAC's second role is to assess if the applicant has demonstrated that the socio-economic benefits arising from the use of the SVHC outweigh the risk to human health or the environment.

Socio-economic assessments provided by applicants lack, in general, an adequate consideration of the risks to human health and the environment and an analysis from a societal, rather than the applicant's perspective. They also tend to overestimate the costs of not using the SVHC. For example, the applicant for HBCDD[74] assumes that if it cannot produce the substance production would cease by 2015-2019. According to SEAC, such a non-use scenario is not realistic and the associated costs are overestimated.

In some cases SEAC acknowledges that large uncertainties in the socio-economic analyses make it difficult to use cost-effectiveness as the sole basis on which to conclude if the benefits of an authorisation would outweigh the risks (as it is the case for HBCDD AfA). Even more, "some applicants did not demonstrate if benefits outweighed risks".[75] However, SEAC has recommended all applications for authorisation to be granted to date.

SEAC opinions are also lacking consistency, clarity and predictability, and therefore are discouraging potential suppliers of alternatives to participate in the authorisation process.

A fundamental problem in SEAC's opinion development is the fact that when applicants do not provide the necessary socio-economic information to deliver a justified opinion or when the applicant does not demonstrate that the benefits of the use outweigh the risks, this committee looks for the needed information and carries out its own assessments and calculations.

For example, during the opinion development of the applications for the use of DEHP in PVC, SEAC did not use the applicants' socio-economic analyses because it considered that the assumptions regarding the relation between exposure and effects were arbitrary, and because the assumptions made for the general population were applied to the workers population. Instead of delivering a negative opinion, SEAC made its own worst case scenario calculation to conclude that the benefits of continued use of DEHP outweigh the risks, although RAC did not calculate the remaining risks due to a lack of appropriate information.

As commented in the section on RAC, the legal text establishes the burden of proof on the applicants.

71 ECHA. Appendix B: Estimating Impacts. Guidance on the preparation of socio-economic analysis as part of an application for authorisation. Helsinki: ECHA, 2011.

72 REACH Art. 62(3) states … Applications may be made for the applicants' own use(s) and/or for uses for which he intends to place the substance on the market.

73 ClientEarth, EEB, HEAL & CHEM Trust. NGO Observations on the Work of the ECHA Committee on Socio-Economic Analysis in the Context of Authorisations under REACH.

74 AfA for HBCDD by INEOS Styrenics et al. consultation No 0013-01 and 0013-02. Detailed information available at: *http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1602/term* and *http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1603/term*

75 Experience in the Committee for Socio-Economic Analysis. Lessons learnt on Applications for Authorisation 10-11 February, 2015. Tomas Öberg, Chairman of SEAC.

Furthermore, ECHA's common approach on opinion development on applications for authorisation[76] states: "*It is the responsibility of the applicant to demonstrate that the risks are adequately controlled and/or the benefits of continued use outweigh the remaining risks.... RAC and SEAC should be reticent to gather additional information or data, other than specified in Article 64(1) and 64(3), and should not redo the applicants assessments.*"

EEB recommendation:

In our view, SEAC serves as the viewpoint of the applicant rather than a "neutral" judge for society (including the alternatives users/producers). Taking into account only the applicant's point of view is a narrow approach since benefits for society and companies producing safer alternatives are disregarded.

Weighing socio-economic benefits and risks as well as deliberating about the proportionality of regulatory action is a political (and hence not an ECHA) task. Further elaboration on this is needed by the Commission and Member States.[77]

SEAC should apply REACH's allocation of the burden of proof, which is on the applicants. It is a challenging exercise for SEAC to adequately assess if the applicants demonstrate that the benefits of continued use outweigh the remaining risks given the poor information provided in many cases by the applicants. We believe that this committee can improve its opinions by improving the methodology used in socio-economic assessments.

A better balance between costs for the applicant and external costs associated with SVHC is needed.

Opinions delivered by SEAC

All the opinions delivered by SEAC until now have supported the granting of authorisations, even in cases where the applicants failed to prove that adequate control was reached, that no safer alternatives were available and that the socio-economic benefits outweigh the risks to human health and the environment.

SEAC prefers to propose short review periods for these applications than to give a negative opinion. This has been the case for DEHP in raw PVC, HBCDD and trichloroethylene.

76 Ibid 38

77 "REACH and Beyond - Challenges and Options for Improvements" Conference: ***http://conferencemanager.events/REACHandBeyond***. Alexander Nies (German Federal Ministry for the Environment)

A fundamental problem in SEAC's opinion development is the fact that when applicants do not provide the necessary socio-economic information to deliver a justified opinion or when the applicant does not demonstrate that the benefits of the use outweigh the risks, this committee looks for the needed information and carries out its own assessments and calculations.

It is RAC's role to assess the risks of the use(s) of the SVHC and suggest the length of the review period taking this in account. However, SEAC does not always follow RAC's recommendations, and in several cases (e.g. DEHP for recycled PVC, HBCDD and diarsenic trioxide) it has suggested longer review periods. In several opinions SEAC has even proposed longer review periods than those needed or solicited by the applicants. This is the case of the application from Rolls Royce, which stated that the company needed 18 months to implement the alternative, however SEAC proposed a seven-year review period.[78] This is also the case for the opinion on the applications for the use of HBCDD in FR EPS, where SEAC proposed a longer review period (24 months) than the period requested by the applicant (18 months).[79]

SEAC's and RAC's reluctance to give negative opinions reflects the positions expressed by some ECHA officials that applying for authorisation under REACH is "[j]ust like getting any other permit".[80]

78 AfA for DEHP by Rolls Royce. Available at: ***http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1601/term***

79 AfA for HBCDD by INEOS Styrenics et al. Available at: ***http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1602/term***

80 Vainio, ECHA, "Lessons learnt from applications for authorisation", presentation given on 21.05.2014, slide 5, available at ***http://echa.europa.eu/documents/10162/21688319/13_shd9_applications_auth_mv_en.pdf***

EEB recommendation:

Instead of shortening the review period, SEAC should follow the REACH legal text and deliver negative opinions to those applications that do not meet the legal requirements.

SEAC should not override the view of the RAC. If RAC concludes that workers are not adequately protected from the SVHC (e.g. in the phthalate case), SEAC should not recommend authorisation because the profits from the companies (choosing to not invest in protection but rather gain money) are giving sufficient benefits to the company that it is worth it.

We consider that positive opinions to all applications is undermining the REACH authorisation process, and penalising and giving a very negative signal to companies that are developing safer alternatives.

Recommending that all authorisations should be granted by default is contrary to the primary aim of Title VII on authorisation, this is, to foster substitution in a well functioning internal market (Article 55, first sentence).

2.7. Impacts of Better Regulation on REACH Authorisation

As a response to some industries' claims that authorisation is expensive, burdensome, unpredictable and complex, the European Commission committed in its Better Regulation package published in May 2015, to "simplify the authorisation procedure, reduce the amount of information required and increase the predictability of the process" in order to "reduce burdens".[81]

Instead of shortening the review period, SEAC should follow the REACH legal text and deliver negative opinions to those applications that do not meet the legal requirements.

In contrast, during ECHA's Conference on Lessons learnt in the Authorisation Process, several stakeholders, including industry, agreed that the authorisation process was, in general, delivering results.

Nevertheless, the Commission has initiated in 2015 the process of "simplifying and streamlining" applications for the authorisation process with the aim to "improve the perception of and trust in functioning of the authorisation process" and to "work on improvements to reduce the burden of the application phase".[82]

To date, the Commission has initiated various activities including:

— **Taking socio-economic elements into account before taking decisions on the future Annex XIV update through additional public consultations** (see section 2.2).

As stated in section 2.2, the Commission now asks ECHA to launch additional public consultations to gather more socio economic information than the requested to applicants although the uses that will be applied for are still unknown. This public consultation opens the possibility for industry to seek for new exemptions and derogations, is duplicating information to the process and shifts the burden from companies using SVHC to third parties.

81 Better regulation for better results -An EU agenda. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Strasbourg, 19.5.2015. COM(2015) 215 final. Available at: *http://ec.europa.eu/smart-regulation/better_regulation/documents/com_2015_215_en.pdf*

82 European Commission. Berend. Conference on "Lessons learnt on Applications for Authorisation". 10-11 February 2015 | Helsinki. Available at: *http://echa.europa.eu/documents/10162/21825501/afa_201502_2_berend_en.pdf*

— **Drawing up legal interpretation and guidance** (e.g. on the scope of authorisation or the suitability and availability of alternatives for the applicant and for the downstream users);

— **Streamlining and simplifying the authorisation application procedure in specific cases.**

The European Commission is preparing implementing acts to simplify REACH authorisation for uses of substances in low volumes and in legacy spare parts. Other uses are under consideration, such as uses in products subject to type-approval and uses as biologically essential elements or recycled materials.

The Commission's proposal is to consider low volume applications as those wanting to use 100 kg or less of a substance per year and per legal entity. The proposal does not differentiate between threshold and non-threshold substances, but this is an error since by definition no level of exposure is safe for non-threshold substances and therefore the volume limit is meaningless. Furthermore, the Commission does not take into consideration the conditions in which the substances are used by companies nor the size of the company applying for authorisation. It is well known that SMEs have less knowledge and resources to manage chemicals safely.[83] The use of 100 kg/year in a workplace with high exposure potential or by an SME could imply a considerable risk.

In our view, the thresholds proposed by the Commission are too arbitrary to form a reliable basis for an exception from the general requirements provided by REACH as there is no data supporting that these thresholds are adequate.

The purported justification for simplifying the authorisation of the use of SVHC in legacy spare parts is that the use of the substance is necessary for the production of the spare part and the spare part is necessary for the proper functioning of an existing legacy article ("chain of necessity"). However, no such necessity exists when the legacy article is not only maintained but upgraded.

— **The general streamlining of authorisation applications (for all cases, more fit-for-purpose).**

It will focus mainly on the information required in chemical safety reports, analyses of alternatives and socio-economic analyses. The possibility to exempt certain information to be provided is also considered by the Commission. This is the case for information on alternatives, for example, for uses requiring a "type-approval" and socio-economic aspects information "when clear, very high socio-economic value" is seen. It is not clear who will have the responsibility to judge (before the committees consider the applications) whether there are no suitable alternatives; whether adequate control is proven; or that socio-economic benefits outweigh the costs.

According to the Commission, "*the potential for actually substituting the use of the Annex XIV substances is probably limited*" in certain cases. This assumption is not substantiated and not true for downstream users and is 'putting the cart before the horse'. There is no single source of information confirming that for certain SVHC there are no alternatives available or will be in the near future for specific uses.

In our view, these exemptions imply a fundamental change of REACH and its goals. With this proposal, the Commission is suggesting to by-pass the whole REACH procedures and its scientific committees.

According to the Commission, "the potential for actually substituting the use of the Annex XIV substances is probably limited" in certain cases. This assumption is not substantiated and not true for downstream users and is 'putting the cart before the horse'.

— **The reduction of fees for some cases** (such as low volume uses).[84]

To develop these activities and define its scope, a task force on AfA simplification was established by ECHA and the Commission, together with Member States.

83 COM (2004) 62 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions on the practical implementation of the provisions of the Health and Safety at Work Directives 89/391 (Framework), pp.15-17.
EU-OSHA: "Expert forecast on emerging chemical risks related to occupational safety and health, "Poor control of chemical risks in small and medium enterprises"

84 European Commission. Borras. Conference on "Lessons learnt on Applications for Authorisation". 10-11 February 2015 | Helsinki. Available at: *http://echa.europa.eu/documents/10162/21825501/afa_201502_16_borras_en.pdf*

EEB recommendation:

The claims that authorisation is expensive, burdensome, unpredictable and complex are not well founded or properly justified. Furthermore, the Commission proposal disregards the harm caused by SVHC used in the EU, the interests of civil society and sustainable companies ,and ignores the long-term benefits of the authorisation process for public health and the environment.

The potential exemptions to providing information on alternatives and socio-economic aspects imply an unacceptable fundamental change of the REACH legal text, its goals and principles. It is therefore not an implementation issue and the Commission has no mandate to change the REACH text through an implementing act.

Legal interpretation and guidance to applicants on the scope of an AfA and to applicants and SEAC on the availability of alternatives is needed.

Further, so-called "low volumes" should be subject to the general information requirements. If the Commission proceeds with this proposal, the simplification of applications should in any event not apply to non-threshold substances as, by definition, exposure to any amount of those substances poses a risk. The Commission should also ensure that it is not possible for producers of a substance to apply for downstream users using less than 100 kg each.

Given the exceptional nature of any derogation from the general requirements provided by REACH and the danger posed by the continued use of SVHC, a narrow definition of spare parts needs to be applied if the Commission intends to go forward with this proposal.

The availability of alternatives must not be prejudged, especially given the importance of substitution and innovation.

The Commission's efforts to simplify and streamline the applications for authorisation process have led the process to become more burdensome and ineffective and should not continue beyond drawing up more legal interpretation and guidance.

REACH already provides all the tools for exceptions, consideration of socio-economic aspects and granting authorisations as well as allowing applicants to make their applications simple and clear. We believe that the Commission should focus on improving the quality and reliability of the AfA instead of re-interpreting the legal text or favouring certain industrial sectors.

Adjusting the level of fees according to the volume of SVHC whose continued use is applied for seems to be the most reasonable route to take to lessen the purely cost-related burden without undermining the goal of REACH to ensure a high level of protection of human health and the environment.

The mandate of the task force on applications for authorisation should be expanded to include the implementation of the authorisation process as a whole, on how to achieve its main goal of substitution and making it more efficient both for applicants as well as the authorities.

2.8. Main conclusions on the progress of the authorisation process

1. **Authorisation has started to deliver!**

The authorisation process, introduced in REACH in order to hasten the substitution of substances of high concern with safer alternatives, is starting to work:

- **The publication of the Candidate List has been an important driver for companies to replace SVHC with safer alternatives.**
  "Gemini Adhesives Ltd sees the management of hazardous chemicals as a key part of our business mission and strategy… The authorisation procedure is designed to drive innovation and it has played a key role for the development of our products. The work that the REACH authorities are undertaking is in our view essential to ensuring that we will have all of the information necessary to assess and manage the risks associated with all of the materials we work with and where necessary to substitute hazardous chemicals with safer alternatives".[85]

- **Applications have not been submitted for half of the substances included in Annex XIV with its application deadline expired, meaning that these substances are no longer on the market in the EU** (unless they are introduced through imported articles).

- **Public consultations have provided new information on alternatives not considered by applicants and have shown the technical and economic feasibility of safer alternatives in the supply chain.** Chemical producers, companies manufacturing alternative materials, processes or technologies, downstream users, public authorities, research institutes and NGOs among others are participating in public consultations and showing the availability of safer alternatives for most uses of the SVHC, in particular for broad use applications.

- **Substitution plans are foreseen for several uses**. In many cases, downstream users applying for authorisation are engaged in substitution plans that will result in the use of safer alternatives.

- **The risk management of chemicals is improving in companies as a result of the authorisation process**. Applicants have improved monitoring, operating conditions and risk management measures after deciding to submit applications, in order to be able to- demonstrate that they are able to adequately control the risks from SVHC.

85 Ibid 19

2. **Despite these first achievements, the way the Commission and ECHA are implementing the REACH Regulation authorisation chapter is stopping the authorisation process reaching its final goal of protecting people from dangerous substances.**

So far it seems that ECHA and the Commission are more focussed on assuring that all applications, even if safer alternatives are available, are granted an authorisation. RAC and SEAC have become the European Commission's scientific alibi by rubber-stamping the process:

- **Pre-submission information provided to companies is focused on how to prepare their applications in order to have the authorisation granted, instead of advising them on how to avoid the need to use the SVHC**, and therefore avoid the need to submit an application.

- **All applications are deemed in conformity by default even if they do not conform with the information requirements.** ECHA's consideration of the conformity check as a bureaucratic step or a completeness check, is shifting the burden of proof and information provision on the committees instead of on the applicants. This is one of the main failures of the implementation of the authorisation process.

- **Applications for broad uses are not being rejected.** Broad use applications provide very general descriptions of uses that are not documented by corresponding exposure and alternatives assessments. As a result, it is not possible to understand the risks from the continued use of the substance or the availability of alternatives for all the uses. Broad scope applications do not conform to the requirements of Article 62 (as required by Article 60(7)) and should be rejected at the conformity check stage.

- **Applicants are being allowed to complete their applications throughout the RAC and SEAC opinion development process.** The RAC and SEAC have constantly requested information from the applicants after the applications had already been deemed complete by ECHA's secretariat. Although REACH article 64(3) allows further information from the applicant can be requested, it is only SEAC who can request such information in relation to possible alternative substances or technologies. However, both committees have requested information (not related with alternatives), much later, after the conformity check phase. Therefore, any information that is received by the committees after that phase may not be taken into account for the final opinions or the Commission decisions.

- **The RAC and SEAC roles have been distorted** - instead of assessing if applicants meet the requirements for having an authorisation granted, the committees are doing the applicants' work and carrying out information searches, calculations and assessments in order to conclude that the applications should be always granted.

- **Instead of giving negative opinions to applications that do not meet the legal and quality requirements, the ECHA committees are proposing shorter review periods.** Even in cases where the application is lacking very basic information or where the applicants failed to prove that adequate control was reached, that no safer alternatives were available and that the socio-economic benefits outweigh the risks to human health and the environment. Instead of proposing short review periods, RAC (and SEAC) should follow the REACH legal text and give negative opinions to those applications that do not meet the legal requirements according to the legal text.

With these decisions, the Commission and ECHA are undermining the authorisation process and creating an economic disadvantage for front-runners, as the companies that have invested in safer alternatives claim:

RAC and SEAC have become the European Commission's scientific alibi by rubber-stamping the process

"*Granting this authorisation will cause an economic disadvantage to those companies who have invested resources in substituting HBCDD, such as the FR manufacturers due to idling of plant and EPS bead manufacturers, other than the Applicants, due to increased costs and cause confusion in the industry about the regulatory process. Finally, it will stifle innovation in the European industry to develop substances with improved toxicological profiles and run counter to the policy objectives underpinning the*

authorisation process." Response from Chemtura to the public consultation on application for authorisation of HBCDD.[86]

"As part of our commitment to providing safer and more sustainable solutions for our customers, AkzoNobel phased out the use of lead compounds in paints some years ago. In 2011 we phased out the last remaining uses of lead chromate in all our industrial paints. As safer and effective alternatives to lead chromate pigments are available for industrial paints and have been fully accepted in the marketplace, we are surprised that the EU looks set to grant an authorisation for the continued use of lead chromate in these paints for at least 12 more years under REACH."[87]

Granting all applications for authorisations automatically is discouraging proactive companies to remain willing to innovate and substitute early.

The granting of all authorisations is an indicator of the failure of the process; a system that works against its fundamental principles will always fail.

3. **The RAC and SEAC need to improve their assessments.**

In particular SEAC's narrow interpretation of technical and economic feasibility leads to the opinion that no alternatives are ever suitable for the applicants. SEAC's methodology for socio-economic assessment is overestimating the benefits for applicants and underestimating the costs for society as a whole for the continued uses of the SVHC.

Regarding RAC, the committee should stop assuming that certain substances such as reprotoxicants have a safe threshold (i.e. DNEL) by default. RAC should also consider the combined exposure to several SVHC in the same use.

86 Ibid 19

87 Ibid 19

4. **Exemptions to information requirements are unacceptable for all SVHCs in Annex XIV and there is a need to improve the implementation of the authorisation process as a whole, to ensure it achieves its main goal of substitution and to make it more efficient both for applicants and the authorities.**

So far, the Commission's efforts to simplify and streamline REACH application for authorisaiton process have led the process to become more burdensome and ineffective.

Granting all applications for authorisations automatically is discouraging proactive companies to remain willing to innovate and substitute early.

The potential exemptions to providing information on alternatives and socio-economic aspects imply an unacceptable fundamental change of the REACH legal text, its goals and principles.

We believe that the Commission should focus on improving the quality and reliability of the applications for authorisation as well as on achieving its main goal of substitution and making it more efficient both for applicants as well as the authorities. This should be instead of favouring certain sectors, namely those that lobby hardest, and making it easier and cheaper for companies producing and using obsolete SVHC to get authorisations.

photo: Takashi Ota

3. EEB RECOMMENDATIONS TO MAKE AUTHORISATION WORK TO PROTECT PEOPLE AND THE ENVIRONMENT

To the Commission:

- Speed up the inclusion of substances in the Candidate and Authorisation Lists.
- Simplify and streamline the whole process of including substances in the Candidate List in order to help Member States submit their proposals and be able to better contribute to the overall goal of the authorisation process, this is to assure that SVHC are replaced by safer alternatives.
- Give a clear mandate to ECHA to give favourable opinions only for specific, well documented and well justified applications and to reject applications for broad uses of SVHC at the conformity check stage.
- Reject granting authorisations for broad uses of SVHC and for applications that do not meet the requirements established in the REACH legal text or where the conditions for granting are not fulfilled, including authorisations for the use of DEHP in raw and recycled PVC, HBCDD in FR EPS and lead chromate pigments.
- Reject granting authorisations for uses for which safer alternatives are already available in the European market.
- Start to prepare an Annex XV restriction dossier for SVHC in the Candidate List that may be present in imported articles before the sunset date in order to effectively protect EU citizens and the environment from SVHC. Article 68(2) regarding the restriction of uses of CMRs in consumer articles should be used in order to avoid the need for full Annex XV dossiers. Other measures, such as product-specific legislations should also be considered. These measures will also help to overcome the competitive disadvantage for EU producers with respect to SVHC in imported articles can still be used in articles produced by non-EU based companies.
- Provide incentives and support to companies to substitute SVHC, especially downstream users and SMEs. Improved communication about the real aims of the authorisation process is needed. Furthermore, economic and technical support is key to encourage companies to innovate and substitute SVHC from their production processes.
- Stop earlier initiatives like RMOAs or additional public consultations not foreseen under the REACH legal text that have made the process more cumbersome.
- Maintain general information requirements for all SVHCs and uses included in Annex XIV. If the Commission proceeds with this proposal to simplify and streamline them in some specific cases this should not in any event apply to non-threshold substances.
- Consider all intrinsically hazardous properties of the SVHC when deciding to permit the continued or new use of such substances.
- Expand the mandate of the task force on applications for authorisation to include the implementation of the authorisation process as a whole, the achievement of its main goal of substitution and how to make it more efficient both for applicants as well as the authorities.
- Address during the upcoming REACH review, the deficiencies in the legal text that are hindering the implementation of the authorisation process.
- Discuss with Member States how to properly differentiate between scientific and political deliberations by RAC and SEAC. While describing and attempting to quantify risks, costs and benefits is a technical problem to be undertaken by committees like RAC and SEAC, we must remember that the actual weighing of costs and benefits is inherently a political and social task. While SEAC evaluates costs and benefits, we believe it is the job of the Commission, a political body, to weigh these issues and to evaluate the overall proportionality of any regulatory measure.

The Commission should focus on improving the quality and reliability of the applications for authorisation as well as on achieving its main goal of substitution and making it more efficient both for applicants as well as the authorities.

To ECHA

- Apply the REACH allocation of the burden of proof on applicants for authorisation.
- Develop guidance for companies to provide fit-for-purpose, brief, meaningful and transparent and only relevant information in their applications for authorisation.
- Evaluate the confidentiality claims by applicants for authorisation.
- Reject applications with broad uses not covering all downstream uses with sufficient and relevant exposure scenarios or insufficient data during the conformity check.
- Reject applications at the conformity check stage if exposure scenarios are not described in detail for all uses covered by the application.
- Treat all applications in the same way instead of favouring broad applications by not demanding the same detailed level of information in the exposure scenarios and socio-economic parts as for more specific applications.
- Encourage third parties' contributions to the public consultations on alternatives.
- Improve the limitations of risk assessments.
- Set clear standards to evaluate both technical and economic feasibility.
- SEAC to improve socio-economic assessments by including all costs for society and the profits for competitors producing alternatives. A better balance between costs for the applicant and external costs associated with SVHC is needed.
- RAC to first critically evaluate whether a safe DNEL can be set for the SVHC in question in order to define whether it is or it is not a threshold substance. RAC should take all available most recent science into account, including combined effects or overlapping endpoints or modes of action.
- MSC to consider extra criteria for substance prioritisation in Annex XIV, such as evidence on occupational diseases linked to SVHC.
- MSC to consider all SVHC remaining in the Candidate List for each new recommendation for Annex XIV.
- Give clear instructions to RAC and SEAC not to support recommendations for authorisation for poorly described or insufficiently justified applications for authorisation.
- Actively provide guidance and support on the substitution of SVHC by adequately informing companies on how to avoid their use instead of helping them to apply for authorisation. ECHA should also develop guidance on how to identify alternatives and on alternatives assessment. Furthermore, economic and technical support is key to encourage companies to innovate and substitute SVHC from their production processes.
- To establish a process for regularly reviewing if new information on possible substitutes becomes available.

To Member State Competent Authorities

- Speed up the inclusion of SVHC in the Candidate List.
- Demand the speeding up of the inclusion of SVHC in the Authorisation List.
- Commit to a minimum number of proposals of SVHC in the Candidate List. Member States with limited resources could make use of Article 59 to submit proposals of SVHC with a harmonised classification while Member States with greater resources could focus on Article 57(f).
- Vote against the granting of authorisations to applications that did not fulfil the criteria established by the REACH legal text or when alternatives are shown to be available during consultations in the REACH Committee.

To Members of the European Parliament

- Demand the Commission speeds up the inclusion of SVHC in the Candidate and the Authorisation lists.
- Follow up and review the procedures and outcomes of the Commission's and ECHA's work regarding the authorisation of SVHC.
- Demand the Commission follows the requirements established in the REACH Regulation when deciding on granting authorisations and oppose authorisation decisions otherwise.

4. GLOSSARY

AfA: application for authorisation

AoA: analysis of alternatives

CMR: Carcinogenic, Mutagenic or toxic to Reproduction

CLP: Regulation on classification, labelling and packaging of substances (Directive 67/548/EEC)

CSA: chemical safety assessment

CSR: chemical safety report

DNEL: derived no-effect level

ECHA: European chemicals agency, so called the Agency

EDC: endocrine disrupting chemicals

FR EPS: flame retarded expanded polystyrene

MS: Member State

MSC: member state committee

OC: operational conditions

PBT: persistent, bioaccumulative and toxic

PC: public consultation

RAC: risk assessment committee

RCR: risk characterisation ration

RMM: risk management measures

RMOA: Risk Management Option Analysis

REACH: Regulation on registration, evaluation, authorisation and restriction of chemicals

SEAC: socio economic analysis committee

SVHC: substance of very high concern

vPvB: very persistent and very bioaccumulative

5. ANNEXES

Annex I. Legal text authorisation in Regulation 1907/2006 (REACH)

Regulation 1907/2006 REACH

Article 55. Aim of authorisation and considerations for substitution

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

Article 60. Granting of Authorisations

2. ...an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

If adequate control is not demonstrated and in the case of non threshold substances:

4. … an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies.

…

5. When assessing whether suitable alternative substances are available, all relevant aspects shall be taken into account by the Commission, including

... 5.b. the technical and economic feasibility of alternatives for the applicant.

Annex II. Progress of the candidate listing[88]

Date of inclusion	Number of substances
28/10/2008	13
13/01/2010	12
30/03/2010	1
18/06/2010	8
15/12/2010	8
20/06/2011	8
19/12/2011	20
18/06/2012	13
19/12/2012	54
20/06/2013	6
16/12/2013	7
16/06/2014	4
17/12/2014	7
15/06/2015	2
Total	163

88 Candidate List, ECHA. *http://echa.europa.eu/candidate-list-table*

Annex III. Progress of RMOA.[89]

Outcome of the RMOA	Number of substances
Under development	73
On hold	14
Appropriate to initiate regulatory risk management action.	26
No need to initiate further regulatory risk management action at this time.	6
Total of substances under the screening process	119

Annex IV. Number of Annex XV SVHC dossiers submitted by Member States and ECHA.[90]

Submitter	Number of Annex XV SVHC dossiers	%
ECHA	55	28
Germany	44	23
France	17	9
Netherlands	14	7
Austria	13	7
Sweden	13	7
Denmark	9	5
Poland	9	5
Belgium	7	4
Norway	6	3
Slovakia	2	1
UK	2	1
Slovenia	1	
Spain	1	
Total	193	100

89 *http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact* Consulted the 19 May, 2015.

90 ECHA. Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures. Annual Report. Helsinki: ECHA, 23 March 2015

Annex V. Registered chemicals in the EU by country.[91]

Overview of all Countries	Registrations	Substances
Germany	10957	4750
United Kingdom	5061	2092
France	3713	1828
Netherlands	3647	1663
Italy	3331	1651
Belgium	3005	1585
Spain	2958	1455
Ireland	1429	716
Poland	1125	485
Sweden	1118	705
Finland	932	470
Czech Republic	727	439
Austria	691	428
Greece	520	187
Hungary	458	357
Romania	372	232
Norway	339	232
Denmark	336	256
Bulgaria	314	175
Portugal	285	189
Luxembourg	276	156
Slovakia	218	173
Lithuania	159	104
Slovenia	134	95
Cyprus	113	52
Estonia	94	70
Croatia	81	71
Latvia	61	46
Malta	22	19
Iceland	21	15
Liechtenstein	10	9

91 *http://echa.europa.eu/regulations/reach/registration/registration-statistics/overview-all-countries*

Annex VI. Candidate List. Applications have been submitted for the substances that are shaded.

Substance Name	EC Number	Sunset date	Latest application date
Pentazinc chromate octahydroxide	256-418-0	22/01/19	22/07/17
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	22/01/19	22/07/17
Dichromium tris(chromate)	246-356-2	22/01/19	22/07/17
Strontium chromate	232-142-6	22/01/19	22/07/17
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	22/11/17	22/05/16
1,2-Dichloroethane (EDC)	203-458-1	22/11/17	22/05/16
Ammonium dichromate	232-143-1	21/09/17	21/03/16
Potassium chromate	232-140-5	21/09/17	21/03/16
Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5, 236-881-5	21/09/17	21/03/16
Chromium trioxide	215-607-8	21/09/17	21/03/16
Potassium dichromate	231-906-6	21/09/17	21/03/16
Sodium chromate	231-889-5	21/09/17	21/03/16
Sodium dichromate	234-190-3	21/09/17	21/03/16
Arsenic acid	231-901-9	22/08/17	22/02/16
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	22/08/17	22/02/16
Bis(2-methoxyethyl) ether (Diglyme)	203-924-4	22/08/17	22/02/16
Trichloroethylene	201-167-4	21/04/16	21/10/14
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	21/08/15	21/02/14
Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane	221-695-9, 247-148-4	21/08/15	21/02/14
Tris(2-chloroethyl)phosphate (TCEP)	204-118-5	21/08/15	21/02/14
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	21/05/2015	21/11/2013
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	21/05/2015	21/11/2013
Diarsenic pentaoxide	215-116-9	21/05/2015	21/11/2013
Diarsenic trioxide	215-481-4	21/05/2015	21/11/2013
Lead chromate	231-846-0	21/05/2015	21/11/2013
Benzyl butyl phthalate (BBP)	201-622-7	21/02/2015	21/08/2013
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	21/02/2015	21/08/2013
Diisobutyl phthalate (DIBP)	201-553-2	21/02/2015	21/08/2013
Dibutyl phthalate (DBP)	201-557-4	21/02/2015	21/08/2013
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	21/08/2014	21/02/2013
4,4'-Diaminodiphenylmethane (MDA)	202-974-4	21/08/2014	21/02/2013

Annex VII. Applications for authorisation received by ECHA.

Substance	Use	Tonnage band used	Scope	Route
DEHP	Manufacture of aero engine fan blades.	1t/y	Specific	Adequate control
	compounds, dry-blends and Plastisol formulations	> 1000 t/y	Broad	Adequate control & socio-economic
	Production of PVC articles	> 1000 t/y	Broad	Adequate control & socio-economic
	Formulation of recycled soft PVC containing DEHP in compounds and dry-blends	> 1000 t/y	Broad	Adequate control & socio-economic
	Production of recycled PVC articles	> 1000 t/y	Broad	Adequate control & socio-economic
	Ceramic sheets and printing pastes	<= 20 t/y	Specific	Adequate control
	Solid propellants and motor charges for rockets and tactical missiles	300 kg/y	Specific	Adequate control
Dibutyl phthalate (DBP)	Manufacture of maleic anhydride	< 1000 t/y	Specific	Adequate control
	Formulation propellants	50 t/y	Specific	Adequate control
	Ceramic sheets and printing pastes	<= 20 t/y	Specific	Adequate control
	Solid propellants and motor charges for rockets and tactical missiles	< 0.01 t/y	Specific	Adequate control
	Specialty paint in manufacture of motors for rockets and tactical missiles	< 0.04 t/y	Specific	Adequate control
Diarsenic trioxide	Purification of metal impurities from the leaching solution in the zinc electrowinning process	<1000 t/y	Specific	Socio-economic
	Purification of the leaching solution in a zinc electrowinning process	<1000 t/y	Specific	Socio-economic
	Formulation of diarsenic trioxide into a mixture	< 50 kg/y	Specific	Socio-economic
	Industrial use of diarsenic trioxide as processing aid in gold electroplating	< 50 kg/y	Specific	Socio-economic
	processing aid to activate the absorption and desorption of carbon dioxide by potassium carbonate from synthesis gas formed in the production of ammonia	5 t/year	Specific	Socio-economic

Substance	Use	Tonnage band used	Scope	Route
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	Solvent-based paints for non-consumer use	>1000t/y	Broad	Socio-economic
	Industrial application of paints on metal surfaces	>1000t/y	Broad	Socio-economic
	Professional, non-consumer application of paints on metal surfaces	>1000t/y	Broad	Socio-economic
	Formulation of liquid or solid premix to colour plastic/plasticised articles for non consumer use	>1000t/y	Broad	Socio-economic
	Colour plastic or plasticised articles for non-consumer use	>1000t/y	Broad	Socio-economic
	hotmelt road marking	>1000t/y	Broad	Socio-economic
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	Solvent-based paints for non-consumer use	>1000t/y	Broad	Socio-economic
	Industrial application of paints on metal surfaces	>1000t/y	Broad	Socio-economic
	Professional, non-consumer application of paints on metal surfaces	>1000t/y	Broad	Socio-economic
	Formuation of liquid or solid premix to colour plastic/plasticised articles for non consumer use	>1000t/y	Broad	Socio-economic
	Colour plastic or plasticised articles for non-consumer use	>1000t/y	Broad	Socio-economic
	Hotmelt road marking	>1000t/y	Broad	Socio-economic
HBCDD	Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets (for onward use in building applications)	8000 t/y	Broad	Socio-economic
	Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications		Broad	Socio-economic

Substance	Use	Tonnage band used	Scope	Route
Trichloro-ethylene	Solvent for the removal and recovery of resin from dyed cloth	4t/y	specific	Socio-economic
	Solvent in a process to recover and purify resin from process water	4t/y	specific	Socio-economic
	Degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries	10-100t/y	specific	Socio-economic
	Extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries	10-100t/y	specific	Socio-economic
	Processing aid in the biotransformation of starch to obtain betacyclodextrin	3t/y	specific	Socio-economic
	Process solvent for the manufacturing of modules containing hollow fibre gas separation membranes	20-48 t/y	specific	Socio-economic
	Extraction solvent for the purification of caprolactam from caprolactam oil	245 t/y + 100-1000 + 150	specific	Socio-economic
	Solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers	20 t/y	specific	Socio-economic
	Industrial Parts Cleaning by Vapour Degreasing in Closed Systems	1000-2000t/y	broad	Socio-economic
	Process chemical in Alcantara Material production	10-100	specific	Socio-economic
	Packaging	10000 – 100000 t/y + 100-1000 t/Y	broad	Socio-economic
	Formulation	1000 – 10000 t/y + 100-1000t/y	broad	Socio-economic
	Extraction Solvent for Bitumen in Asphalt Analysis	100-1000 t/y tonnes.	specific	Socio-economic
	Degreasing agent in closed systems	200 t/y	broad	Socio-economic
	Vulcanising and bonding agents for endless connections and repair of chloroprene rubber coated conveyor belts in underground hard coal mining	1.4 t/y	specific	Socio-economic
Lead chromate	Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection	12 kg/y	specific	Socio-economic

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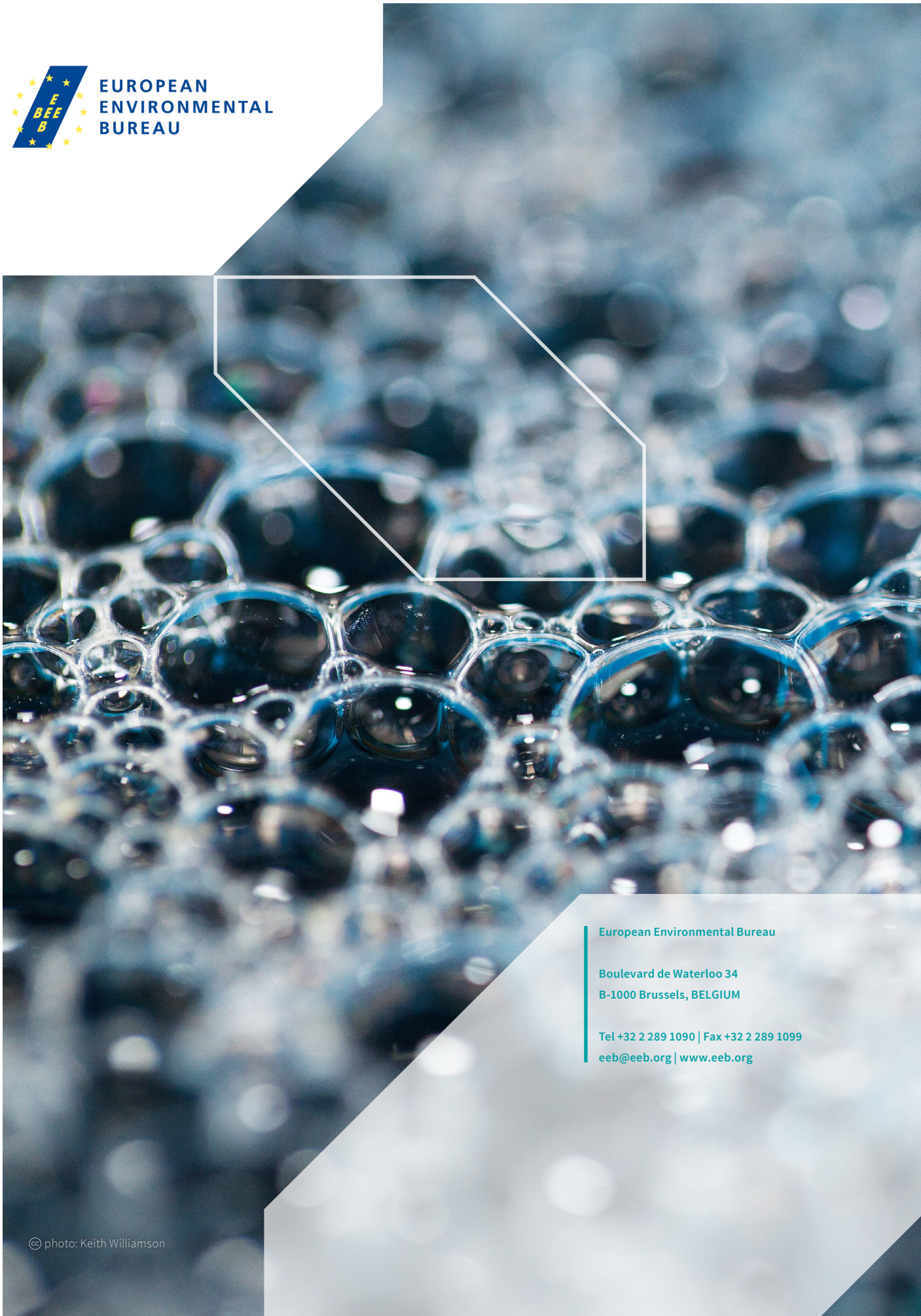

European Environmental Bureau

Boulevard de Waterloo 34
B-1000 Brussels, BELGIUM

Tel +32 2 289 1090 | Fax +32 2 289 1099
eeb@eeb.org | www.eeb.org