Dow Europe GmbH
Bachtobelstrasse 3
CH-8810 Horgen
Switzerland

Trichloroethylene and Authorization under REACH (Regulation (EC) 1907/2006)
Information Letter no. 6:

Potential upcoming inclusion of Trichloroethylene (TRI) into ANNEX XIV requires preparation and strategic decisions from downstream users

Dear Mme/Sir,

This letter informs you about the process of authorizations and considerations on the continuous use of TRI in your particular application/use.

1. What are my responsibilities related to an extended SDS?

If you receive an extended SDS you are obliged to:

- Assess whether your own uses (for own activities) are covered by exposure scenarios
- Comply with the Risk Management Measures in the relevant exposure scenario to ensure safe use (if no 100% match, scaling may be possible)
- Communicate the information from the extended SDS to your customers

2. How can I continue to use TRI?

TRI is anticipated to be listed in ANNEX XIV of REACH. As we have informed you in our prior information letter, European manufacturers and importers of TRI brought forward a request for exemption of TRI for industrial use for surface cleaning in closed systems. This request is still under discussion within the EU commission.
For all other uses you and/or your suppliers can request an authorization if you want to continue using the substance. This authorization will require:

- A chemical safety report / risk assessment
- An analysis of (all available) alternatives whether they are technically and economically suitable to substitute the substance within your process

If it is shown that suitable alternatives exist, a substitution plan needs to be attached to the authorization request. The request will be reviewed by ECHA committees and become subject to a public consultation where third parties can place comments.

3. What is a suitable alternative?

Your analysis of alternatives will conclude that there is a suitable alternative available when an alternative substance(s) or technology/ies or their combination:

- Provide an **equivalent function** to that provided by the substance or make the **substance use redundant**
- Will result in **reduced overall risks** to human health and the environment, taking into account appropriateness and effectiveness of risk management measures
- Are **technically and economically feasible** (for substitution in the uses applied for) and available, for the applicant.[1]

[1] Further information can be found in the Data Submission Manual Part 22 - How to Prepare and Submit an Application for Authorisation using IUCLID 5 on the ECHA webpage (link on second page)

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It is strongly recommended to substitute TRI if a suitable alternative exists. SAFECHEM Europe GmbH (SAFECHEM) has a range of products that could be possible for substitution. Please contact SAFECHEM or your distributor for further information.

4. If no alternative exists to my particular use, what do I need to do?

The submission of an application for authorization needs to be considered. Get information about the authorization process, which is available on the ECHA website.[2]

As supplier Dow/SAFECHEM currently reviews which uses (described by exposure scenario) it will bring forward to authorization. For certain uses, you need to consider applying for authorization by yourself.

In both cases information is needed on the analysis of alternatives. Please start to review all existing information on alternatives including ongoing developmental work. Be prepared to share this information with us in case Dow/SAFECHEM as supplier will compile an application for authorization.

5. What are the timelines in the authorization process I have to consider?

We expect an inclusion of TRI into ANNEX XIV earliest in Febuary 2013. In this case, given the transitional arrangement as proposed by ECHA this would lead to

- An Application Date[3]: date of inclusion in Annex XIV plus 18 months (August 2014)
- A Sunset Date[4]: 18 month after the application date, 36th month after inclusion into ANNEX XIV (Feb 2016)

However, due to the administrative process within ECHA the application should be submitted at least 3 months before the application date. If you want to take advantage of a so called notification and a respective meeting with ECHA, the notification has to be done approx. 9 months before the application date, which will be followed by an ECHA meeting within the next 2 months after notification. ***Hence a preparation work for the application should start early enough, ECHA recommends to start 18-24 months before the application date. This means you should develop your internal strategy towards the continuous use of TRI and start respective preparation.***

P. Angelov

Marketing Director Europe/IMEA,
Dow Europe GmbH

[2] http://echa.europa.eu/web/guest/regulations/reach/authorisation/applications-for-authorisation

[3] Application Date = date by which applications for authorization must be submitted to allow continued uses after the sunset date until a decision on the application for authorization is taken

[4] Sunset Date = date from which placing on the market is prohibited unless authorization is granted