NEWSLETTER JANUARY 2017

REACH and CLP

New REF-5 project will target quality of SDS according to ECHA.

According to ECHA the new REF-5 (Reach Enforcement) Project will be focused on the quality of the SDS. The REF-5 will start later this month and will continue throughout all 2017 and the inspectors will check also if the eSDS (extended Safety Data Sheets) match the information between the CSRs, the exposure scenarios and the substance manufacturers prepare. The REF-5 also will check if workesr comply with the safety information provided to us in their workplaces and how effectively eSDS are passed and communicated all the way through the SC (supply chain).
The results of the REF-5 will be available in the fourth quarter of 2018.

ECHA adds 4 new SVHCs to the Candidate List:

With the last new 4 SVHCs (Substances of Very High Concern) to the Candidate List the total number is 173 substances. The 4 new ones are:

a) BPA (bisphenol A): as toxic for reproduction.
b) PFDA (nonadecafluorodecanoic acid) and its sodium and ammonium salts: as having PBT properties and also as a toxic for reproduction.
c) p-(1,1-dimethylpropyl)pieno (EC n° 201-280-9, CAS n° 80-46-6. Equivalent level of concern having probable serious effects to environment.
d) 4-4-Heptylphenol, branched and linear substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof. No EC n°. no CAS n°.

ECHA adds 4a new entry to the current SVHC intentions registry.

Substance called ethylenediamine (EC n°, CAS n°) has been added by ECHA to its registry of current SVHC intentions due to its respiratory sensitiser potentiality. The dossier will be submitted by next 7th August.

ECHA has received 2 new CLH proposals.

ECHA has received from The Netherlands and from Austria respectively two proposals to harmonise the C&L (Classification and Labelling) of the substances:

a) Cobalt, with hazard classes open for comment of germ cell mutagenicity, carcinogenicity and reproductive toxicity.
b) Pyridate (ISO), with hazard classes for comment of specific target organ toxicity (STOT) –single and repeated exposure and hazardous to aquatic environment.

REACH-LIKE REGULATION IN THE WORLD

South Korea's MoE (Ministry of Environment) has proposed a 3 phase-in registration deadlines and a pre-registration process similar to EU REACH.
The MoE recommends that pre-registered existing chemicals will have the following registration deadlines:

a) For substances made or imported >1.000 Tpa: 2021.
b) For substances made or imported at 100 Tpa: 2024.
c) For substances made or imported at 10 Tpa: 2027.

Pre-registration requirements are: information on the name of the material and the expected amount of production.
MoE has stated that if the Law is amended and published in 2017, it will be enforced 1 year later. The Law is expected to be adopted by 30 June 2017 and will enter into force one year later.

The **US EPA (Environmental Protection Agency)** has issued the so called "inventory reset rule"; a rule setting on how it will designate substances as active or inactive on the TSCA Inventory.
According to the newly reformed TSCA this rule (and some others) must be finalized one year after the entry into force of the Frank R. Lautenberg Act (the TSCA reform).
The proposed rule requires manufacturers and importers to electronically report to EPA the substances manufactured for non exempt commercial uses within 10 years preceding 22 January 2016. The reporting period would run for 180 days as required by the Lautenberg Act. Processors will have the option to report for a 360-day period.

Health Canada in compliance with schedule 3 of the **CEPA (Canadian Environmental Protection Act)** has issued an order amending it and requiring open mixtures containing more than 95% of elemental mercury by weight to Canadian's ECL (Export Control List).
The scope of the order is to align Canada position to ratify the ***Minamata Convention on Mercury and mercury compounds*** (signed by 33 countries on 10 October 2013).
Currently there are no measures in Canada controlling/prohibiting the export of elemental mercury (except when contained in hazardous waste or hazardous waste recyclable material).

US EPA has proposed prohibitions or restrictions on the use of two solvents:

a) dichloromethane (methylene chloride) and
b) NMP (n-methylpyrrolidone).

Both in paint removal applications.
Also, EPA has announced that in accordance with Section 6 of the new TSCA, the use of TCE (trichloroethylene) in vapour degreassing has been proposed to be restricted.
In Europe, NMP is on the REACH Candidate list of Authorisation as a reproductive toxicant category 1 B, but the Netherlands had also proposed a restriction on the substance.

BIOCIDES & PESTICIDES

ECHA's BPC has adopted 17 new opinions.
During ECHA's last BPC (Biocidal Products Committee) meeting a new 17 opinions supporting the approval of 6 active substances to be used as disinfectants and preservatives have been adopted.
The 6 active substances are:

1. Active chlorine released from sodium hypochlorite: for PTs 1, 2, 3, 4 and 5.
2. Active chlorine released from calcium hypochlorite: for PTs 2, 3, 4 and 5.
3. Active chlorine released from chlorine: for PTs 2 and 5.
4. MIT (2-methyl-2H-isothiazol-3-one (MIT): for PT 11.
5. OIT (2-octyl-2H-isothiazol-3-one (OIT): for PT 8.
6. Peracetic acid generated form TAED (tetra-acetylethylenediamine) and sodium percabonate: for PTs 2, 3 and 4.

ECHA has concluded that these 6 active substances may be approved in the above mentioned PTs. The approval of an active substances is granted for a maximum time of 10 years.
Active substance MBIT (2-methyl-1,2-benzothiazol-3(2H)-one) has been rejected by the Committee for PT-3 due to unacceptable risks identified for groundwater for several metabolites of MBIT.

ECHA & EFSA (European Food Safety Authority) outline their guidance plans for ECD.
Both agencies had published an outline of the guidance they are developing on how to identify substances with EDC (Endocrine Disrupting Chemicals) properties in biocides and pesticides.
The draft outline includes a projected table of contents and a plan of the drafting process with timelines, responsibilities, consultations with relevant parties, etc.
The scope of the guidance is to enable applicants and regulatory authorities to identify EDCs in chemical substances proposed as pesticides and biocides.
A public consultation on the draft guidance is expected by summer of 2017.

ECHA's Board of Appeal decision of Triclosan.
An appeal by BASF Grenzach GmbH had been rejected by ECHA's BoA (Board of Appeal) on substance evaluation decision for active substance Triclosan (EC n° 222-182-2, CAS n° 3380-34-5).
Triclosan is a broad-spectrum antibacterial mainly used in dentifrices, soaps and ,many other human hygiene h products.
The contested decision required the appellant to perform persistence testing in marine and freshwater and additional elements of an EOGRTS (Extended One-Generation Reproductive Toxicity Study) regarding the cardiotoxicity of Triclosan.

NANOMATERIALS

OECD conclusions on nanomaterials and test guidelines disputed.
According to Danish and US researchers the test guidelines of the OECD's Sponsorship Testing Programme for Nanomaterials are not suitable for use on nanomaterials. Researchers said that the programme's conclusion that the test guidelines used for normal chemical substances are in the most part suitable for use on nanomaterials is not supported by the evidence in the dossiers.
Their opinion is that a new programme is needed to systematically evaluate the applicability and interpretation of toxicity assays for nanomaterials and to develop new methodologies.

US EPA has published the final Nanoscale materials reporting rule.
The final version of the Nanoscale materials reporting rule under Section 8(a) of TSCA has been done after 11 years in the making.

This rule specifies the one-time reporting obligation for existing nanoscale materials and for new discrete nanomaterials before they are manufactured or processed.

The rules does not apply to:

a) Chemical substances manufacture or processed in forms that contain < 1% by weight of any particles between 1 and 100

One year after the rule's effective date, manufacturers, importers and processors must report electronically to the US EPA certain information of the covered substances (such as production volume and method of manufacture).

COSMETICS

EU Cosmetics nano Inventory is still delayed after 3 years.

The EU Cosmetics Regulation required the EU Commission to publish an Inventory of nanomaterials used in cosmetics products present in the EU market. The Cosmetics Regulation had specified that "the Inventory must be published by 11 January 2014"… which has not happened.

The EU Commission said that the publication of the Inventory has been delayed due to the poor quality of information received from the cosmetics industry through the CPNP (Cosmetic Products Notification Portal) and that the delay is not caused by any specific nanomaterials substances, but an overall need to ensure that the Inventory only contains correct, true and consistent information".

The EU Commission said that they can adopt enforcement measures (such as pulling out from the EU market all cosmetics containing nanomaterials) until adequate information is provided.

MEDICAL DEVICES

EU to adopt a new Medical devices Regulations next May 2017.

The EU Commission has said recently that a new Medical devices Regulation is expected to be adopted next May 2017.

The new Regulation will be adopted on medical devices and on *in vitro* diagnostic medical devices (or IVDs).

The final consolidated text had been endorsed by the CoRePer (Council of Ministries Permanent Representatives Committee) and by EnVi (EU's Parliament Environment Committee) and once approved it will replace the existing Directives.

The provisions of the new Regulation will apply 3 years after publication for medical devices and 5 years for IVDs.

Within a year of the Regulation's entry into force, the Commission will provide a mandate for the relevant scientific committee to prepare guidelines on phthalates. This would include a benefit-risk assessment of their presence, as they are CMRs or EDCs. And such assessments would have to be updated within five years.

The Commission would also issue similar mandates for the preparation of guidelines on other CMRs.

The Regulations include labelling provisions. A label on the device and the packaging would have to say if the devices, their parts or materials contain a CMR or EDC above the concentration limit. And a list of such substances must be included.

According to the estimations by the first week of April a plenary vote and signature is expected at EU level, the it will published in the Official Journal of the EU and will enter into force 20 days after its publication.