3E Services

3ESC REACH SVHC Compliance Fact Sheet

SVHC Obligations Under REACH

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Article 57 outlines the following criteria for inclusion of substances on the REACH Annex XIV, Substances Subject to Authorization List.

- Carcinogenic, mutagenic or toxic to reproduction (CMRs)
- Persistent, bio-accumulative and toxic (PBTs), very persistent and bio-accumulative (vPvBs)
- Seriously and/or irreversibly damaging the environment or human health, as substances damaging the hormone system

Substances on this list are assigned a sunset date, which identifies the day, month and year that a substance can no longer be manufactured, imported or used in the EU, without European Chemicals Agency (ECHA) authorization for specific use or conditions. The precursor to the Authorization List is the Substance of Very High Concern (SVHC) Candidate List. All entries on this list are ultimately intended to make it to the Authorization List.

Supporting REACH Articles mandate that immediately after a substance is included in the SVHC List, suppliers of materials and products which contain a listed substance in a concentration above 0.1% (by weight) or that is present in quantities totaling over one metric ton per year must

- Provide sufficient information to allow for the safe use of the product
- Notify ECHA no later than six months after the substance is listed
- Provide information to consumers within 45 days of the requests

If necessary information (i.e. full ingredient/substance disclosure with percentages) is not readily available, it will have to be created via testing, analysis and risk assessment or solicited. Though suppliers should proactively distribute this information to B2B customers, ECHA has indicated that where the information received is not sufficient to check compliance with REACH, producers, importers and suppliers of products may need to proactively engage their upstream supply chains.

Proactive Compliance

Understanding the precursors that drive additions to the SVHC and Authorization Lists can position compliance professionals to “forecast” the regulatory climate before the storm hits. ECHA stated in its Progressing together to identify substances of concern that ECHA is half way to the goal of having currently known SVHC all on the Candidate List by 2020. At least 500 substances are currently having new data generated or are having data assessed for this list. In Figure 12 of this same report the SVHC list is shown to keep growing as well as “Recommendations for inclusions” in Annex XIV and actual “Inclusions in Annex XIV”. It is crucial for Product Stewards and Product Developers to watch the precursors to the Annex XIV list.

It's also important to know that before a substance arrives on the SVHC list it undergoes a process of scrutiny that has taken on some predictability. ECHA's SVHC Registry of Intentions creates a venue for ECHA officials and Member States to prepare, propose, submit and withdrawal dossiers for the addition of SVHCs and restricted substances (Annex XV of REACH). Keeping up with these activities and understanding the impact they will have on your business when and if substances are added is mission critical.

Another predictor is the SIN (Substitute It Now!) List. The SIN List is composed of >860 substances evaluated by the environmental NGO ChemSec as meeting EU criteria for being SVHCs under Article 57 of REACH. ChemSec has had substantial influence on REACH and the SVHC List and is the driving force behind the emergence of endocrine disruptors. The SIN list has been growing over the last 5 years and shows no signs of slowing down.

Pillars of Success

Whether you sell directly into the EU or that happens in your downstream supply chain, there is work to be done to ensure that your raw materials and/or finished goods are prepared to enter and compete in EU markets. Compliance requires tapping into a multitude of global data sources and subsequently transforming that data into actionable intelligence . Three pillars necessary to stand up and maintain effective and efficient product compliance programs are data, systems and expertise.

Data can refer to product, material, or substance level information as well as global regulatory content (lists of lists and full text regulations). Systems must be designed to account for the solicitation, validation, integration, analysis and enrichment of information, as well as distribution to key stakeholders in the supply chain and regulatory agencies. Staff or third party expertise is critical to complete the compliance cycle and interpret and align regulatory complexities with internal compliance programs.

Getting Started

In order to understand the size and scope of your compliance obligations with the newly listed substances:

- Perfluorohexane-1-sulfonic acid and its salts (PFHxS) added for being very persistent and bio-accumulative (vPvB) (Article 57e) used as a plasticizer, lubricant, surfactant, wetting agent, corrosion inhibitor and in fire-fighting foams.

5 previous added chemicals were additionally re-named for also having Endocrine disrupting properties (Article 57(f) – human health. Those chemicals are:

- BPA used in the manufacture of Polycarbonate, epoxy resins, an antioxidant for PVC and in thermal paper production
- BBP; DEHP and DBP all phthalates used in PVC
- DIBP used in coating products, fillers, putties, plasters, modeling clay and polymers

all potentially impacted materials and products must be identified. Once identified, a compliance profile will need to be created to itemize all data points and required documentation that will be needed for evaluation. Next, data must be mapped to its source (internal, upstream supply chain), collected, validated and integrated with regulatory lists and your customers' requests for information.

- **Identification**
  - Determine if use of these substances on their own, or as part of mixtures or articles.
  - Identify and maintain the lists you must monitor and integrate at the substance level.
- **Impact Analysis** – Complying depends on the use of the substance as it relates to concentration, annual import/export quantities, current registered uses, and exposure exclusions. Retain a REACH expert that guides your compliance decision making.

- **Information Collection and Distribution** – Make sure you can provide documentation and information up and down your supply chain.
  - Determine how far up the supply chain you must go to determine the presence of SVHCs.
  - What end user markets do your customers and their customers operate in?
  - Deploy mechanisms to engage your supply chain to pull information upstream, consolidate and push downstream.

Intelligent Compliance

3E offers a comprehensive solution set to help our customers satisfy the obligations set forth by REACH Article 33. As the 2018 registration deadline draws closer and sunset dates for substances on the Authorization List hit, it becomes increasingly important for manufacturers and importers to examine their supply chains in order to ensure conformance. 3E Supply Chain Solutions (3ESC), 3E's web-based supply chain platform, stores and analyzes REACH information so that customers can evaluate not only their compliance status, but the compliance status of their suppliers. Supplier engagement is an ongoing activity that enables the mapping of data sources and establishes a communication network to exchange critical information.

To receive additional information, please contact 3E at info@3ECompany.com.

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3E Company, a Verisk Analytics business, is a global provider of data and information services which enable companies to improve compliance with EH&S regulations and supply chain obligations through the entire lifecycle of chemicals and products. Whether you are a manufacturer, distributor or corporate user of chemical products, 3E can tailor a program specific to the compliance information and management needs of your organization. For more than 25 years we have led the industry in obtaining and managing content, offering unique insights and solutions that enable customers to reduce cost and risk while improving processes across the enterprise and throughout the supply chain. Global locations include our corporate headquarters in Carlsbad, California along with offices in Bethesda, Maryland; Canton, Ohio; Copenhagen, Denmark; Kingsport, Tennessee; Montreal, Quebec and Tokyo, Japan.

Want to learn more?
Contact 3E at info@3ecompany.com or +1 760.602.8700 / +1 800.360.3220.

