The European Chemicals Agency Experience

by Derek J Knight

The European Chemicals Agency (ECHA) is the driving force for implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. It helps companies to comply with the legislation, advance the safe use of chemicals, provide information on chemicals, and address chemicals of concern. Founded in 2007 and based in Helsinki, Finland, ECHA is a modern, science-driven organization that has rapidly grown to become one of the largest EU agencies.

ECHA is responsible for the main EU laws governing chemicals:

- Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Regulation
- Classification, Labelling, and Packaging (CLP) Regulation.

These regulations ensure a high level of protection for human health and the environment by requiring that industry manufacture and use chemical substances safely. One of the main reasons for REACH is to fill information gaps for the large number of substances already in use in the EU. Under REACH, ECHA is responsible for obtaining, communicating, and using good-quality information on chemicals. Industry has to assess the hazards of substances for classification and risk assessment, and then adopt appropriate risk management measures to protect human health and the environment.

Another key strategic purpose of REACH is to address substances of concern that require regulatory intervention. The identification of such substances is facilitated by the process of compiling information on all chemical substances. The REACH and CLP processes and different actors involved are summarized in the figure on page 7.

REACH registrants have to provide information in the registration dossier on the intrinsic properties of all substances manufactured or imported at one tonne per annum or more. A key facet of REACH is to deal with old substances; these so called "phase-in" substances have to be registered by one of three deadlines according to their tonnage. The non-confidential information from registrations is disseminated by ECHA from the searchable database ECHA CHEM.

The standard information required for substances depends on the tonnage; the higher the tonnage, the more information needed. Substances are registered first with core data, with higher-tier studies applying at >100 tonnes and further studies at >1000 tonnes per annum. Registrants make testing proposals for such higher-tier studies and await approval to proceed with the testing following examination of the testing proposal by ECHA as part of the dossier evaluation work. ECHA also undertakes compliance checking of some of the registration dossiers to ensure that no mandatory information has been omitted.

The CLP Regulation requires chemical producers to use labelling and safety data sheets (SDSs) that communicate the hazardous properties of substances to end users. Some substances have mandatory classification and labelling that has been harmonized at the EU level. For other substances, self-classification applies, and industry has to use the available information, which for registered substances can be comprehensive. The classifications used by industry are disseminated by ECHA in the Classification and Labelling Inventory.

Addressing Substances of Concern

ECHA works with the European Commission and EU member states to regulate or restrict substances that pose a risk to human health or the environment. When necessary, the member states or ECHA (on a request from the commission) initiate the appropriate regulatory risk management process:

- Authorization is for "substances of very high concern" (SVHC), such as carcinogens; mutagens; or substances toxic for reproduction (CMRs); persistent, bioaccumulative, and toxic (PBT); very persistent and very bioaccumulative (vPvB); or of "equivalent concern." Substances with SVHC properties are first formally identified in the "Candidate List" then transferred, if appropriate, onto the "Authorization List." They can then only be marketed or used after the "sunset date" if they have been authorized based on a successful authorization application.
- Restriction is for when an unacceptable risk to humans or the environment has been identified.
- EU harmonized classification and labelling is for CMR substances or respiratory sensitizers (or for other hazards if justified for pesticide or biocide active substances).

REACH and CLP principles, processes and actors

Industry

Obtaining, using and communicating high-quality information on substances

- Pre-registration
- Data sharing
- Registration
- Self-classification
- Notification to the Classification and Labelling Inventory

➢ Industry obtains information on substances to assess hazards for classification and risk assessment to ensure safe use.
➢ Industry communicates to downstream users by labelling and by safety data sheets, including the exposure scenarios, i.e. operational conditions with associated risk management measures.
➢ ECHA disseminates registration and classification & labelling information.

Information on substances is of use in screening for potentially problematic substances

ECHA
EUROPEAN CHEMICALS AGENCY

Member State competent authorities

Dossier evaluation

- Testing proposal evaluation for decisions on conducting higher-tier studies
- Handling of compliance checks of some dossiers for compliance that no mandatory data are missing

Substance evaluation

- Community rolling action plan list of substances of potential risk
- Obtain any necessary information to clarify risk

Screening, prioritisation, risk management option analysis and selection of substances of concern for risk management

European Commission

Address substances of concern that warrant regulatory intervention

- Authorisation of substances of very high concern
  - Identification onto the candidate list
  - Transfer onto the authorisation list
  - Authorisation of use for successful applicants
- Restriction when unacceptable uncontrolled risks
- Harmonised classification and labelling of CMRs, respiratory sensitisers (and other hazards if justified)

➢ Member State competent authorities and European Commission initiate proposals, with the support of ECHA.
➢ European Commission applies the appropriate EU regulatory measure.

Substance evaluation is, in a sense, a link between registration and the risk management activities of REACH because it is the means of clarifying what to do regarding particular problematic substances. This is a separate process undertaken by Member States, coordinated by ECHA, to examine if more information, either on substance properties or their use and exposure, is needed to clarify whether there really is a risk. The substances to be evaluated are listed in the Community Rolling Action Plan (CoRAP). If the final outcome is that there is an uncontrolled risk, then a Member State can propose appropriate action under one of the REACH and CLP processes or refer to another EU regulatory instrument.

ECHA's Priorities and Strategic Aims

A key priority for ECHA is to ensure full readiness for the second registration deadline of 31 May 2013 for "phase-in" substances at >100 tonnes per annum. Toe meet this goal, the agency will continue to provide support to lead registrants to assist them in preparing high-quality dossiers and chemical safety reports (CSRs), and to carry out targeted communication activities to reach out to new registrants.

Another major priority is the ongoing dossier evaluation work. ECHA has a deadline of 1 December 2012 for examining the testing proposals from the first registration deadline. It also has an ambitious target of completing compliance checks of 5% of the highest tonnage band by the end of 2013.

Authorization is the third driver for this year, because after the 1 December deadline for the first substances on the Authorization List, industry will submit applications for authorization to use those particular substances.

ECHA also has to prepare for two new regulatory schemes:

- When the EU Biocidal Products Regulation enters into effect on 1 September 2013, the EU biocides scheme will be transferred from the European Commission to ECHA. Therefore, ECHA has to

prepare its IT systems to receive biocides dossiers, to create a biocidal products committee, and to recruit and train experts.
- Changes to the Prior Informed Consent Regulation will result in the transfer on 1 March 2014 of responsibility for tracking the export and import of hazardous chemicals from the European Commission to ECHA.

In its Multi-Annual Work Programme for 2013 to 2015, ECHA identifies strategic goals for achieving its ambitious vision. Although the following goals go beyond 2015, they provide direction to the agency about how to allocate resources and motivate staff:
- maximize the availability of high-quality data to enable safe manufacture and use of chemicals
- mobilize authorities to use data intelligently to identify and address chemicals of concern
- address scientific challenges by serving as a hub for the scientific and regulatory capacity-building of member states, European institutions, and other actors
- embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints

References

1. ECHA website: http://echa.europa.eu/
2. Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
3. Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Disclaimer: The views expressed in this paper are solely those of the author and the content of the paper does not represent an official position of the European Chemicals Agency.

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IUPAC at the Helsinki Chemical Forum

by Nicole J. Moreau

As IUPAC past president, I had the opportunity to represent IUPAC at the 4th Helsinki Chemicals Forum organized 24–25 May 2012 at the ECHA headquarters. This important global forum brings together international and national authorities, politicians, industry leaders, NGOs, academics, and media representatives. The goal of the forum is to allow dialog on key issues of global relevance related to chemical policy and chemical safety.

Geert Dancet, executive director of the ECHA, welcomes attendees to the Helsinki Chemicals Forum.

After the meeting, some delegates were invited to visit ECHA headquarters, where Derek Hansen, senior scientific advisor to the executive director, presented an "Introduction to ECHA, REACH, and CLP." Furthermore, I had the great pleasure of having a discussion with some ECHA representatives and presenting some information about IUPAC.

I had the utmost interest in attending this very informative conference, which confirmed my feeling that IUPAC should collaborate with ECHA for the mutual benefit of the two organizations.

A simple look at the ECHA website and at the information it provides on chemicals legislation in Europe, reveals that ECHA shares with IUPAC several elements of vocabulary: terminology, data submission, name of the substances, and classification. It is evident that the IUPAC nomenclature is known by ECHA workforce, and that this nomenclature should be used by the registrants. For instance, REACH regulation requires registrants of the same substance to share data in order to avoid duplication of tests. Therefore, for some tricky problems such as new compounds, nano or biological ones, IUPAC could be of help if needed. ECHA could also benefit from the InChI IUPAC system.

REACH and IUPAC share some common goals, such as ensuring the protection of human health and environment. So, how could we formally establish a fruitful collaboration? Could ECHA become a member of IUPAC? What would this necessitate from our respective organizations? These are questions I strongly think IUPAC officers and the Executive Committee should try to answer.

The fifth Helsinki Chemicals Forum will take place 18–19 June 2013 in Helsinki, Finland.

www.helsinkicf.eu//news/23052012.php