NEWSLETTER JULY 2017

REACH and CLP

IUCLID Cloud for SME from July (said ECHA)

ECHA claimed that the new full version of the software IUCLID (version 6) will be available from July 2017 for trials. The system has been created to help Small Medium Enterprises (SME) to prepare their own dossier online in a web browser. It is expected that by the end of the year, a final IUCLID Cloud system will be fully implemented with the target of making the creation of a registration dossier easier. This will help especially non-frequent users.

Regulation (EU) 999/2017

COMMISSION REGULATION (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), was published on the Official Journal L150/7/2017.
This an important regulation as it introduce in the Annex XIV *12 new substances* to be subjected to the authorization process with related Latest Application and Sunset dates.
Among the various substances we can particularly mention:

DMF (N,N-Dymethyl Formamide)

The inclusion in the REACh Annex XIV was delayed as "the Commission considers appropriate to postpone the decision on the inclusion of DMF in Annex XIV as has already been done for DMAC when the Commission considered the Agency's recommendation of 17 January 2013". This is the consequence of the willing to treat the three aprotic solvents with a harmonized approach. DMF, NMP (N-methyl-2-pyrrolidone) and MAC (N,N-dimethylacetamide) have similar properties, industrial application and hazard profile. NPM, in particular, is under and ongoing restriction procedure. DMF is under evaluation by Italian Competent Authorities for a possible restriction procedure too.

Boric acid and others

Boric acid, disodium tetraborate (anhydrous), diboron trioxide, and tetraboron disodium heptaoxide (hydrate) are used in lots of different industrial and consumers application. They were object of huge discussion among Industry and Regulators about their hazard profiles. The final outcome was they are toxic for reproduction (category 1B). In this case, the Commission postponed the inclusion in Annex REACH XIV as currently the experience for handling authorization applications covering broad ranges of uses is still limited.

4-Nonylphenol, branched and linear, ethoxylated

The substance group 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (covering well-defined substances as well as substances of unknown or variable composition, complex reaction products or biological materials i.e. UVCB substances, polymers and homologues) are substances which through their degradation have endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment. They are used in various industrial application. The Commission included them all in the authorization process with Latest Application date of July 4, 2019 and Sunset Date of January 4, 2021.

Regulation (EU) 776/2017

COMMISSION REGULATION (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures. It's the so called 10 ATP.
Herewith a brief description of the major changes

- Some classification and labeling proposal have been added, updated or cancelled including M factors and specific concentration limits
- A total of 24 new harmonized classifications and 13 updated classifications
- Acute Toxicity Estimates (ATE) values have been added (only one case for nicotine CAS 54-11-5)
- Under part A of Annex VI two new notes (8 and 9) respectively for carcinogenicity and mutagenicity have been added concerning the classification of mixtures containing formaldehyde. The limit value was set at 0.1% but soon corrected to 1%

References to Directive 67/548/EEC (DSD) and Directive 1999/45/EC (DPD) have been deleted as those old EC Directives have been repealed from June 1st 2017. Further consequence is the repealing of table 3.2 from Annex VI of CLP regulation as the old classification criteria (ECC Directive 67/548/EEC) is no longer applicable. From that moment all substances and mixtures are classified by the CLP criteria (EC 1272/2008).
This regulation (10°ATP) shall be applied from December 1st, 2018 but anticipated voluntary application is possible.

EDC criteria adopted

EU member states have adopted the European Commission's proposal for criteria to identify endocrine disrupting chemicals (EDCs), after many years of discussion about the identification criteria of such chemicals. The proposal will have to go to now the Council of Ministers and the European Parliament before final adoption by EU.
The vote did not include the majority of states because 21 member states votes in favor, Denmark, Sweden and Czech republic voted against; Latvia, Hungary, Poland and UK abstained.
The European Commission says it "will not delay any action" in applying the criteria to pesticides and biocides with potential endocrine disrupting properties with the possibility to extend to other products, such as toys, cosmetics and food packaging, the same approach.
Industry and NGOs expressed regret at the vote. The European Crop Protection Association (ECPA) called the adopted criteria "fundamentally flawed (imperfect) and not sufficient". They claim the adopted criteria will not allowed authorities to clearly separate those substances that have the real potential to cause harm from those that do not. Discussion, therefore, is still strongly open.

CL proposals

ECHA has received proposals to harmonize the classification and labeling (CL) of:

- phosphine, submitted by France, with a proposed future entry of acute toxicity 1;

- sulphur dioxide, submitted by Germany, with proposed future entry of gas under pressure, acute toxicity 3, skin corrosion 1B, respiratory sensitisation 1, skin sensitisation 1A, and mutagenicity 2.

Guidances

The following guidances have been release by ECHA recently:

- update (version 5.0) of Guidance on the application of CLP criteria;
- translations of version 3.1 Guidance on data sharing; and
- update of version 3.0 Guidance on labeling and packaging in accordance with the CLP Regulation.

Tattoo ink and permanent make-up substances

Submission of a dossier on restricting the placing on the market of certain chemicals in tattoo inks and permanent make-up has been delayed until 6 October. The Commission asked ECHA to assess the risks late last year and the dossier was expected on 14 July. However the agency says that "given the complexity of the dossier, which covers many thousands of substances", the submitters did not consider it possible to meet the deadline.

Corap evaluations

Two new concluded documents, evaluating substances on the community rolling action plan (Corap) list, are now available on the agency website:

- 2-aminoethanol. Added to the list in 2014, the evaluating member state was the UK; and

- mixture of two components: 1) N-(1,3- dimethylbutyl)-N´-phenyl-p-phenylenediamine, with 2) N1-(1,3-dimethylbutyl)-N4-(4-(1-methyl-1- phenylethyl)phenyl)ben zene-1,4-diamine. Added to Corap in 2013, the evaluating member state was Slovakia.

BIOCIDES

Reg. (EU) 2017/698

We'd like to recall the following regulation that was already discussed in March 2017.
Reg. (EU) 2017/698 has been published in the Official Journal L 103 on February 3rd, 2017.
Such a regulation is aimed to updated the Annex II of Regulation EU 1062/2014 "COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work program for the systematic examination of all existing active substances contained in biocide products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council"
In brief, the new regulation updated the combination between active biocidal substances and product types included in the review program of existing biocide active substance up to August 4, 2014.
Such update was necessary to cancel from the list the following active substances:
• "supported" (Annex. II - part 1) but no notification has been submitted to ECHA (Art. 14.3 of Reg. 1062/2014) regarding the intention to be kept in the review program:
• "non supported" (Annex. II – part 2) no notification has been submitted to ECHA in order to be added to the review program;

Art. 14.3 of Reg. 1062/2014 has been deleted as no longer need to notify any active substance

Peracetic acid (CAS 79-21-0)

The substance was approved as active biocide substance with COMMISSION IMPLEMENTING REGULATION (EU) 2016/672 of 29 April 2016 approving Peracetic acid as an existing active substance for use in biocidal products for product types 1, 2, 3, 4, 5 and 6 on April 29, 2016.
Such regulation include an approval date for Peracetic acid of October 1st, 2017 and an Expiry date of approval on September 30, 2017.
All commercial products containing Peracetic acid as active biocide substance must be regulated by submitting a full biocide dossier within October 1,st 2017 to the relevant Competent Authority (National Bodies in case of National Authorization or ECHA in case of Union Authorization.

WASTES

Reg. (UE) 2017/997

COUNCIL REGULATION (EU) 2017/997 of 8 June 2017 amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 'Ecotoxic' was published on the Official Journal L150 of June 8, 2017.
The Regulation modify the Annex II of European Directive 2008/98/EC regarding the environmental hazard HP 14 "Ecotoxic". The new regulation will apply from July 5 2018.
When determining the hazard classification of a waste and in relation of the hazard class HP14 "Ecotoxic" using the calculation method, threshold generic values should be used as for CLP Reg. (EC 1272/2008).
HP14 will be applied on wastes which satisfy one of the following conditions:

Substances classified with H400 and/or H410 with a threshold level of 0.1% and substances with H411, H412 or H413 with a threshold level of 1%

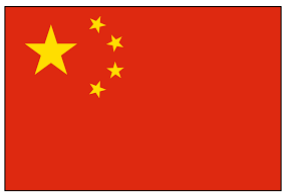
It is expected that this approach will lead to an increase of wastes classified as Ecotoxic.

WORLWIDE

ITALY

The 2017 "*Piano Nazionale delle attività di controllo sui prodotti chimici*" was released by the Ministry of Health some time ago. It consists in the actions to be implemented in the year 2017 related to the control/inspection of the Regulations REACH and CLP. Target of the controls are many and summarizing the old requests from REACH Enforcement ECHA plans. Very clear is the target of the substances to be controlled. They consist of

- substance itself or contained in mixtures and/or article classified as carcinogenic, mutagenic or toxic for reproduction, sensitizers or identified as for REACH Art.59 (SVHC) listed in Annex XIV (authorization) or listed in Annex XVII (restriction).
- Substances potentially included in articles to the final consumers with particular attention to more sensible categories such as infants, children, teenagers, pregnant women or articles used by a high number of people.



CHINA

China RoHS2 law was issued on 29 June by the country's Ministry of Industry and Information Technology (MIIT).
RoHS2, Administrative Measures for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products, came into force on 1 July 2016. It added significant new obligations on companies, extending the scope of products covered, as well as the labeling and information-disclosure requirements.
The catalogue is comprised of 12 product types. They are:
Refrigerators and air conditioners;
washing machines;
electric water heaters;
printers and photocopiers;
fax machines;
televisions and monitors;
microcomputers;
mobile communication devices and telephones.

These products must comply with the hazardous substance restriction limits set out in national standard GB/T 26572 2011. This covers the same six substances and their homogenous materials as those by the EU RoHS Directive, namely: mercury, lead, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers.