E^xponent^{*} Chemical Regulatory Compliance in Consumer Products

Five ways for manufacturers and EU importers to manage chemical compliance in consumer products

Consumer product manufacturers and importers in the EU need to ensure that their products are compliant with relevant regulations and safe for consumer use. This "duty of care" includes the chemicals in those products, which are regulated under EU and national legislation, including Regulation (EC) No 1907/2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Per REACH, some chemical substances are banned, and some may only be present below established limits. If products contain restricted chemicals above REACH limits, they may need to be recalled or destroyed, with potentially severe penalties for the companies involved.

Specific chemicals of concern: PAHs and phthalates

Polycyclic aromatic hydrocarbons (PAHs) may be found in consumer goods such as toys, tools, and sporting goods. PAHs have been restricted under REACH since 2015 due to their carcinogenic properties. The restriction applies to articles sold to the public that come into direct, prolonged, or repeated contact with skin or the oral cavity and contain more than 1 mg/kg of eight different types of PAHs. For toys the limit is even lower: 0.5 mg/kg.

Phthalates (DEHP, DBP, DIBP, and BBP) have been restricted under REACH since 2020 due to their toxic effects on reproduction and development. These chemicals are commonly added to plastics to increase flexibility, transparency, durability, and longevity. Despite the restriction, the EU rapid alert system "Safety Gate" registered 312 measures taken against manufacturers and importers related to products containing phthalates between 2020 and 2024. The interventions predominantly involved action taken against importers and distributers for affected items such as toys, electronic equipment, shoes, and household products.

Since 2010, the number of chemicals registered under REACH has <u>increased exponentially</u>, from approximately 50 to approximately 2,000. Over this same period, an increasing number of chemicals have required EU-wide risk management measures based on their hazard profiles. This rising trend is expected to continue as more substances are assessed.

Given the changing regulatory landscape, how can industry stakeholders confirm what chemicals — and what levels of chemicals — are contained in consumer products? How often should these assessments be performed? What actions should be taken if an exceedance is detected?

Here are five steps to get started:

- **1.** Identify your responsibilities: Are you a manufacturer, importer, or distributer?
- 2. Identify what regulations apply to your product: Is it an article?
- **3.** List the components of your product and contact your suppliers to request that they provide REACH compliance statements.
- **4.** Arrange testing of the product if required.
- **5.** Develop a plan for future testing, compliance monitoring, and reporting.

How we help clients

Exponent helps consumer products manufacturers and importers understand complex regulatory requirements, including developing plans for corrective actions and maintaining compliance. We support product testing and monitoring studies aligned to our clients' specific needs. For products that contain chemicals beyond established regulatory limits, we conduct rigorous risk assessments to help inform critical decision-making, including assisting with regulatory reporting and communications.

Chemical regulatory compliance is complex and challenging, but with our multidisciplinary experts in product regulation, product safety, chemical safety, and toxicology, Exponent can help ensure that consumer products are safe and compliant.

What Can We Help You Solve?

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