NEWSLETTER JUNE 2017

REACH and CLP

EU Commission has published the new Regulation on Mercury.
Last 24 May it has been published on the Official Journal of the European Union Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (L 137/1).
The new Mercury Regulation includes a ban on the use of mercury in dental amalgam for pregnant, breast feeding women and children under 15 years, unless absolutely medically necessary.
The Regulation will come into force on 1 July 2018.

ECHA's List of Lead Registrants has been updated.
ECHA has published on their website a new updated List of known Lead Registrants.
Up to now, the number of JS (joint submissions) is 10.662 substances.

PIC update.
The new version of the ePIC (electronic Prior Informed Consent) will be available from 30 May according to ECHA. The new ePIC system will improve search criteria and will give more detailed information on the chemicals subject to the PIC Regulation.

ECHA updates its Registration Guidance.
ECHA has updated its Guidance on how to prepare Registration also its PPORD dossiers; including a new chapter on how to create a full opt-out in case of a dispute, some clarifications on how to describe intermediate uses and which are the requirements for submitting a CSR (Chemical Safety report).

ECHA's CLH consultations on 4 substances.
Until next 7 July ECHA is consulting on 4 CLH (Harmonized Classification and Labelling) for the following substances:

a) Paclobutrazol (EC n° 616-379-6, CAS n° 76738-62-0): for physical, health and environmental hazards classes. Proposed by the UK.
b) Pyrithione zinc (EC n° 236-671-3, CAS n° 13463-41-7): for physical, health and environmental hazards classes(hazardous to the ozone layer). Proposed by Sweden.
c) Dimethyl disulphide (EC n° 210-871-0, CAS n° 624-92-0): for aspiration hazard, hazardous to aquatic environment, flammable liquid, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitization, germ cell mutagenicity, reproductive toxicity, STOT (single and repeated). Proposed by the EU industry.
d) 2,2-bis(bromomethyl)propane-1,3-diol (EC n° 221-967-7, CAS n° 3296-90-0): for germ cell mutagenicity and carcinogenicity hazard classes. Proposed by Norway.

PlasticsEurope CHA updates its Registration Guidance.
Plastics Europe, the EU leading Plastics Trade Association based in Brussels, has present a file against ECHA's decision to include BPA (bisphenol A, EC n° 201-245-8, CAS n° 80-05-7) on the REACH Candidate List of SVHCs (Substances of Very High Concern).
ECHA decided to include BPA on the Candidate list last 12 January because of its reprotoxic properties.
Their legal claim is that the majority of uses of BPA are as an intermediates, which is excluded from REACH.
Next MSC (Member Sates Committee) meeting in June will see the discussion of BPA as an endocrine disruptor chemical in humans.

The legal case has been presented at the European Court of Justice and according to PlasticsEurope Lawyers a court hearing is probably to begin next year at the earliest.

REACH-LIKE REGULATION IN THE WORLD

According to the Canadian Government the deadline requiring manufacturers and importers SDS (Safety Data Sheest) and labels to comply with the updated WHMIS (Workplace Hazardous Materials Information System, of 2015) has been postponed at least for a year to 1 June 2018.
The extended period will allow companies to use both the WHMIS 1988 and the WHMIS 2015.
The Canadian Government published in 2015 the HPR (Hazardous Products Regulations, or SOR/2015-17) and the HPA (Hazardous Products Act, or R.S.C., 1985-H. 3) in order to modify the workplace hazard communication standards in order to incorporate the UN GHS.

GREENPEACE

NGO Greenpeace is asking the Chinese Government to adopt and execute the protocols adopted by the UNEP (United Nations Environmental Programme) on "Practices in the Sound Management of Chemicals 2010) on pollution prevention, precaution, internationalization of environmental and human health costs and ensuring the public's right to know.
Currently China regulates chemical safety under the SAWS (State Administration of Work Safety), Decree 591, RSMHCC (Regulations on the Safe Management of Hazardous Chemicals in China).
Chinese Government prioritize those chemicals listed in the CHC (Catalogue of Hazardous Chemicals), but revisions to the La are very complex because 10 different ministries are involved in the implementation of the Law.

According to US ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods) US industry altogether with regulators from different federal agencies had drafted US strategic roadmap for alternative approaches.
The roadmap describes a need to identify and collate sources of high quality human toxicological data, in order to assess new alternative methods.
The roadmap will be open for consultation until 31 August, will be discussed at the Scientific Advisory Committee on Alternative Toxicological Methods in September and expected to be published in December 2017.

South Korea's NIER (National Institute for Environmental Research) has published, last 11 May, some guidelines for acceptable alternative data that companies can use to submit their registration dossiers in place of test reports produced by a certified GLP (Good Laboratory Practices) Laboratory or RSSs (Robust Study Summaries).
NIER will allow data from qualifying scientific literature, toxicity databases and assessment reports from well recognized industry organizations including:

a) Academic Journal papers;
b) Science handbooks,
c) Toxicity databases (i.e. ICLID, US EPA IRIS, etc).

d) OECD's SIDS (Screening Information Data Set).
e) IARC (International Agency for Research on Cancer) monographs;
f) WHO (World Health Organization) chemical substances assessments;
g) EU RARs (Risk Assessments Reports);
h) And US EPA RED (Registration Eligibility Decisions) for pesticides.

Japan's MHLW (Ministry of Health, Labour and Welfare) has notified the WTO that wants to introduce some obligations on "business operators" for the labelling, safety data sheets and RA (risk assessment) on 10 substances, plus preparations containing them. The substances are:

1) Asphalt;
2) Portland cement;
3) Boric acid;
4) Carbonyl sulfide;
5) Diacetyl (also known as butanedione);
6) Terbufos;
7) TAME (also known as tert-amyl methyl ether);
8) Isocyanate (also known as phenyl isocyanate)
9) 1-chloro-2-propanol, and
10) 2-chloropropan (also known as 2-chloro-1-propanol).

WTO has until 15 June to submit comments on Japan's MHLW proposal.
The new rules, in the amended Order, are due to be adopted in July 2017 and into force in July 2018.

NANOMATERIALS

ECHA has recently published a document in the form of nanomaterials Guidance.
The scope of the published documents is to help companies using nanomaterials to understand how to comply with the current chemicals legislation in Europe.
The21 page document (v.1.0. May 2017) is called "How to prepare registration dossiers that covers nanoforms" and is to be considered more an advisory best practice document rather than a traditional Guidance made by ECHA.
The origin of the advisory best practice document is the BoA (ECHA's Board of Appeal) ruling on case A-011-2014 by a group of TiO2 (CAS 13463-67-7, EC 236-675-5) which was based on the provision of information on the nanoforms of a substance in its registration dossier.
The conclusion of the case was that ECHA cannot demand such information on the basis that the dossier fails to provide sufficient information on substance identity.

PHARMA AND MEDICINAL PRODUCTS

EMA (European Medicines Agency) and regulators from the EAC (East African Community) has recently met in London to discuss the possibility of using the EMA as a model for a future regional agency. EAC is formed by the States of Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda.
The role of the future Agency will be the coordination of the regulation of medicines in Africa, which began in 2012 with the harmonization of legislation under the African Medicines Regulatory Harmonisation Initiative. The EAC has been granted an official observer position at the ICH (International Council for Harmonization) and a member position at the IPRF (International Pharmaceutical Regulators Forum).

Dr. José V. Cantavella Cabedo, Attorney at Law and Head of Legal department, will leave ChemSafe next 19 June 2017 on a new professional journey.

Dear All,
It's been a pleasure to have been working with so many of you during the last seven years, but from *19 June 2017* I will start a new professional career abroad.
It has been a difficult decision to take but I want to *THANK ALL OF YOU* for your support and understanding.
Maybe we will find again somewhere around the World!