

REACH authorisation process. Is it delivering?



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The Union has agreed to achieve, by 2020, the objective for a **non-toxic environment** that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions.



Living well, within
the limits of our planet

7th EAP — The new general Union Environment Action Programme to 2020

Decision No 1600/2002/EC; Johannesburg Plan of Implementation (WSSD 2002).

Authorisation under REACH



Aim

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...

To this end all manufacturers, importers and downstream users applying for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution

REACH {Art. 55}.

Authorisation under REACH



MAIN TOOL FOR ELIMINATION/SUBSTITUTION OF Substances of Very High Concern (SVHC)

SVHC: carcinogens, mutagens, reprotoxicants, PBT, vPvB, and of similar concern (EDC, sensitisers, etc.).

Authorizations should be an exception.

Only for specific uses and for very limited time.

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In order to obtain an authorisation, the applicant has to demonstrate:

1st.- That the risks related to the use of the substance concerned are “**adequately controlled**”.

If that is not the case, authorisation may nonetheless be granted if

2nd. It is shown that **socio-economic benefits outweigh the risk** to human health or the environment arising from the use of the substance; **and**

3rd **If there are no suitable alternative** substances or technologies.

AUTHORISATION PROCESS



OUR GOAL: Authorisations are not granted for SVHC for which feasible alternatives are available in the market

NGO PARTICIPATING THROUGH:

Public consultations on alternatives

Trialogues

Observers at RAC/SEAC meetings

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The authorisation process comprises the following steps.

Step 1: Identification of substances of very high concern and inclusion in the candidate list.

Step 2: “Prioritisation of substances in the candidate list and inclusion in Annex XIV (Authorization list)

Step 3: Applications for Authorisation

Step 4: RAC and SEAC opinions

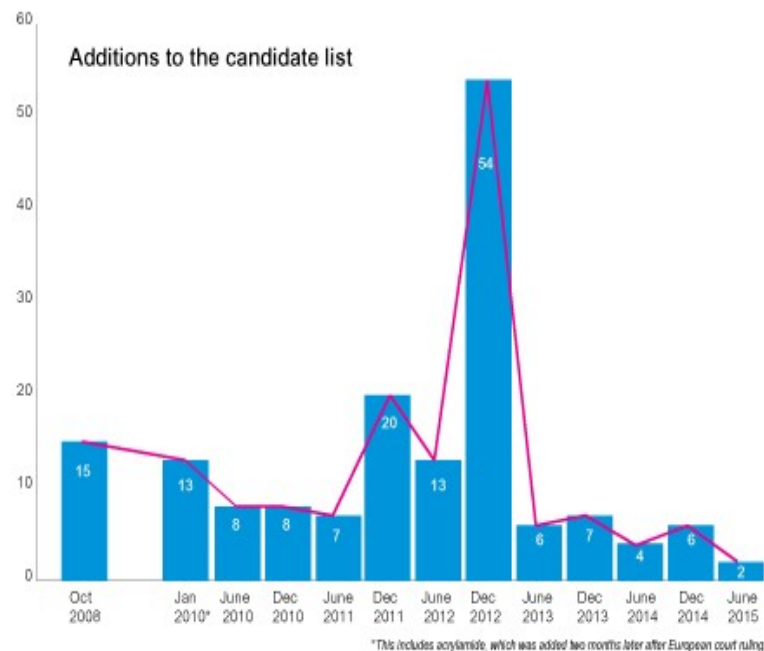
Step 5: Decisions on authorisations by the European Commission

Step 1: Identification of substances of very high concern and inclusion in the candidate list.

Who is responsible: Members States & ECHA make proposals,
Member State Committee decides

Number of SVHC: 1500-4000??

Number of substances in candidate list: 163



CANDIDATE LIST for NGOs

NGOs' goal: All substances with SVHC properties (e.g. all CLH CMR, EDC,..) are included in the Candidate list

SIN LIST



TOX FOX



Trade Union List

CANDIDATE LIST for businesses

Main driver for innovation of the chemicals industry!

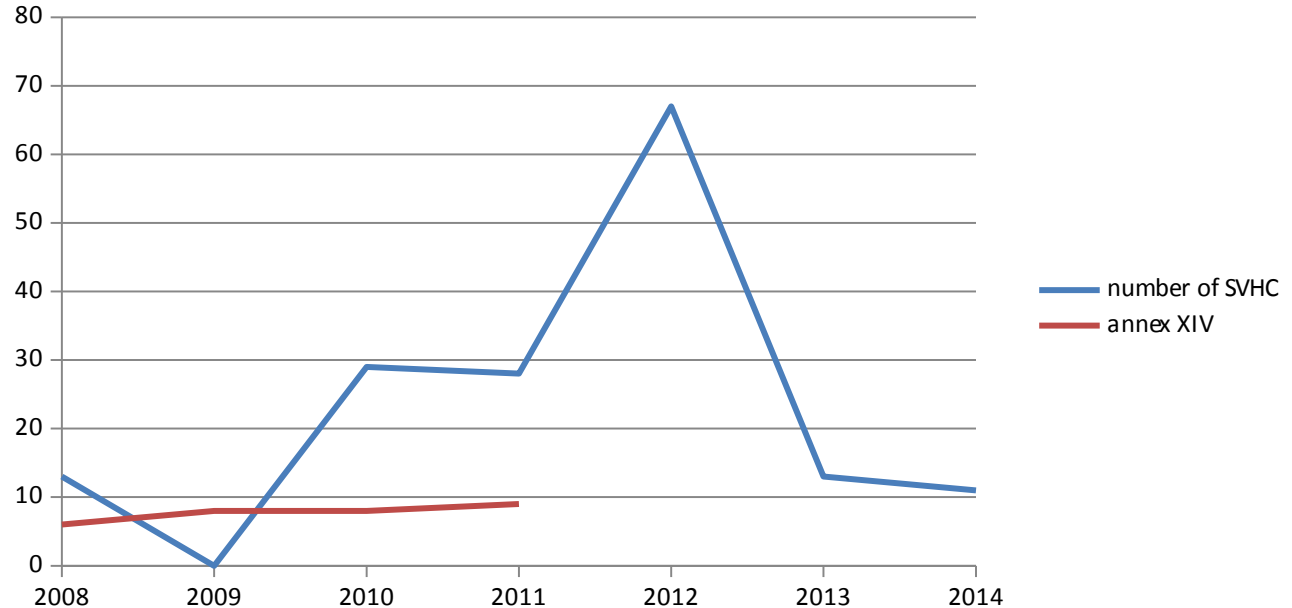
And for downstream users:

When substances are listed on the REACH candidate list the demand for more innovation and finding better alternatives 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. “ H&M

Step 2: “Prioritisation of substances in the candidate list and inclusion in Annex XIV (Authorization list)”

Who: ECHA makes a proposal, Commission decides

Substances in authorisation list: 31



Step 3: Applications for Authorisation

Application deadline for 15 substances has already expired.

ECHA has received submissions for 7 substances:

DBP, DEHP, Diarsenic Trioxide, Pigment Yellow 34,
Pigment Red 104, HBCDD, Trichloroethylene

ECHA has received 28 applications from 44 applicants, for 56 uses of 8 SVHC.

Step 3: Applications for Authorisation

Scope: many applications for very broad uses (even 100,000t/y).

Information missing!

Downstream applications better quality than upstream!

- Specific use applications showing substitution efforts & improvement of risk management measures (RMM) and working conditions in order to submit applications

Step 4: RAC opinion

Threshold substance RAC should assess **if the applicant demonstrates** that the risk to human health and the environment from the use(s) applied for **are adequately controlled.**

Non-threshold substance RAC should give an opinion on the **appropriateness and effectiveness of the proposed RMMs** in attaining the exposure levels in the applicant's exposure assessment and ensure that the exposure levels are as low as technically and practically possible.

Step 4: RAC opinion

All opinions have been positive even when adequate control or effectiveness of RMM not demonstrated.

Not rejecting applications lacking the required information.

Doing applicants job: giving advise on how adequate control may be achieved instead of assessing if the applicants have demonstrated that they can adequately control the SVHC.

However, decisions generally consistent with the information and assessments provided by applicants.

Step 4: SEAC opinions

SEAC role is to assess:

- the availability, suitability and technical feasibility of alternatives;

- if the socio-economic benefits arising from its use outweigh the risk to human health or the environment.

Step 4: SEAC opinions

All opinions have been positive

Alternatives have been considered not to be suitable.

Socio economic analysis has high deficiencies

In general not in consistent with the information and assessments provided in the application

SEAC opinions contradicting RAC opinions

Step 5: Granting of authorisations by the European Commission

Should hear first REACH Committee opinion

All opinions positive until now:

DEHP_ Rolls Royce

DBP _ Sasol-Huntsman GmbH & Co. KG

DEHP&DBP Roxel (UK Rocket Motors) Ltd

Diarsinic trioxide_Yara France

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Conclusions:

- Authorisation is delivering!
 - Candidate list, relatively few applications, substitution plans, risk management improvements...
- But...
 - Granting authorisations to all applications hinders the process.
 - RAC and SEAC need to improve limitations of their assessments.
 - Deficiencies in the legal text showing up!

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Recommendations to the Commission and ECHA:

- Speed up the process
- Reject certain authorisations such as upstream/broad uses
- Support substitution and green companies
- Improve guidance (e.g. socio-economic analysis and economic feasibility)

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Other EEB activities:



The EEB wishes you
a healthy Christmas &
a DEHP-free 2015

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REACH AUTHORISATION SCORE CARDS

EEB gives amber light to Rolls-Royce DEHP application

"The aim of authorisation 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." {REACH Art. 55}.

What is a scorecard? EEB's verdict on authorisation applications, the opinions handed down by ECHA's Committees, and overall compliance with REACH requirements for granting authorisations to substances of very high concern (SVHC).

The aim? To improve the authorisation process in order to ensure that SVHC are progressively replaced by safer alternative substances or technologies.

Rolls-Royce application for the use of DEHP during the manufacture of aero-engine fan blades			
Uses applied for are specific and sufficiently documented.	Green		
Information provided by the applicant conformed with the legal text requirements.	Green		
Information was accessible to the public.		Yellow	
Applicant demonstrated adequate control or that the proposed risk management measures were appropriate and effective.	Green		
Applicant demonstrated that there were no suitable alternatives.		Yellow	
Applicant demonstrated that the socio-economic benefits of using the substance outweighed the risks.		Yellow	
RAC's opinion	Green		
SEAC's opinion		Yellow	



REACH AUTHORISATION SCORE CARDS

Stop! EEB sees red over DEHP authorisation application for PVC

"The aim of authorisation 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." (REACH Art. 55).

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Application by Arkema, Azoty and Deza for the use of DEHP in the production of PVC articles.			
Uses applied for are specific and sufficiently documented.			Red
Information provided by the applicant conformed with the legal text requirements.			Red
Information was accessible to the public.			Red
Applicant demonstrated adequate control or that the proposed risk management measures were appropriate and effective.			Red
Applicant demonstrated that there were no suitable alternatives.			Red
Applicant demonstrated that the socio-economic benefits of using the substance outweighed the risks.			Red
RAC's opinion		Yellow	White
SEAC's opinion			Red



Thank you for your attention!

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