

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}.

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.

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.			
Information provided by the applicant conformed with the legal text requirements.			
Information was accessible to the public.			
Applicant demonstrated adequate control or that the proposed risk management measures were appropriate and effective.			
Applicant demonstrated that there were no suitable alternatives.			
Applicant demonstrated that the socio-economic benefits of using the substance outweighed the risks.			
RAC's opinion			
SEAC's opinion			

Comments:

- The scope of these applications is very broad. In essence, they are requests for general authorisation for an industrial sector.
- The applicants didn't specify for which specific use(s) the authorisation is sought and did not cover the use of the substance in articles.
- The applications didn't cover all the potential risks to human health and/or the environment from the use of the substance. The information was insufficient for the Committees to deliver an opinion so they had to request additional information even though the application was deemed in conformity and the public consultation was already launched.
- The public was denied the information necessary to properly contribute to the public consultation on alternatives as 70% of the documentation was deemed confidential, including the whole of the chemical safety report.
- The applicants failed to demonstrate adequate control and that no alternatives were available for all uses applied for. Extensive information provided through the public consultation demonstrated that alternatives are available for many downstream uses.
- RAC set a reference derived no-effect level (DNEL) for DEHP even though it is a known endocrine disrupting chemical. This annuls the basic principle of REACH that the burden of proof regarding the safety of a substance is on the user. RAC accepted non-public and non peer-reviewed information on population exposure to deliver its opinion. RAC considered in its opinion that the applicant did not demonstrate adequate control for workers.
- The applicants could not demonstrate that the socio-economic benefits of continued use outweighed the risks to human health or the environment. However, SEAC carried out its own assessments and recommended granting an authorisation with a four-year review period.

Scoring criteria

Uses applied for are specific and sufficiently documented.

Green: specific uses sufficiently described.

Amber: specific uses not sufficiently described.

Red: broad uses.

REACH legal text Art 60(7) establishes that the authorisations should be use specific.

Information provided by the applicant conformed with the legal text requirements.

Green: applicant provided sufficient information for the Committees to be able to develop an opinion.

Amber: after RAC and/or SEAC requested further information, the applicant provided sufficient information.

Red: even after RAC and/or SEAC requirements, the applicant didn't provide sufficient information.

REACH legal text Art 62 establishes the information requirements that applications must fulfil.

Information was accessible to the public.

Green: no information was deemed confidential.

Amber: part of the information was deemed confidential.

Red: relevant and adequate information was deemed confidential.

REACH Articles 64 (2) and (3) establish that broad information on the uses of the SVHC should be made publicly available and that third parties should have the opportunity to submit information on alternatives. Moreover, any decision on authorisation shall be taken after consideration of all third party contributions submitted under Article 64(2) according to article 60(4c). Therefore, meaningful information is key to the process.

Applicant demonstrated adequate control or that the proposed risk management measures (RMM) were appropriate and effective.

Green: applicant demonstrated adequate control or appropriate and effective risk control.

Amber: adequate control or appropriate and effective risk control was not demonstrated, but RAC considered it could be achieved with the information provided.

Red: applicant did not demonstrate adequate control or appropriate and effective risk control and RAC considered it couldn't be achieved.

Applicant demonstrated that there were no suitable alternatives

Green: applicant documented in its application that no alternatives were suitable for the use applied for. No information on alternatives was provided during the public consultation.

Amber: applicant partially documented in its application that no alternatives were suitable. Information on alternatives was provided during the public consultation, but the alternatives proposed were questionable (regrettable substitutes) or the information was insufficient and/or not relevant.

Red: applicant didn't document in its application that no alternatives were suitable. Information on available alternatives for the use applied for (for the applicant or downstream users) was provided during the public consultation.

Applicant demonstrated that the socio-economic benefits of using the substance outweigh the risks

Green: applicant documented in its application that the socio-economic benefits outweigh the risks.

Amber: applicant partially documented in its application that the socio-economic benefits outweigh the risks.

Red: applicant didn't document in its application that the socio-economic benefits outweigh the risks.

RAC opinion

Green: consistent with the information and assessments provided in the application.

Amber: partially consistent with the information and assessments provided in the application.

Red: not consistent with the information and assessments provided in the application.

SEAC opinion

Green: consistent with the information and assessments provided in the application.

Amber: partially consistent with the information and assessments provided in the application.

Red: not consistent with the information and assessments provided in the application.