Italy: Piano Nazionale dei Controlli 2019 (Italian National Inspection Plan for 2019)

The document has been recently released by the Italian Ministry of Health in cooperation with Centro Nazionale delle Sostanze Chimiche (in ISS= Istituto Superiore di Sanità) as well as in cooperation with the Technical Inter Regional Group (Gruppo Tecnico Interregional REACH-CLP). It is focused on giving criteria and information on how inspections on chemical products (substances and mixtures) will be carried out and reported all along the year 2019. The document established the general methodology used to carried out the REACH-CLP inspections to companies with the definition of:

- Substances Target groups (mainly those included in Annex XIV and XVII)
- Company priority selection criteria
- List of sources to identify companies to be subjected to inspection
- Type of substances
    - CMRs (Annex XIV and XVII)
    - Substances used as intermediates under SCC
    - Articles intended to be used by the final consumer
    - Substance with wide spread use or epidemiologically relevant

Target of inspections

- registration obligation
- authorization obligation
- restriction obligation
- notification to ECHA for substances included in articles
- obligation to inform along the supply chain
- SDSs compliance
- CSA/CSR obligation including the RMM information and application
- obligation to keep information
- obligation to classify as for CLP criteria (substances and mixtures)
- check of exemptions to classify (substances and mixtures)
- obligation to classify liquid laundry detergents in special cases
- obligation to notify to ECHA a classification
- obligation to notify to Italian ISS mixture classification
- advertisement obligation

A part is also dedicated to analytical controls on substances and mixtures

Endocrine Disrupting Chemicals: more actions required in EU

A French scientific report commissioned by the European Parliament Committee on Petitions concluded that the current EU regulatory framework does not protect human health and the environment from the impact of Endocrine Disrupting Chemicals (EDCs) properly. The report provided background before the European Parliament voted to adopt a resolution calling for greater EU action to regulate EDCs. It seems very unlikely that the aim of having all EDCs recognized as substances of very high concern by 2020 will be achieved as promised by the 7th Environment Action Program.

The experts call for "identical management of EDCs across all sectors for which EDC use is very likely to entail population exposure, notably pesticides, food contact materials and additives, consumer goods, cosmetics, medical devices and toys". There are currently "insufficient data requirements" to efficiently

identify EDCs in any sector. Hence, the use of EDC tests covering all EDC modalities and endpoints should be made compulsory in all application dossiers submitted by the industry.

As a consequence, there is an urgent need to accelerate test method development and validation, especially for the thyroid system and metabolic hormones. Regulators also need to make better use of academic publications when assessing EDC properties. It is well known that the current OECD test guideline validation process can take decades. "One of the main problems is that the country proposing the test has to find the financial and infrastructural resources to carry the tests out which, in the current economic climate, can be challenging,"

France is aware of the problem and has proposed a National Centre for EDC testing and validation in its EDC strategy. Beyond test development, the experts suggest six research areas that need prioritizing:

- epigenetic effects of EDCs;
- effects across generations;
- effects on the microbiome;
- green chemistry;
- novel EDC modalities;
- characterizing dose-response functions for EDC effects in humans.

A particular concern is addressed for low-dose effects. The scientific report covers non-monotonic effects, where EDCs have been observed to cause stronger adverse effects at low doses than at higher exposures. As a result, "trying to characterize dose-response functions and identify safe thresholds by testing a small number of doses (usually three in some regulatory tests) may be inefficient for EDCs”
There is caution that "it is unlikely that safe levels can be set", given the scientific knowledge on specific actions of EDCs. "In consequence, if a substance is an EDC, an 'authorized level' (or risk assessment) logic needs to be replaced by a no exposure logic."

The researchers are confident that their recommendations will not lead to a ban of a large number of poorly characterized substances". Following the recommendations "would only lead to decreased use or ban for substances with evidence of an adverse effect and their use in products entailing exposure of the general population”

Member States will evaluate 31 substances in 2019

ECHA has adopted the updated Community Rolling Action Plan (CoRAP) for substance evaluation, with 100 substances listed to be evaluated in 2019-2021. Registrants of the listed substances are encouraged to keep their registrations up to date and to contact the evaluating Member States.

19 Member States are to evaluate 100 substances over the next three years. For the 31 substances specified for 2019, the evaluating authorities have 12 months from today to carry out their evaluations.

The aim of the evaluation is to clarify whether further information is needed to conclude whether a substance poses a risk to people or the environment. If necessary, the registrants will be asked to provide this information. The authorities will assess the suspected concern and, where relevant, initiate regulatory risk management actions.

ECHA encourages registrants of the listed substances to coordinate their actions and to contact the evaluating Member State. Registrants are also urged to update their dossiers, especially for uses and exposures. They will have the opportunity to comment before any decision to request further information is taken. The draft decisions by the evaluating authorities will be reviewed by the other Member States and ECHA before the final decision is issued.

Substances are selected for evaluation based on concerns related to their suspected serious hazard properties. The substances may be suspected sensitizers, persistent, bioaccumulative and toxic (PBT) substances, carcinogenic, mutagenic and repro-toxic (CMR) substances or Endocrine Disruptors. The selection also considers wide dispersive worker or consumer use. The evaluation may also result in the identification of other concerns on the substances.

RAC and SEAC agreed conformity of the intentionally added microplastics restriction proposal

The Committee for Socio-Economic Analysis (SEAC) adopts its final opinion supporting the proposal to restrict hazardous chemicals in tattoo inks and permanent make-up. The Committee for Risk Assessment (RAC) concludes on sixteen opinions on harmonised classification and labelling.

SEAC adopted its final opinion backing the proposal to restrict the placing on the market and use of hazardous substances in tattoo inks and permanent make-up, meaning both the Committees have agreed to support the restriction proposed by ECHA in collaboration with Denmark, Italy, and Norway. Substances within the scope of the restriction include carcinogenic, mutagenic and repro-toxic (CMR) substances, skin sensitizers or irritants, substances corrosive or damaging to the eye, metals as well as other substances regulated in cosmetic products.

Furthermore, RAC has adopted sixteen opinions for harmonized classification and labeling, including opinions on eleven active substances used in plant protection products and five industrial chemicals, including one adopted by written procedure prior to RAC 48.

Both Committees agreed that ECHA's restriction proposals for intentionally added micro-plastic particles, for D4, D5 and D6 and for formaldehyde and formaldehyde releasers in articles are all in conformity with the requirements of Annex XV of REACH. All proposals are checked for conformity before the committees can start their evaluation and develop opinions. A public consultation on these restriction proposals will be launched soon.

CLP new proposal for classification harmonization

A proposal to harmonize the classification and labeling of **perfluoroheptanoic acid** (EC 206-798-9, CAS 375-85-9) has been submitted by Belgium.

BREXIT
Companies recommended to transfer registrations before the UK's withdrawal

ECHA continues to recommend companies to prepare for the UK withdrawal without a transition period,

Companies are reminded to initiate the transfer of their registrations and other assets through ECHA's IT tools before the UK withdrawal takes effect and not to leave these transactions to the last moment.

The number of registrations for which a transfer was initiated from a UK-based registrant to an EU-27 based company is increasing, with the cumulative figure exceeding 4.800 by the end of March out of approximately 12 000 UK registrations in total.

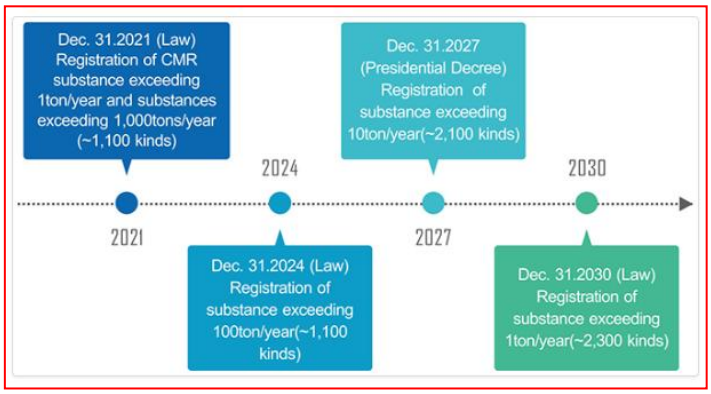
Companies can still benefit from the advice and practical instructions on ECHA's website to minimize the impact of the UK's withdrawal on their business, concerning REACH, CLP, PIC and the Biocidal Products Regulation.

Chemsafe new Partnership

In the frame of implementing its activity worldwide Chemsafe has established a partnership with CIRS China. Our Chinese partner is offering a huge panel of services in the far east area which is absolutely complementary to the Chemsafe one in Europe and western countries. Among these activities K-Reach (Korean Chemical legislation) is a crucial one due to the actual transitional phase in period.

K-REACH Pre-registration

The amended Act on Registration and Evaluation of Chemicals, also known as K-REACH, has been officially implemented on 1 Jan. 2019. Enterprises obligation under the amended K-REACH has been tremendously changed including the introduction of pre-registration. According to the requirements of the amended K-REACH, Korean manufacturers/importers of existing chemicals (excluding substances listed in the first batch of registration list) that manufactured/imported over 1t/y during 2016-2018 must submit pre-registration between 1 Jan. 2019 and 30 Jun. 2019. If an overseas manufacturers need to export existing chemical substance (excluding substances listed in the first batch of registration list) exceeding 1ton/ year to a Korean enterprise, the overseas enterprise could also complete pre-registration by appointing a Korean Only Representative. Related enterprises can enjoy the corresponding grace period based on the registration tonnage and hazards of substances.



From 1 Jul. 2019, substances (exceeding 1 ton/y) that have not completed pre-registration/registration **cannot** be manufactured/ imported/ used in Korea. If related enterprises violate the law and continue to manufacture/import/use such substances, enterprises responsible person may be given a fine of no more than five years imprisonment or no more than 100,000,000 won, depending on the time and seriousness of the incidents.

Pre-registration Process

-Fill in the substance information survey

-Determine the type of substances and the pre-registration tonnage

-Enter into contract and POA (Power of attorney)(enterprises outside South Korea)

-Prepare the pre-registration dossier

-Send the pre-registration number and completion notice

-Maintain pre-registration information (if necessary)

Chemsafe/CIRS service for K-Reach can be summarized as follows:

K-REACH Only Representative
K-REACH Pre-registration
K-REACH Registration
K-REACH Lead Registrant Service
New Substance Inquiry
K-REACH Registration Exemption Application
Risk Assessment Report
Technical Support and preparation of Korean SDS and label

CHEMSAFE attendance 2019

Milan (ITALY) February 26-2
Regulatory Toxicology, IKN workshop
Teachers: Antonio Conto (Chemsafe), Marco Rodda (Chemsafe)

Baltimore (USA), March 10-14
USA SOT (Society of Toxicology), Exhibition booth + two poster presentations, 4 people

London (USA), March 20-21
BCPA PESTEX, 1 people attending

Nurnberg (GE), May 21-23
MEDTECHLive, Exhibition booth + 3 people

Basel (CH), May 7-9
VITAFOODS 2019, Exhibition booth + oral presentation, 4 people

Rimini (ITALY) June 5-7
AFI 59° SIMPOSYUM, Exhibition booth + MD workshop organization, 6 people

Bruxelles, June 12-13
CHEMICAL WATCH EXPO: GLOBAL CHEMICAL REGULATION, Exhibition booth + oral presentation, 2 people

Helsinki (FI), September 8-11
EUROTOX 2019, Exhibition booth + two poster presentations, 3 people

End of the newsletter