SVHC, AUTHORIZATION, RESTRICTION

USE OF INDUSTRY DATA TO TRIGGER REGULATORY ACTION UNDER EU REACH

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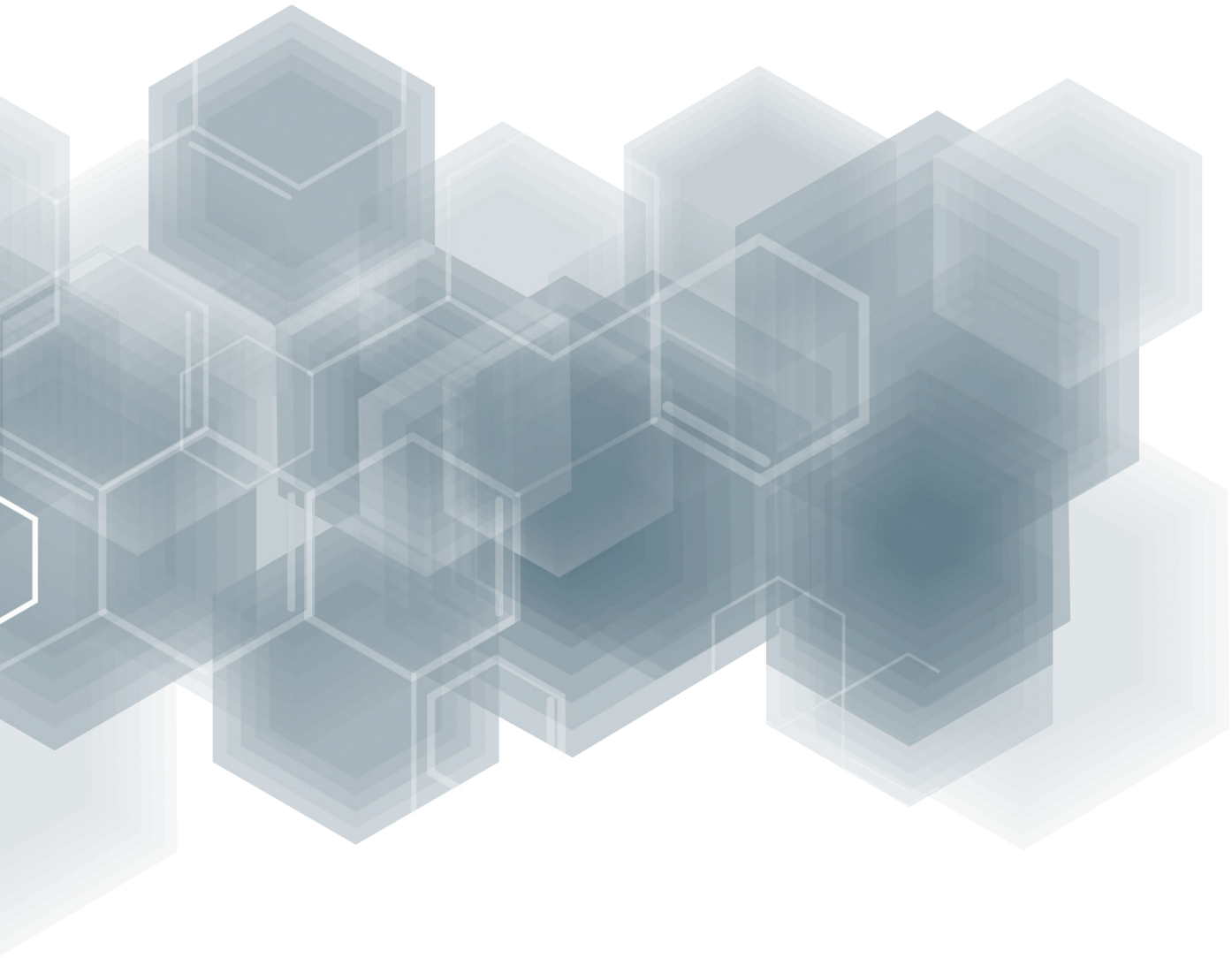

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Many companies are interested in knowing about the presence and amount of Substances of Very High Concern (SVHC) chemicals in their raw materials, because of the regulatory requirements that must be met, and also due to the expectation that their use may ultimately be phased out. Any SVHC chemical must be identified in an article or a component article of a complex article, if it is present at greater than 0.1% w/w. This means that these SVHC regulations apply to packaging, including imported packaging materials, or the packing used on imported goods. One is also required to provide available information regarding safe use and disposal. Knowing that an SVHC is present in a raw material, and the amount, will enable an EU article manufacturer or importer to determine if his article will have that SVHC above the regulatory threshold of 0.1%. He can also work with his supplier to follow the progress of that SVHC through the European Chemicals Agency (ECHA) system to understand when it is likely to be subject to Authorization.

The REACH (Registration, Evaluation, and Authorization of Chemicals) Regulation, Regulation **(EC) No 1907/2006**[1], in the European Union (EU) established a new regulatory system for managing chemicals. It requires industry to **register**[2] their chemicals with a supporting data package, called a registration dossier, that includes hazard information as well as use and exposure information. Although the onus is on industry to prepare a registration dossier that complies with the regulatory requirements, no less than 5 percent of the registration dossiers are reviewed by ECHA, the Agency that administers REACH, in a process called Dossier Evaluation, also known as **Compliance Check**[3]**.**

During Dossier Evaluation the ECHA can order registrants to improve the quality of their registration dossiers and fill any identified data gaps. In parallel, substances can be nominated by the ECHA or the Member State competent authorities for assessment of identified concerns in a process called **Substance Evaluation**[4]. If a substance is selected for Substance Evaluation, the nominating authority can request that the registrants provide any data that is necessary to assess the identified concern. Together these review processes can lead to a range of regulatory actions including changes in the classification and labeling, authorization or restriction of the substance. The ECHA web site captures the information about their evaluations on their **Public Consultations**[5] web pages.

The ECHA and the Member States screen the data provided by industry against a set of criteria to identify **Substances of Potential Concern**[6] . The screening process is explained **here**[7]**.** This is followed by a **risk management option analysis (RMOA)**[8] to help decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate regulatory instrument to address the concern. An RMOA can conclude that regulatory risk management is required for a substance or that no regulatory action is required.

If this further assessment validates the concern, then an Annex XV dossier is prepared by either the ECHA or a Member State. The **Registry of Intentions**[9] provides information on Annex XV dossiers that are under consideration and provides advanced warning to industry. Depending on the proposed type of action, this intention can be one that would result in a new **hazard classification**[10] for the chemical, a proposal to place the chemical on the **Substances of Very High Concern (SVHC)/AUTHORIZATION**[11] list, or a proposal to impose certain **Restrictions**[12] on the use of the chemical.

By looking at the information on these pages one can see the chemicals that ECHA is looking into, follow their progress, and be aware of the final outcome. An overview of the process and a list of chemicals under review can be seen on the **Public Activities Coordination Tool**[13] . There are numerous opportunities for industry to provide input into the process.

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20140410
[2] https://echa.europa.eu/web/guest/regulations/reach/registration
[3] http://echa.europa.eu/regulations/reach/evaluation/compliance-checks/
[4] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation
[5] https://echa.europa.eu/public-consultations
[6] https://echa.europa.eu/substances-of-potential-concern
[7] https://echa.europa.eu/screening
[8] https://echa.europa.eu/rmoa
[9] https://echa.europa.eu/registry-of-intentions
[10] https://echa.europa.eu/regulations/clp/classification
[11] https://echa.europa.eu/candidate-list-table
[12] https://echa.europa.eu/substances-restricted-under-reach
[13] https://echa.europa.eu/pact

Implications of the analysis:

SVHC/AUTHORIZATION: The most stringent control of chemicals falls in this category. At the outset, part of the design of REACH was to provide a regulatory mechanism to identify and phase out the use of certain chemicals, those considered as Substances of Very High Concern (SVHCs). The criteria for an SVHC is that it is classified as a CMR health hazard (category 1A or 1B carcinogen, mutagen, reproductive toxin), or environmental hazard (Persistent, Bioaccumulative, Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB)), or a substance of like concern such as an endocrine disruptor or respiratory sensitizer. The SVHC/AUTHORIZATION regulatory process involves four steps: identification of possible SVHCs, formally listing a chemical as an SVHC on the Candidate list of SVHCs, prioritizing the substances on the Candidate list for possible inclusion on the Annex XIV authorization list, and reviewing application for the authorization of substances on the Annex XIV list.

After a substance is included on the Candidate List of SVHCs certain information on articles or component parts of complex articles containing greater than 0.1 percent w/w of the SVHC needs to be provided in the supply chain and to consumers upon request. **REACH Article 33**[14]. Notification to the ECHA can also be required. **REACH Article 7(2)**[15].

Under Authorization a date (sunset date) is assigned whereby a chemical is banned from all use, except those where an authorization has been applied for and approved. The process is very rigorous, and once a chemical is proposed to be an SVHC (step 1) it is very difficult for it not to ultimately go through all of the steps and become subject to Authorization unless a Restriction is proposed. The ECHA has a **program in place**[16] to identify all SVHC chemicals by 2020, and one can follow the chemicals on the web: **Proposed SVHC**[17]**; Listed SVHC**[18]**; Authorized chemicals**[19].

RESTRICTION: The evaluation of the data on a chemical may lead to the conclusion that it is appropriate to restrict or ban certain uses of the chemical. Such a Restriction might involve applications in children's articles or applications which might result in high levels of release to the environment. In this case an Annex XV dossier is submitted, and if passed the chemical is prohibited from use in that application. These **Restrictions**[20] are all incorporated under what is termed Annex XVII of REACH. Companies may ask if a chemical is listed in this Annex, and if so, what is the use restriction.

CLH (Classification and Labeling Harmonization) INTENTION: This is a proposal to adopt a formal harmonized hazard classification for a chemical based on the submitted data. These hazard classifications are those set forth by the UN GHS system which is codified under the EU Classification, Labeling, and Packaging (CLP) regulation. While there are many chemical classifications under GHS, the only ones of real concern are those related to the SVHC classifications noted above, CMR category 1A or 1B and respiratory sensitizers. For this reason nearly all of the CLH proposals will be recommendations that a chemical is classified as CMR or a respiratory sensitizer. The intent behind this filing, and this part of the evaluation is that once a chemical is assigned one of these classifications, it then can become a candidate for SVHC listing and Authorization. This can be seen then as the starting point for the entire process.

MONITORING: By looking at the web pages given in the links above, one is able to see what chemicals are being evaluated, where they are in the process, and what the possible outcomes are.

[14] https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/communication-in-the-supply-chain
[15] http://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles
[16] https://echa.europa.eu/svhc-roadmap-to-2020-implementation
[17] https://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations
[18] https://echa.europa.eu/candidate-list-table
[19] https://echa.europa.eu/authorisation-list
[20] https://echa.europa.eu/substances-restricted-under-reach

Reference

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https://echa.europa.eu/rmoa
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https://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations
https://echa.europa.eu/authorisation-list
https://echa.europa.eu/svhc-roadmap-to-2020-implementation

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1425 K Street NW, Suite 500, Washington, DC 20005

P 202.974.5200 | plasticsindustry.org