Cefic Analysis of 2021 Cases of Non-compliance with the EU Chemical Legislation

Data confirms an urgent need to step up enforcement of chemicals legislation for imported goods and online sales

Cefic has analysed the 2021 data reported through ‘Safety Gate’, the EU’s rapid alert system for products established under the EU General Products Safety Directive. These are the key findings:

- While 77% of all chemicals non-compliant to REACH come from outside the EU/EEA, we again see a steep increase in cases where the country of origin of the product containing REACH-non-compliant chemicals is unknown (18% vs 12% in 2020 and 4% in 2019). This is likely due to ongoing increased online shopping during the COVID-19 pandemic.

- The most common chemical non-compliance, roughly 25%, were restricted phthalates, followed by heavy metals (cadmium, lead), which are also reprotoxic. The most common restricted phthalate was bis(2-ethylhexyl) phthalate or DEHP for short, a substance that has been restricted in Europe for years, but still frequently shows up in plastic dolls imported from China.

- Reported non-compliances that involve Endocrine-Disrupting Chemicals (EDCs) increased from 23% to 27%, while (suspected) reprotoxic substances increased from 27% to 36%.

- Concerning the origin of the EDCs, the situation is similar to 2020: while there were only six instances of endocrine disruptors found inside the EU/EEA, there were 228 instances coming from outside the EU/EEA.

- The percentage of all chemical non-compliances in products reported to the EU Safety Gate increased from 18% in 2020 to 25% in 2021 (compared to other risks covered in the EU Safety Gate like injuries or electrocution).

- The percentage of reported non-compliances related to REACH has slowly increased over the last three years (2019: 42%, 2020: 50%, 2021: 57%). This could reflect an increased rate of non-compliance in enforcement activities, an increase in imports (thus in non-compliances), or more REACH restrictions to comply with.

- There is a slightly decreasing trend in non-compliances related to hand sanitisers (37 vs 71 instances) that are not marked as flammable, contain methanol (not compliant with classification and labelling rules) or polyhexanide, or that contain a percentage of ethanol/isopropanol that is not sufficient to kill viruses (meaning it is not compliant with the biocides regulation).
Sylvie Lemoine, Cefic Executive Director Product Stewardship, commented: “Regulation only makes sense if it is accompanied by enforcement. It is striking that with online sales, the origin of many of the products entering the bloc is unknown. We continue to call for stronger surveillance and enforcement efforts, particularly on imported goods and online sales. As online shopping grows, it is a matter of consumer safety.”

These conclusions come not only from the Safety Gate analysis but are corroborated by studies from Nordic Member States. Cefic sees ECHA’s EU-wide REF-8 pilot project on enforcement of online sales as a step in the right direction, but further action is needed to make it effective.

We call for actions to be prioritised to better enforce EU chemicals legislation. This is particularly important as restrictions increasingly address groups of chemicals in different uses (e.g., microplastics) and will become even more generic in the upcoming revision of REACH.

Those actions, echoes by recommendations issued by the Chemicals Strategy for Sustainability High-Level Round Table, should include, among others, tightened controls of imports (online marketplaces); ensuring new restrictions are enforceable by developing standard control methods and lab capacity; sufficient resources and funding for enforcement; and improving coordination and sharing data to further support enforcement actions.

**Highlights**

- **Decrease in Skin-Lightening Products with Mercury:** From 18% (2020) to 11% (2021)

- **Stronger Focus on Enforcement of Restriction of Hazardous Substances in Electrical and Electronic Equipment**

- **Too high migration of boron, frequently found in so-called “slime toys”, seems to be largely under control in 2021 compared to 2020 (2% vs 7%).**

- **A decrease in “skin-lightening products” with mercury was recorded** (11% of all cosmetics, down from 18% in 2020). However, producers seem to perform a “regrettable substitution” with pharmacologically active substances.

- **Regarding non-compliant chemicals in products, toys – like in the years before – were the most prominent category (33%). However, jewellery has increased to 23% (up from 6% in 2019), overtaking chemical products (11%), clothing (7%) and cosmetics (6%).**

- **In 2021, we see a stronger focus on Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) enforcement** (11% vs 3% in 2020), similar to the situation in 2019 (17% vs 1% in 2018). In both cases, the Commission launched RoHS activities the following year.
Research methodology

This analysis is based on the European Commission’s 2021 Safety Gate article data but broken down into individual chemicals. Through the Safety Gate rapid alert system for dangerous non-food products, EU/EEA member states and the European Commission exchange information about products posing a risk to health and safety of consumers. For 2021, the Cefic report listed 964 instances of chemicals that were not in compliance with the law (2020: 1136).

Cefic’s analysis excludes button batteries and motor vehicles. The raw data has also been adjusted for the fact that a product can sometimes be found in other countries or in different colours, and more than one non-compliant chemical can be found in one product.

This analysis does not reflect the number of all non-compliant articles placed on the EU market and is only based on the cases reported by EU Member State enforcement authorities through Safety Gate.

For more information about the methodology, please contact Bernd Kappenberg, Cefic Product Stewardship Manager: bka@cefic.be
RAPEX 2021 – BREAKDOWN OF NON-COMPLIANCES PER LEGISLATION

RAPEX 2021 – chemicals by law (all countries) (964 instances)

- REACH; 345; 37%
- Tobacco Products Directive; 41; 4%
- POP Regulation; 34; 4%
- RRoPS; 104; 11%
- Toy Safety Directive; 87; 9%
- Cosmetic Products Regulation; 72; 7%
- PFOA Regulation; 2; 0%
- PPR Regulation; 5; 0%
- Tattoo Resolution; 31; 1%
- CLP; 18; 2%
- General Product Safety Directive; 17; 2%

➢ CHEMICALS BY LAW

RAPEX 2021 – REACH (all countries) (545 instances)

- outside the EU/EEA; 421; 77%
- unknown; 96; 18%
- inside the EU/EEA; 28; 5%
RAPEX 2021 – Breakdown of non-compliances by chemicals

- Bisphenol A: 16, 2%
- Parabens: 25, 3%
- Nickel release: 50, 5%
- Lead: 135, 14%
- Cadmium: 145, 15%
- Restrictive phthalates: 267, 28%
- Not compliant to REACH: 26, 4%
- Other: 111, 12%

RAPEX 2021 – Breakdown of non-compliances by endocrine-disrupting and reprotoxic properties vs others

RAPEX 2021 – chemicals by EDC / (suspected) reprotoxic / other, all countries (964 instances)

- Reprotoxic: 547, 56%
- EDC: 261, 27%
- Other chemical risk: 356, 37%
RAPEX 2021 – **EDCs**, all countries (261 instances)

- unknown: 27; 10%
- inside the EU/EEA: 6; 2%
- outside the EU/EEA: 238; 88%

RAPEX 2021 – (suspected) **reprotoxic**, all countries (347 instances)

- unknown: 55; 16%
- inside the EU/EEA: 29; 8%
- outside the EU/EEA: 284; 78%
RAPEX 2021 – BREAKDOWN OF NON-COMPLIANCES
PER CATEGORY OF PRODUCT

RAPEX 2021 – chemicals by category, all countries
(51 weeks / 964 instances)

- Toys: 320, 33%
- Clothing, textiles and fashion items: 71, 7%
- Chemical products: 110, 11%
- Jewellery: 220, 23%
- Chemical products and children's equipment: 20, 3%
- Toys: 320, 33%
- Electrical appliances and equipment: 51, 5%
- Cosmetics: 56, 6%
- Hobby/sports equipment: 34, 4%
- Kitchen/cooking accessories: 19, 2%
- Bath: 19, 2%
- Other: 18, 2%