ECHA
EUROPEAN CHEMICALS AGENCY

FACTS & FIGURES

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General Report 2015 – Executive summary

In 2015 ECHA continued its pursuit of the four strategic objectives by concentrating the efforts to:

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

2015 was a year of preparation for the 2018 REACH registration deadline. It was notable that the number of registration dossiers received, especially new registrations, was much higher than expected. This suggests that companies have already started to submit their registrations for the last registration deadline. However, only 17% of all registrations came from SMEs. Compared to the forecasted 30% it underlines the fact that awareness of SMEs on their registration obligations remains a major concern.

In this respect ECHA started implementing actions under REACH 2018 Roadmap and publishing the first two phases of new SME friendly multilingual support material accessible via dedicated web pages. In addition, the Agency started preparing to release the next generation of dossier preparation and submission tools which will be much more user friendly. To better understand the needs of SMEs in these regards, ECHA launched a specific SME visits programme with targeted visits to SMEs from certain sectors and countries.

Also the Chemical Safety Assessment programme included actions targeting SMEs via short explanation videos, webinars and presentations. Overall improvements in communication in the supply chain under the Chemical Safety Report

/ Exposure Scenario Roadmap will result in more relevant information communicated in a standardised way to downstream users. Altogether, these actions help SMEs without registration obligations to better understand the impact REACH has on their business and how to comply with their downstream user obligations.

ECHA started implementing the compliance check strategy established in 2014 with over half of all performed compliance checks addressing substances of high relevance for risk management. Selection and priority setting of the dossiers was based on the integrated IT and manual screening as well as previous assessments. In 2015 ECHA changed also its approach towards dossier updates, promoting pro-active dossier improvements by publishing lists of substances which may potentially be selected for future compliance check.

Reaching a major planning milestone, ECHA completed by year end, the work that allows all EU citizens to access summary safety information on up to 120 000 chemicals directly on the Agency's website. The collected extraordinary amount of data is tailored to various audiences' needs and structured in three layers: 'Infocard', 'Brief Profile' and 'Source data'. This new way of disseminating information allows the interested stakeholders to scrutinise the information on substances of their interest while helping companies to become more aware of the quality of their dossiers and eventually giving an incentive for further improvements. It also benefits the SMEs as they can identify if their substance has already been registered or check information from their suppliers. The official launch of the new platform was, for promotion reasons, postponed to January 2016.

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

2015 was a second year of implementation of 'The EU Roadmap for SVHC identification and implementation of REACH risk management measures to 2020' which resulted in further development of the common screening approach, integrating all processes, defining screening scenarios and focusing on the substances that matter the most for human health and environment safety. An increasing number of Member States participated in the manual screening that followed the IT screening.

The Member States Competent Authorities continued to evaluate substances listed on the updated Community Rolling Action Plan. As a result further information was proposed to be requested for 39 substances while conclusions were reached for 11 substances, of which majority showed no further concern. ECHA supported the evaluating Member States by providing consistency screening and assisting in finalisation of the draft decisions. To improve the substance evaluation process, ECHA launched a review which identified several areas for improvement. This was further strengthened by the feedback received from the first decisions of the Board of Appeal on the process and substance evaluation decisions. The proportion of substance evaluation decisions which have been appealed remained relatively high (over 20%).

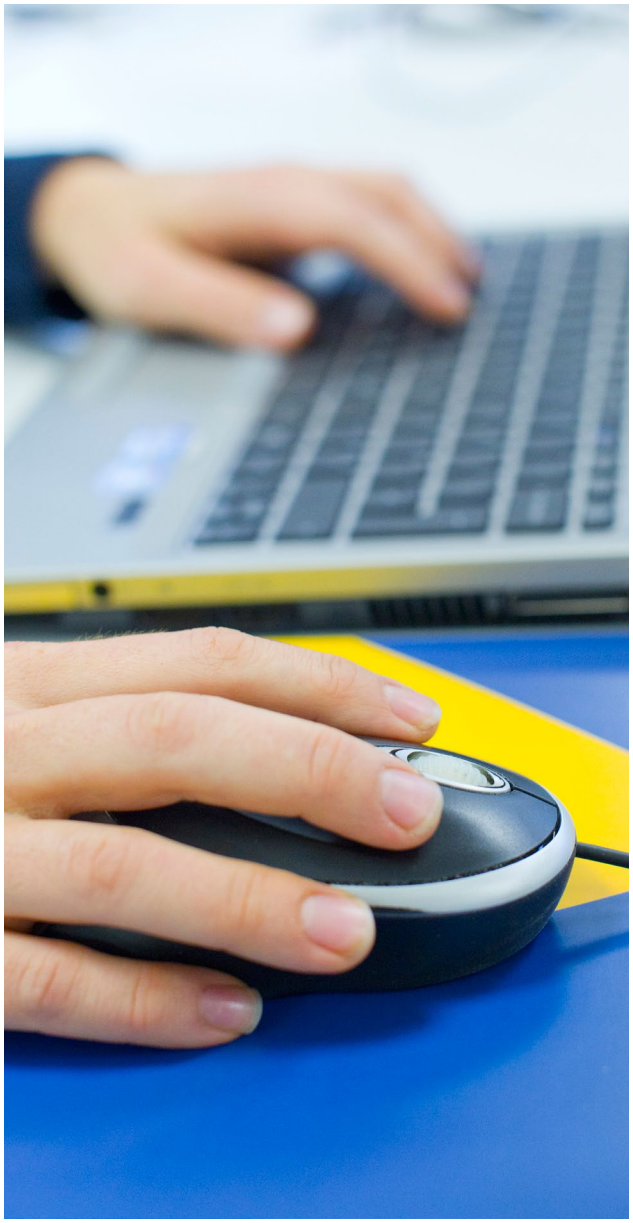
In terms of identifying substances of concern, 7 new SVHCs were added to the Candidate List in 2015 based on member states proposals and Commission's request. Although less than expected, it brings the total number of identified SVHCs to 168 by the end of 2015. Moreover, ECHA provided its sixth recommendation for inclusion of 15 more priority substances in the Authorisation List to the Commission and developed its draft seventh recommendation. As a direct result of the SVHC Roadmap implementation ECHA published on its website conclusions on 24 Risk Management option analyses, 21 of which identified a need for further regulatory action.

ECHA continued raising awareness on the authorisation requirements by means of pre-submission information sessions, publication of clear and well-structured examples of authorisation applications evaluated by RAC and SEAC and SME-friendly web guide to authorisation. Moreover, the application process was simplified to render it more fit-for-purpose. Also the Implementing Regulation establishing simplified rules for special cases advanced well and is awaiting the Commission adoption.

During the year, ECHA received 7 new applications for authorisation covering 13 different uses, while RAC and SEAC adopted 25 opinions on applications

submitted mostly in 2014. In addition, ECHA's Committees adopted opinions on restriction reports submitted by Member States (ammonium salts, cadmium in artists paints, perfluorooctanoic acid and its salts, Bisphenol-A) and by ECHA (Asbestos and Decabromodiphenylether).

Finally, RAC adopted 38 opinions on harmonised classification and labelling proposals on substances in consumer products, in wide industrial uses and several plant protection and biocidal products, reaching the milestone of 200 such opinions since it started its work.



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

In 2015 ECHA continued implementing the Science Strategy defined in 2014. This was achieved through its contributions to the OECD Test Guidelines and Guidance Documents on the priority endpoint areas of skin sensitisation, genotoxicity, endocrine disrupters and aquatic and terrestrial ecotoxicity. Furthermore ECHA co-organised a Topical Scientific Workshop on Soil Risk Assessment and designed training programmes to strengthen the competences in the relevant priority areas.

ECHA promoted a dialogue between authorities and researchers on scientific issues, especially to promote alternatives to animal testing. Further scientific advice was provided to authorities and registrants through publishing the Read-Across Assessment Framework on how to build and assess read-across justifications for human health information requirements.

Significant work has also been dedicated to 'nanomaterials', with ECHA continuous chairmanship of the OECD steering group for testing and assessment under the Working Party on Manufactured Nanomaterials and especially with the view to an expected, although postponed, revision of REACH Annexes to explicitly include the 'nanoforms' of substances.

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

Throughout the year ECHA paid special attention to the ways its work is organised to further strengthen the effectiveness and efficiency of the REACH and CLP processes. Furthermore ECHA continued to strengthen its processes through the integrated regulatory strategy which shall overall increase effectiveness and coherence of all operations ECHA and its partners have at their disposal to ensure improved dossier compliance and safe use

of substances. A number of initiatives including a wide-scope efficiency programme and introduction of change management to work leaner helped the Agency to mitigate the regulatory staff reductions. The achievement of the Work Programme targets was to a large degree possible thanks to the smooth functioning or upgrading of many of the administrative and scientific IT workflow systems.

In preparation for an expected peak in workload on authorisation applications, the Management Board concurred with the Secretariat on the need to encourage the nomination of more regular committee members and nine co-opted members were consequently appointed to the two committees (RAC and SEAC).

Despite the significant financial and human resources constraints under Biocides Regulation ECHA managed to meet and exceed its targets for the Biocides, keep the Registry for Biocidal Products (R4BP 3) up-to-date and hold a workshop with the national authorities to review the active substance approval process and explore possible ways of increasing further its effectiveness and efficiency.

In 2015 ECHA achieved also a cruising speed in handling PIC notifications, which increased by 19% compared to 2014. ECHA managed to effectively co-ordinate gathering of information for the yearly report on realised imports and exports.

REACH 2018

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