ECHA
EUROPEAN CHEMICALS AGENCY

In brief

ECHA-17-B-04-EN

General Report 2016 Highlights

In 2016, ECHA continued to pursue its four strategic objectives as well as carrying out supportive action for small and medium-sized companies (SMEs).

1 Maximising the availability of high quality information to enable safe manufacture and use of chemicals

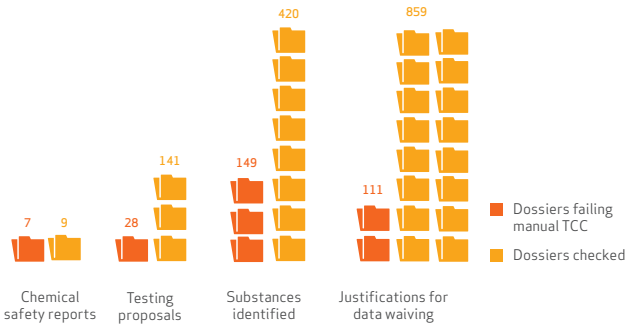
2016 was crucial in preparing for the 2018 REACH registration deadline. Significant efforts were made to provide user-friendly, stable tools and guidance to help registrants submit their registration dossiers.

Registration was further simplified. A support package for SMEs and inexperienced companies to help them understand their registration obligations, was published in 23 official EU languages. New material on alternatives to animal testing was also made available.

Under the REACH 2018 Roadmap, ECHA's IT tools for registration (REACH-IT) and dossier preparation (IUCLID and Chesar) were significantly upgraded, with a new generation released in the first half of 2016, with the needs of SMEs in mind. A free cloud-based service for SMEs will also be online in July 2017.

Enhancements were made in 2016 so that certain data in dossiers is now manually verified when it cannot be assessed automatically. Further to this, technical steps have been taken to stop companies illegally submitting their registrations outside of joint submissions.

Types of information requested for the 267 dossiers that failed the completeness check upon manual verification by ECHA staff.



With the release of the new version of the chemical safety assessment and reporting tool, Chesar in June 2016, it can now be used to assess complex substances and practical guides are included to help downstream users. The upgraded tools are expected to improve the quality of registrations and help communication of information throughout supply chains.

In January 2016, ECHA's dissemination portal was further tailored to meet the needs of different users. Access to data became available in three levels of detail. This is particularly beneficial for the public as key information on chemical substances is now summarised in an infocard . The brief profile goes deeper into human health,

environmental and physico-chemical properties. The third level is the source data, which is the raw data that ECHA receives in the dossiers.

In October 2016, Cefic[1], DUCC[2] and ECHA committed to encouraging improved supply chain communication by promoting use maps. Use maps provide a harmonised template to help registrants improve the quality of their registrations. In 2016, five sectors published theirs on ECHA's website. This commitment and the recommendations following the Chemical Safety Report/Exposure Scenario (CSR/ES) Roadmap's evaluation have reinforced how ECHA's work with industry on using chemicals more safely can further develop in 2017-2020.

Under dossier evaluation, registrants of high-volume priority substances received more than 140 compliance check decisions asking them to address data gaps for endpoints critical for human health and the environment. Similarly, the remaining registrants with testing proposals from the 2013 registration deadline received draft decisions by the legal deadline of 1 June 2016. For both processes, ECHA adopted 270 decisions.

2 Mobilising authorities to use information intelligently to identify and address chemicals of concern

Throughout 2016, Member States and ECHA used the common screening process of substance data to identify and evaluate the substances that matter most. Screening of ECHA's data resulted in 162 substances being identified because of their hazard properties and widespread uses.

Substance evaluation continued to generate information that enables risk management processes under REACH and CLP to start. Following the Community rolling action plan (CoRAP) 2016–2018 adoption in March, evaluating Member States began assessing 39 substances and ECHA took 26 decisions based on previous evaluations.

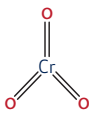
Example of an infocard and information it contains

Chromium trioxide

Other names: IUPAC names [18] Regulatory processes names [3] Trade names [5] Groups:

Substance identity

EC no: 215-607-8
CAS no: 1333-82-0
Mol. formula: CrO3



Hazard classification & labelling

Danger! According to the Harmonised Classification and Labelling approved by the European Union, this is fatal if inhaled, is very toxic to aquatic life with long lasting effects, causes damage to organs through prolonged or repeated exposure, is very toxic to aquatic life, may cause cancer, causes severe skin burns and eye damage, may cause genetic defects, is toxic if swallowed, is toxic in contact with skin, may cause fire or explosion (strong oxidiser), is suspected of damaging fertility, may cause allergy or asthma symptoms or breathing difficulties if inhaled and may cause an allergic skin reaction.

Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is fatal in contact with skin and is very toxic to aquatic life.

Properties of Concern

C M S

Important to know

- Substance of very high concern (SVHC) and included in the candidate list for authorisation.
- Substance of very high concern requiring authorisation before it is used (Annex XIV of REACH).

About this substance

This substance is manufactured and/or imported in the European Economic Area in 10 000 - 100 000 tonnes per year.

This substance is used in the following products: metal surface treatment products, non-metal-surface treatment products, pH regulators and water treatment products, adsorbents and laboratory chemicals. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used for the manufacture of: chemicals, plastic products and fabricated metal products.

Release to the environment of this substance is likely to occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates), formulation of mixtures, formulation in materials, as processing aid, manufacturing of the substance and in the production of articles. Other release to the environment of this substance is likely to occur from: indoor use as reactive substance.

ECHA has no registered data indicating the type of article into which the substance has been processed.

How to use it safely

- Precautionary measures suggested by manufacturers and importers of this substance.
- Guidance on the safe use of the substance provided by manufacturers and importers.

INFOCARD - last updated: 10/02/2016

1 European Chemical Industry Council
2 Downstream Users of Chemicals Co-ordination Group

Member States evaluated 48 substances and concluded that 32 required registrants to give further information to clarify possible concerns. Regulatory follow-up actions were necessary in 9 out of 20 substance evaluation cases prepared by the evaluating Member States in 2016.

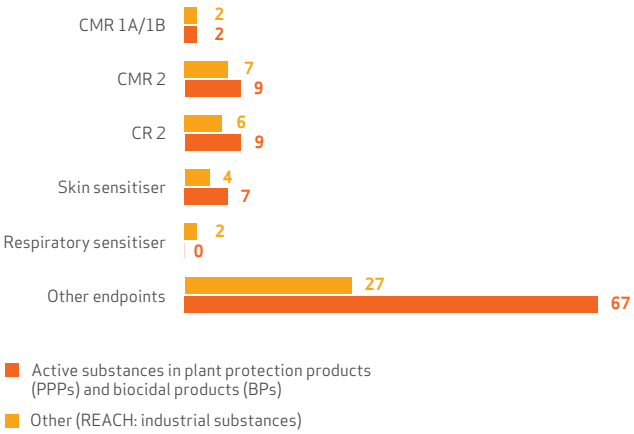
Risk management continued to deliver tangible benefits for society. There are now 173 SVHCs on the Candidate List, five of which were added in 2016 and January 2017. In November, ECHA recommended to the Commission that nine prioritised SVHCs should be added to the Authorisation List.

The two-year peak in the authorisation process reached its summit in 2016. ECHA received 77 applications for 112 uses, each needing an opinion from RAC and SEAC within 15 months. Within this timeframe, authorisation work has increased in efficiency and maturity. RAC and SEAC opinions on applications for authorisation for 63 uses were sent to the Commission. The high workload is expected to continue in 2017.

Measures were taken to streamline the application for authorisation process. Practical guides on 'How to Apply for Authorisation' and 'Checklists for Applicants' were published in December, to help applicants prepare 'fit-for-purpose' applications. High quality applications are essential as they give ECHA's committees the information they need to evaluate efficiently and provide meaningful opinions to the Commission.

On top of the authorisation workload, RAC and SEAC issued two opinions on restrictions and RAC adopted 35 opinions on harmonised classification and labelling. Both committees also made progress on many other dossiers, with the proposed classification of glyphosate, in particular, receiving a lot of public interest.

Number of endpoints classified by RAC in 2016



3 Address the scientific challenges by serving as a hub for building scientific and regulatory capacity of Member States, European Institutions and other actors

ECHA's endocrine disruptor (ED) and persistent, bioaccumulative and toxic (PBT) expert groups continued to support Member States in assessing these hazardous properties.

With the European Food Safety Authority (EFSA) and the Commission's Joint Research Centre (JRC), ECHA began drafting guidance that will set scientific criteria for identifying substances with endocrine-disrupting properties.

Status of received applications for authorisation per year

	Received applications (applicants)	Number of uses	RAC-SEAC opinions per use	RAC-SEAC opinions per use and per applicant	Commission decisions per use and per applicant
2012	0 (0)	0	0	0	0
2013	8 (10)	17	1	1	0
2014	19 (33)	38	30	34	2
2015	7 (20)	13	25	51	10
2016	77 (132)	112	63	180	52
Total	**111 (195)**	**180**	**119**	**266**	**64**

Guidance updates were also published on registration, data sharing and information requirements for endpoints relevant below 100 tonnes. These will support registrants ahead of the final registration deadline and help avoid unnecessary animal testing. Updates to nanomaterials guidance also progressed in 2016, but will be completed in 2017.

In April 2016, ECHA organised a well attended workshop addressing new approach methodologies. These aim to help reduce, refine or replace animal testing, and support regulatory decisions for the use of chemical substances. This may lead to further guidance updates in the future.

4 Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints

During 2016, ECHA's ICT infrastructure and services were upgraded. In support of the integrated regulatory strategy, ECHA continued to develop ways of integrating information on chemicals in a central platform. This enabled more effective data mining and analysis methods leading to significant advances in providing information to the general public and authorities.

IUCLID 6's launch will make implementing REACH and dissemination more efficient and will also help companies, particularly SMEs, to standardise communication in the supply chain.

Progress was made in developing synergies between REACH/CLP and BPR processes, which is expected to bring benefits for the review programme of existing biocidal active substances, the approval of new active substances and of biocidal products.

ECHA's Poison Centres' website was launched in April providing information on upcoming legal requirements and tools.

In 2016, the number of notifications that ECHA received on PIC-relevant substances was 30 % higher than in 2015, and 20 % higher than anticipated. The ePIC submission tool's upgrade allowed ECHA to manage this increase without requiring additional resources.

ECHA's scientific committees, the Forum, the Board of Appeal and ECHA's networks, such as the HelpNet, performed well under an increasing workload. As well as the commitment of the regular committee members, the involvement of co-opted members in RAC and SEAC proved very helpful in strengthening specific expertise and handling the workload peak.

ECHA contributed to a Commission study on the review of the Fee Regulation and assessed the required resources for ECHA up to 2020, which helped to secure adequate resources for 2017.

ECHA also agreed with the Commission to undertake three initiatives next year to:

- launch a feasibility study on the suitability of a centralised notification portal for submitting information to the poison centres;
- build an EU-wide observatory for nanomaterials to deliver reliable information on the safety of nanoforms in the EU market; and
- investigate the possibility of developing an EU chemicals legislation finder.

Preparatory work was undertaken for all three initiatives during 2016 without any new resources being given to ECHA.

Taking on board feedback from all stakeholders, ECHA also published the second five-year report on the operation of REACH/CLP which contributed to the European Commission's preparatory studies for the REFIT evaluation of REACH.

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