

Update on Major EU Chemical- related Regulations (part 2)

**TURI 2019
Norwood, MA**

November 13, 2019

Part 2

Tools and Resources

- ECHA Website
 - Authoritative, well-organized website for EU-level regulations and substance information
- Chemsec
 - Sweden-based non-profit
- BOMcheck
 - Electronics industry service to manage substance disclosures
- GADSL
 - Global automotive industry list of substance for disclosure
- Rapid Alert System
 - EU Commission website for non-compliant consumer products

European Chemical Agency

ECHA's website is a great resource for data as well as regulatory texts and compliance guidance



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Search the ECHA Website



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Search for Chemicals

Search by Name, EC or CAS NO.

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Get ready for new REACH requirements for nanomaterials

REACH

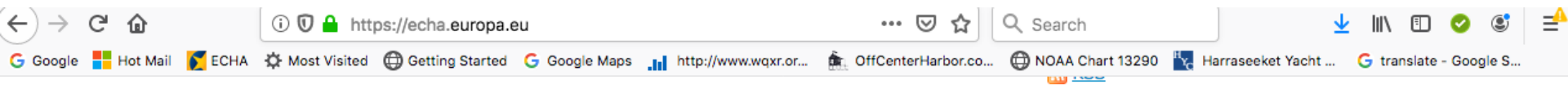
08/10/2019

By 1 January 2020, companies must provide more information on nanomaterials on the EU market under the REACH Regulation. ECHA encourages potential registrants to familiarise themselves with the new legal requirements and get ready.

Substances
in focus

 **The withdrawal of the UK from the EU**

 Interact Portal	 REACH-IT
	



REACH

Applications for authorisation

Consultations: 46

Start date: 14/08/2019
 - Deadline:
 09/10/2019

Calls for comments and evidence

Substances: 1

Start date: 03/10/2019
 - Deadline:
 16/12/2019

Identification of substances of very high concern

Substances: 4

Start date: 03/09/2019
 - Deadline:
 18/10/2019

Restrictions

Consultations on SEAC draft opinion: 1

Start date: 25/09/2019
 - Deadline:
 25/11/2019

Restriction proposals: 2

Start date: 19/06/2019
 - Deadline:
 19/12/2019

Restriction proposals: 1

Start date: 25/09/2019
 - Deadline:

CLP

Harmonised classification and labelling

CLH proposals: 5

Start date: 12/08/2019
 - Deadline:
 11/10/2019

CLH proposals: 5

Start date: 26/08/2019
 - Deadline:
 25/10/2019

CLH proposals: 5

Start date: 23/09/2019
 - Deadline:
 22/11/2019

Harmonised classification and labelling targeted consultations

CLH proposals: 1

Start date: 07/10/2019
 - Deadline:
 21/10/2019

BPR

There are currently no ongoing consultations.

CAD/CMD

There are currently no ongoing consultations.

Techniques for Searching on ECHA

- To see all chemicals on a certain list, go to the specific list (searchable)
- To research a specific chemical, use “Information on Chemicals” function and enter CAS or EC number (chemical name search can be difficult)
 - REACH Registered Substance Factsheet displays public registration data- registrants names, test results, etc.
 - “PACT” will show if a substance is being evaluated for hazards, classification, regulatory control changes, etc.

Chemsec's SIN List

- **Substitute It Now** (“SIN List”)
- Through collaboration with other groups, identifies substances believed to present hazards, and advocates for legislation to replace hazardous substances with safer alternatives
- SIN List: currently over 900 substances
 - Can search on specific substance, or download list
- Chemsec also has “marketplace” to search for safer alternative materials by function, industry and application (based on businesses' self-evaluation)
- “SIN Producers” database of companies Chemsec judge to be producing or importing the most hazardous chemicals in Europe and US (not a sought-after listing!)

SEARCH THE SIN LIST

Search your chemicals and we can identify if they are on the SIN List. If not, the SINimilarity tool can tell you if they are similar to the SIN listed chemicals



[VIEW ENTIRE SIN LIST](#)



[SIN LIST EXCEL](#)

FILTER the SIN LIST ▾

Health & Environmental concerns

Uses

REACH Status

Appearance date on SIN List

BOMcheck 1/2

www.bomcheck.net

- Initially lead by Philips, Siemens, GE, Osram, Sony Mobile, Schneider Electric, Toshiba, Agfa, and Texas Instruments. Now managed by Sphera with industry steering team
- Low cost (approx. €300/yr/user), and free to companies with <€ 3M/yr turnover
- Maintains global lists of restricted and declarable substances applicable to electronics and medical devices, including REACH, RoHS, GADSL, Conflict Minerals, Prop 65, etc.
- Suppliers enter product substance data (full or only controlled substances) into BOMcheck, but control who has access to the part number data
- Manufacturers (customers) can roll-up suppliers' authorized component data to achieve complex product status and compliance declaration

BOMcheck 2/2

- If your products go into electronics, BOMcheck can be a useful tool for collecting compliance data from your suppliers, and providing compliance data to your customers. Can be used to create required RoHS/CE compliance documentation, as well as SVHC, SCIP, etc.
- Can include data from supplies who do not participate in BOMcheck
- Can output IPC 1752A or other Regulatory Compliance Declaration for your product, based on your BOM of components
- Excellent free recorded and live webinars describing the service and use

Global Automotive Substance Declarable List

- Automotive Industry Initiative
- As the industry has complex, global supply chains, the industry has developed a global list of substances that either must be declared down the supply chain, or are prohibited from automotive uses
- Global regulatory scope
- Publicly available and downloadable (Excel)
- Searchable by CAS number
- <https://www.gadsl.org/>

EU Rapid Alert System

- Member States (EEA) submit information on non-compliant products in the EEA market
- Covers consumer products, except food, pharmaceuticals and medical devices
- Public website, so accessible to all
- Note that flexible PVC products are tested precisely!
 - Exercise care if your storage or product systems have retention/clingage of EU-controlled substances!
- Most common violations: DEHP/DBP, MIT/CMIT “Kathon”, boron (in “slime” products), cadmium in jewelry



CONSUMERS

European Commission > Safety Gate: Rapid Alert System for dangerous non-food products > Weekly report



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Rapid Alert System - Weekly Report

Report 40 (Published on: 04/10/2019)

Notification A12/1154/19 has been temporarily withdrawn from report 2019-31 of 02-08-2019 at the request of the notifying authority while waiting for the results of new tests on the product.

Weekly overview report on:

- [Consumer products](#)
- [Other types of alerts](#)



Product category

-- choose -- ▾

Notifying country

-- choose -- ▾

Alert number

-- choose -- ▾

- choose --
- Burns
- ✓ Chemical
- Choking
- Damage to hearing
- Electric shock
- Fire
- Health risk / other
- Injuries
- ...

Weekly report on c

Products with serious risks



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1 of 2 photos

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Alert number: INFO/0109/19



Category: Toys

Product: Hanging plastic doll

Brand: L&H Zabawki

Name: Blyskotka

Type / number of model: 801032

Batch number / Barcode: 5900718010320



Risk type: Chemical

The plastic material of the doll's head contains an excessive amount of bis(2-ethylhexyl) phthalate (DEHP) (measured value: 0,36 % by weight). This phthalate may harm the health of children, causing possible damage to their reproductive system.

The product does not comply with the REACH Regulation.

Measures taken by economic operators: Destruction of the product (By: Distributor)

Description: Plastic doll depicting an angel with wings and dresses in different colours. It has a string which enables it to be hanged. Sold in a plastic foil bag containing 6 units.

Country of origin: China

Alert submitted by: Poland

Type of alert: Other

Issues to Watch/Takeaways

1/4

- If your products are directly or indirectly exported to the EU (including components combined into complex products downstream), be sure you know the REACH Registration obligations and substances status downstream
- Monitor ECHA website “Registry of Intentions” listings:
 - 49 current Restriction Intentions
 - 592 current CLP Classification intentions
 - 227 current Candidate List (SVHC) intentions
 - Additional SVHCs actually added approx. every 6 months
 - 0 Draft recommendations for inclusion in Authorisation List
 - 18 substances added October 2019, including BPA, HHPA, methyl HHPA, DOTE, DOTE/MOTE

Issues to Watch/Takeaways

2/4

■ **Poison Center Notifications (PCN)**

- If your products go into **consumer or professional mixtures**, you will need to be able to make submission by January 2021
 - Note that even if a mixture is initially sold as an Industrial use product, but it is then incorporated into Professional or Consumer use products, the earlier submission deadline applies. (i.e. a pigment dispersion is sold to an ink or toner producer for industrial use, but the ink or toner is then incorporated into a cartridge for general use. The pigment dispersion PCN should be submitted for the earlier deadline)
- If you are supplying mixtures to the EU/EEA, check to see if your SDS software provider is ready to extract the needed information, create a UFI, and prepare the XML submission

Issues to Watch/Takeaways

3/4

▣ SVHCs in Articles

- ▣ If you supply products containing SVHCs which end up in articles imported into the EU (including components combined into complex products downstream), you can anticipate requests from your downstream customers for the Waste Framework Directive database information. Your downstream customers only have about one year to organize their entire supply chain.

▣ TiO₂

- ▣ If your products contain TiO₂, get in close contact with your supplier(s) to understand their plans, particle size data, and any future product changes to eliminate <10µm fractions
- ▣ If not, plan on having the new classification rules and EUH statements for use by early 2021 (unless the EU Parliament or Council vetoes the classification)

Issues to watch/Takeaways

4/4

For both PCN and Waste Framework Directive Reporting

- Given that the Candidate List (SVHC) and CLP Annex VI classifications change with some frequency:
 - “Today’s” evaluation of whether a product is subject to PCN submission (mixtures), or Waste Framework Directive submission (articles) can change when the SVHC list is added to, or an Annex VI classification is added (TiO_2) or changed
 - Stay aware of changes via ECHA’s website or your regulatory provider, so changes affecting your product will be known well in advance and your company can take appropriate action (and inform downstream if needed)

Questions?

- Please note that Syska Voskian Consulting does not take any position on the scientific basis of Authorities' decisions on any substance
- Our consultancy supports clients' understanding of regulations, and strategies to comply with current and announced future regulations, as well as future regulatory contingencies

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