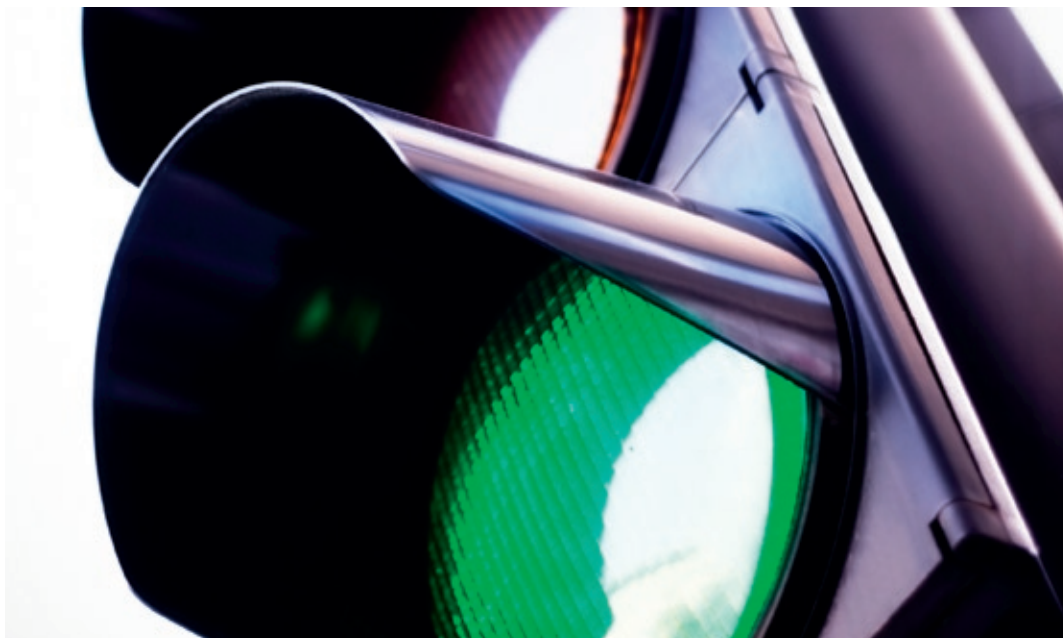


# AUTHORIZATION UNDER REACH – SUBSTANCES OF VERY HIGH CONCERN



**TNO** triskelion bv

'Substances of Very High Concern' (SVHC) is the term in the REACH regulation for chemical substances whose hazard is considered to be sufficiently problematic as to warrant special measures. SVHC will therefore be gradually passed through the **Authorization** rules of REACH for possible inclusion on Annex XIV. Member States may also choose to regulate such substances by formal **Restrictions**.

## SERVICES

TNO Triskelion and partners have developed a range of strategic services for companies facing the challenge of SVHC candidature or Authorization of their substances.

TNO Triskelion and partners offer:

- Advocacy and strategic support, including communication
- Appropriate responses to candidature or Annex XIV prioritization
- Formal replies to ECHA notices
- Revision and optimization of the Chemical Safety Report and Exposure Scenarios
- Socio-economic analyses and report writing
- Preparation of substitution plans

There is strong pressure from the EU Member States (MS) to place substances on the candidate list for authorization. The candidate SVHC list contains

50 substances to date (03 February 2011). Currently we are aware of 400-500 substances on various Member State lists as potential SVHC candidates.

## CRITERIA FOR INCLUSION

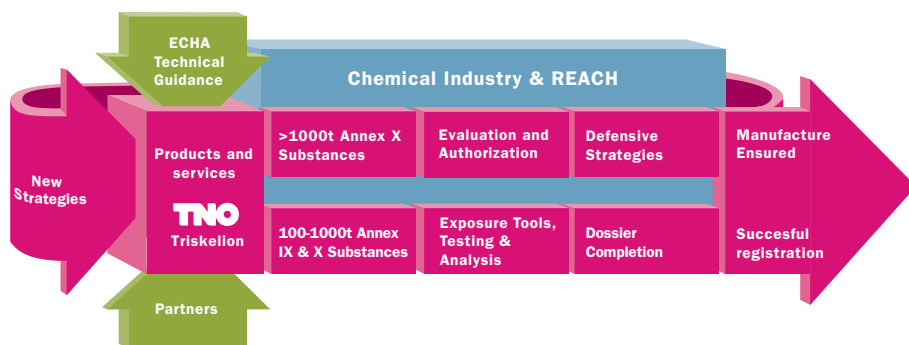
Priority for inclusion in Annex XIV is given to substances with:

- C, M or R classifications;
- PBT or vPvB properties; or
- wide dispersive use; or
- high volumes.

The exact priority setting mechanism for adding SVHCs on the candidate list to Annex XIV remains to be seen but some aspects are clear: CMR (Category 1 and 2) can be prioritised from the list on the condition that they fulfill at least one of the three above mentioned criteria.

## CONSEQUENCES

EU and EEA suppliers of substances on the Candidate List are obliged to provide



**REACH AND TNO TRISKELION:  
SUCCESSFUL REGISTRATION 'WITHIN REACH'**

The aim of REACH is to describe the safe-use of chemicals throughout the product chain. All High Production Volume Chemicals and priority substances must be registered by 2010 or 2013. TNO Triskelion can assist your company in achieving this with our proven expertise in the fields of risk assessment, registration and testing. With TNO Triskelion, your technical dossiers, exposure scenarios and Chemical Safety Reports are safe in our hands.

The added value of TNO Triskelion's REACH services is based on decades of experience with registration and safety studies for the Chemicals Industry. TNO Triskelion is actively involved in the rgw ongoing work of developing technical guidance for REACH and has broad contacts with ECHA and the EU Member State Competent Authorities.

their customers with additional safety data sheet information. Use of substances on the candidate list in articles (at levels > 0.1%) will have to be notified to ECHA as of June 2011. Substances on their own, in mixtures and in articles have separate legal requirements applying from the date of inclusion on Annex XIV and cannot be placed on the market or used after the "sunset date" unless the company is granted an Authorization. There are no tonnage exemptions and downstream users may only use such substances for uses which have been authorized.

**AUTHORIZATION**

The authorization process consists of four steps:

- 1 Identification of SHVC by the Member States (who produce an Annex XV dossier, placement on the candidate list),
- 2 Prioritization: placement on Annex XIV by the EU Commission, determination of sunset date,
- 3 Applications for authorization by industry,
- 4 Granting of authorizations by the European Commission.

An application for Authorization must include among others:

- a **chemical safety report** covering risks related to those properties that cause the substance to be included in the authorization system
- an analysis of possible **alternative substances** or technologies including a substitution plan
- a **socioeconomic analysis** (if safe use cannot be demonstrated and no alternative exists)

**TNO Triskelion and partners can provide all three products.**

**COMMENT**

Legal cases such as the following will become more common as the authorization process of REACH progresses.

*"On 30th March, ECHA added acrylamide (EC No 201-173-7 and CAS No 79-06-1) to the candidate list of substances of very high concern for Authorization. Companies dealing with acrylamide will need to check whether they have obligations resulting from the listing ... In Jan. 2010, two chemical companies brought an action before the General Court of the EU seeking an annulment of ECHA's decision ... the two companies claim that acrylamide is an intermediate and, as such, not subject to the Authorization Title under REACH, including inclusion on the Candidate list ... Case T-1/10. (ECHA Newsletter No. 2 April 2010)*

In our experience, when a company has to resort to legal action, it is already too late: strategic advocacy in the run up to candidacy and solid technical support can help.

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**TNO TRISKELION BV**

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