ECHA
EUROPEAN CHEMICALS AGENCY

# Executive summary of the General Report 2017

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**Executive Summary of the General Report 2017**

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## ECHA in numbers

**17687**
substances registered in our database

**181**
substances of very high concern on the candidate list

6.5 million classification and labelling notifications for **>135000** substances

**9000**
helpdesk replies to companies

**10030**
visits by external visitors

**510000**
visits to REACH 2018 web pages since October 2014

EUR **109**
million annual budget

# Executive summary

*In another dynamic year, ECHA closed out the fourth year of its Multi-Annual Work Programme and five-year time line for implementing its strategic objectives. While edging closer to the 31 May 2018 REACH registration deadline with significant preparatory work and support for smaller-volume chemical registrants, the Integrated Regulatory Strategy reached maturity and ECHA's Management Board selected a new Executive Director in its 10th year of operations.*

ECHA mapped out strategic directions geared towards meeting EU legal commitments (REACH, CLP, BPR, PIC) as well as international goals, including those agreed at the World Summit on Sustainable Development (WSSD) for 2020 and beyond. This provided the basis for the Agency to make progress towards defining its new strategic plan for 2019 to 2021.

Organisation-wide, the Agency made valuable progress at operational level, which led to tangible results in meeting ECHA's four overarching strategic objectives (see box).

Further improvements to the chemical registration process, ranging from better and simpler IT tools to clearer and stronger communication, helped more and more companies, especially small and medium-sized enterprises (SMEs), prepare for the REACH deadline.

Implementation of ECHA's integrated regulatory strategy progressed further and helped to focus efforts and resources on creating the best impact. The interlink between REACH processes together with a common screening exercise among Member States ensure that authorities identify and follow up on appropriate substances of possible concern. The Agency also improved and streamlined technical tools used for running its processes.

# Key achievements in 2017

## Operations

- Intensified support for operators ahead of the 2018 registration deadline; sufficient resources to handle the expected peak of 60000 submissions.
- Introduction of cloud services for the submission tool IUCLID, helping SME operators prepare dossiers online – no need to download software, better data security, and other benefits.
- Enhanced completeness check tool to improve data quality upfront.
- Progress in obtaining information on key chemical properties, including possible hazards and a higher level of compliance needed to demonstrate safe use – with more focus on groups of substances and collaboration with operators.
- More targeted advice to downstream users on safe use based on sector-use maps and generic exposure scenarios.
- Support to Member States allowing them to focus on substances potentially harmful to workers, consumers and the environment.
- Further promotion of substitution with the addition of seven new substances of very high concern (SVHCs) to the candidate list for authorisation, and priority recommendations to the European Commission.
- Opinions on restricting phthalates because of their effect on human fertility, and on lead in shots to reduce bird deaths in wetlands.
- 58 opinions concluded on applications for authorisation.
- Scientific opinion on the hazard classification of the herbicide glyphosate.
- First two opinions on Union authorisation of biocides, paving the way for access to the EU market.

## STRATEGIC OBJECTIVES

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

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

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

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

- Enhanced IT interfaces through which Member State competent authorities access ECHA data – better visibility on regulatory work carried out on a substance or group of substances.
- Greater automation in IT systems leading to higher levels of data integrity, standardisation, integration and accessibility.

## Governance

- Robust scientific opinions and greater efficiency of ECHA's scientific committee work.
- Improved safety data sheets as part of a concerted action for better enforcement between ECHA's Forum and accredited stakeholder organisations (ASOs).
- The Board of Appeal provided clarification on legal and regulatory questions concerning nanomaterials and the interplay between REACH and the Cosmetics Regulation, as well as the rights of downstream users.
- ECHA welcomed a new Executive Director and looked back at 10 years of work.
- The Agency concluded the project on finding new premises and signed the lease agreement ahead of a scheduled move in 2020.

# Meeting strategic objectives – results 2017

*ECHA defined its four strategic objectives in the Multi-Annual Work Programme (MAWP, 2014-2018) adopted by the Management Board on 26 September 2013. Each year, ECHA reports on progress made towards meeting these objectives. The results for 2017 are presented below.*

## Objective 1.
## Maximise the availability of high-quality data to enable the safe manufacture and use of chemicals

The Agency measures progress on the first strategic objective (SO1) with four indicators introduced in 2014. These indicators cover different parts of the registration dossier and diverse aspects of quality: shortcomings in substance identification; inconsistencies in the reported uses of substances registered as intermediate; the level of non-compliance with harmonised classification; and deficiencies identified in the data on physico-chemical, environmental, and human health hazards. These indicators are not a direct measure of information compliance per se, but are measurements of certain identified anomalies or inconsistencies in the data provided by REACH registrants, which are checked during automated screening. Each result expresses the percentage of dossiers successfully passing the screening.

Since the release in mid-2016 of a new generation of registration tools (IUCLID 6 and REACH-IT) and enhancement of the completeness check process, the quality of the registration information has improved in all new and updated dossiers. This has had a direct impact on the overall quality of the registration database since the calculation of the four indicators is partly based on the percentage of dossiers submitted as either new or updates.

**Overall quality** – level of consistency and meaningfulness in the submitted information

Compared to 2016, improvements were observed in the areas of substance identification (+6 %), hazard information (+6 %), use consistency with the intermediate status (+2 %) and +1 % of dossiers compliant with harmonised classification.

In terms of substance identification, 77 % of the nearly 62 500 dossiers passed the screening in 2017. The indicator on uses compatible with substances registered as intermediates is 94 % for all intermediate dossiers (-12 000). The hazard information indicator is up to 46 % for all lead and individual registration dossiers (-9 500), while the indicator on compliance with harmonised classification reached 97 %. These positive trends clearly show that the strategy for raising data quality, improving tools, processes and communication, and enhanced completeness checks are paying dividends.

## Objective 2.
## Mobilise authorities to use data intelligently in order to identify and address chemicals of concern

ECHA's SO2 calls for the intelligent use of REACH and classification, labelling and packaging (CLP) data to ensure that authorities are able to timely and efficiently address the substances of highest concern. To this end, ECHA implements common screening approaches for all REACH and CLP processes, including evaluation, to identify the substances and uses that matter the most and for which potentially regulatory action must be initiated. Ultimately, these processes should as well enable the identification of substances that have no or low priority for further regulatory action.

Around 69 % of the 101 substances (individual or part of a group) screened by Member States in 2017 were found to require further follow-up actions. Another 32 substances, divided over five groups, are still pending the outcome of the screening as they are part of collaborative approach pilot projects (COLLA). Since last year, the manual screening now covers groups of substances: around 77 % of them require further follow-up actions whereas only 60 % of the individual substances do. This seems to confirm the trend identified in the 2016 annual progress report on the SVHC Roadmap1 that it is becoming increasingly difficult to find single substances for further regulatory action and shows the benefit of moving towards addressing groups of related substances. The 22 Member States and European Economic Area (EEA) countries participating in manual screening in 2017 confirms their continued significant interest in this activity.

It is still too early to draw any conclusions on trends and effectiveness regarding substance evaluation as the process has not been completed for most substances. Since 2012, Member States have evaluated 221 substances and concluded 74 (30.4 %). In 43 % of the concluded cases, the evaluators identified a need for further regulatory risk management. This percentage is expected to increase in the coming years, since a higher proportion of the evaluation conclusions will be made once the requests for further information have been fulfilled. In terms of follow-up assessment, of the 221 substances evaluated, 35 % are waiting for the information to be submitted by the registrants, 7 % are undergoing an actual follow-up assessment of the data already submitted, and 1 % are at the stage of preparing the conclusion. The rest are in the decision-making phase.

Overall under substance evaluation, ECHA has requested information on 98 substances. Registrants appealed 18 of ECHA's decisions. Fewer Member States carried out substance evaluations in 2017 than in 2016 (down from 20 to 15) mainly due to the difficulty of including suitable substances on the Community rolling action plan (CoRAP) and the number of cases still pending.

As in 2016, 13 Member States submitted proposals for regulatory risk management measures under REACH or CLP.

Five Member States submitted proposals for regulatory risk management measures under REACH. The extent to which the risk management options analysis (RMOA) conclusions were followed up rose to 94%, in particular for SVHC identification or restrictions. Furthermore, four conclusions on the need to develop harmonised classification and labelling (CLH) proposals also indicate a positive trend. Finally, two of the three conclusions with no follow-up have been submitted as a RMOA, which may explain why the CLH proposal has not yet been submitted.

The trend confirms that most RMOA conclusions now receive a follow-up but Member States need sufficient time to turn their conclusions into proposals for regulatory risk management.

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

This objective aims to ensure that ECHA's regulatory work is based on the latest scientific knowledge. The activities focus on the implementation of ECHA's regulatory science strategy, on capacity building, and on working as a regulatory science hub.

Within the regulatory science strategy, the Agency introduced a new governance cycle to ensure that all scientific projects fall under one of the themes of interest and their outcomes add value to the regulatory processes. On socio-economic analysis, ECHA launched a collaborative research activity with the Organisation for Economic Co-operation and Development (OECD) on evaluating the human health impacts of chemical exposure.

The third statutory report on the use of alternatives to animal testing (Article 117(3) REACH) was published in June. In addition, ECHA undertook a study, requested by the Management Board, on the regulatory applicability of non-animal approaches under the EU chemicals legislation; the resulting report was published in November.

ECHA audited its competency mapping process – first applied in 2015 – in light of its 2017 audit findings and will review the process in 2018 in light of the audit findings. Annual training for inspectors was delivered to a group of national enforcement trainers (see section 'Forum' for details).

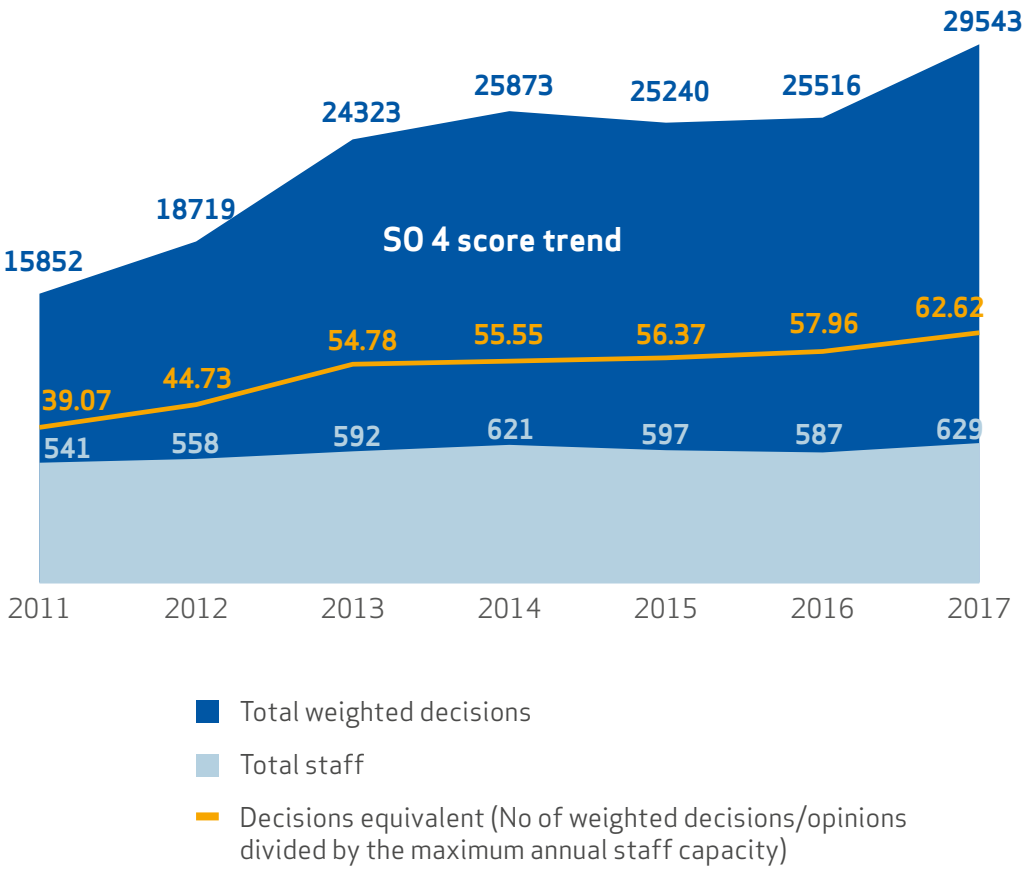
Since the publication of the second report on the operation of REACH and CLP (Article 117(2) REACH) in 2016, ECHA has integrated the commitments made in the report into its programming documents, so that progress can be monitored according to the usual annual cycle. The stakeholders surveyed in 2017 gave typically positive responses (at least 80% for each question) about ECHA's scientific and technical support for the processes in regulatory committees and working groups (WGs).

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

ECHA uses the 'Decisions and opinions equivalent' as a score for measuring its fourth strategic objective and corporate value on efficiency. This is based on multiple variables dividing the number of ECHA's total weighted decisions by the maximum annual staff capacity. In 2017, ECHA once again demonstrated it was able to produce more output with proportionally fewer resources, thereby indicating an increase in its overall efficiency.

Indeed, the Agency's output has grown faster than its staff resources over the years, which is a good indication of efficiency. The results for 2017 – the year before the major registration deadline in 2018 – show a similar pattern to those of 2012, one year before the first REACH registration deadline. In both 2012 and 2017, ECHA processed a significantly higher number of decisions compared to the total number of staff. With this result, the Agency demonstrates good planning and deployment of available and new resources in priority areas in which the temporary work peaks are concentrated.

FIGURE 1: Annual efficiency score – multi-annual trend



## METHOD FOR 'DECISIONS AND OPINIONS EQUIVALENT'

The total weighted decisions represent the number of decisions and opinions produced in a given year, considering the whole process until a decision/opinion is issued and weighted with the time required to process an average case. The maximum annual staff capacity includes both operational and supporting personnel as well as consultants and operational interim personnel present over the whole year. The correlation between the Agency's weighted output and the annual staff capacity gives an indication of an efficiency trend over the years, i.e. producing more/less weighted outputs with the same or proportionally fewer resources.

# Annual efficiency score in numbers

## Table 1: Annual efficiency score

| INDEX TREND | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|
| TOTAL WEIGHTED DECISIONS | 25 873 | 25 240 | 25 516 | 29 543 |
| **TOTAL STAFF** | **621** | **597** | **587** | **629** |
| Decisions equivalent (No. of weighted decisions/ opinions divided by the maximum annual staff capacity) | 55.6 | 56.4 | 57.9 | 62.6 |

## Table 2: Trends in efficiency score between 2014 and 2017

| % change | 2014 -> 2015 | 2015 -> 2016 | 2016 -> 2017 |
|---|---|---|---|
| % change in TOTAL WEIGHTED DECISIONS | -2 % | 1 % | 16 % |
| **% change in TOTAL STAFF** | **-4 %** | **-1.70 %** | **7.2 %** |
| % change in Decisions equivalent | 1.5 % | 2.8 % | 8.1 % |

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