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EUROPEAN CHEMICALS AGENCY

General Report 2017

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European Chemicals Agency

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List of acronyms

ACT	Activities coordination tool
AfA	Application for authorisation
ASO	Accredited stakeholder organisations
BoA	Board of Appeal
BP	Biocidal products
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
C&L	Classification and labelling
CA	Contract agent
CCH	Compliance check
Chesar	Chemical Safety Assessment and Reporting tool
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic or toxic to reproduction
CoRAP	Community rolling action plan
CSA	Chemical safety assessment
CSR	Chemical safety report
DCG	Directors' Contact Group
DNA	Designated national authority
eChemPortal	OECD Global Portal to Information on Chemical Substances
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
ED	Endocrine disruptor
EEA	European Economic Area
EFSA	European Food Safety Authority
ENES	ECHA-Stakeholder Exchange Network on Exposure Scenarios
ES	Exposure scenario
EU	European Union
EUON	European Union Observatory for Nanomaterials
EUSES	European Union System for the Evaluation of Substances
FAQs	Frequently asked questions
Forum	Forum for Exchange of Information on Enforcement
GES	Generic exposure scenarios
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HelpNet	ECHA Helpdesk and the national BPR, CLP and REACH helpdesks
HR	Human resources
IAS	Internal Audit Service of the Commission
ICT	Information and communication technology
IMS	Integrated management system
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated quality management system
IRS	Integrated regulatory strategy
ISO	International Organization for Standardization
IT	Information technology
IUCLID	International Uniform Chemical Information Database
JRC	European Commission's Joint Research Centre
MAWP	Multi-Annual Work Programme
MB	Management Board
MNI	Mandated national institution
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
NEA	National enforcement authorities
Odyssey	ECHA's tool to support evaluation tasks
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
OSOR	One substance, one registration
PBT/vPvB	(very) Persistent, bioaccumulative and toxic
PIC	Prior informed consent
PPORD	Product and process-oriented research and development
PPP	Plant protection products
(Q)SAR	(Quantitative) Structure-Activity Relationship
R4BP 3	Register for Biocidal Products
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
REF	REACH Enforcement Project
RIPE	REACH Information Portal for Enforcement
RMO	Risk management option
RMOA	Risk management options analysis
SCOEL	Scientific Committee on Occupational Exposure Limits
SEA	Socio-economic analysis
SEAC	Socio-Economic Analysis Committee
SID	Substance identity
SIEF	Substance information exchange form
SME	Small and medium-sized enterprise
SO	Strategic objective
SONC	Statement of non-compliance following a dossier evaluation decision
SPC	Summary of product characteristics
SVHC	Substance of very high concern
TA	Temporary agent
TCC	Technical completeness check
TP	Testing proposal
TPE	Testing proposal examination
UN	United Nations
UVCB	Unknown or variable composition, complex reaction products or biological materials
WP	Work Programme
WSSD	World Summit on Sustainable Development 2020

Foreword

For everyone at ECHA, 2017 was a year of many changes, but also one of continuity and consolidation. We celebrated our 10-year anniversary together with 100 years of Finland, our host state, and achieved a number of key actions on our agenda. It is fair to say that this year heralds a new era of operational maturity for our Agency.

We said goodbye to Geert Dancet, ECHA's first Executive Director, whose experience, drive and enthusiasm built an organisation operating at a high level in the way we run our processes, ensure solid outcomes, collaborate with our partners and engage with our stakeholders.

Thanks to his insights and the hard work of the founding team, ECHA is meeting its pledge to protect human health and the environment from the adverse effects of chemicals, while enhancing European competitiveness and innovation in the sector.

A major part of 2017 was spent preparing staff and services for the rapidly approaching deadline, on 31 May 2018, requiring companies manufacturing or importing chemicals above one tonne per year to register under REACH. In particular, we had small and medium-sized companies in mind when paving the way for this final registration deadline.

> *"Courage, efficiency, agility and creativity in the way we serve our customers will overcome the challenges and drive positive change in 2018, and beyond.*

Our efforts over the past few years to create an Integrated Regulatory Strategy reached a critical phase in 2017. The strategy allows us to focus on substances that matter most for ensuring safe use and thereby using our resources in a targeted and efficient way. At the same time, we worked intensively to prepare ECHA for its future strategic challenges, in consultation with our Management Board and stakeholders.

The path for us is clear: to follow the United Nation's Agenda for Sustainable Development. On our way to meeting Europe's contribution to these ambitious global sustainable development goals, we know where the challenges are and what is needed to implement our own objectives. Courage, efficiency, agility and creativity in the way we serve our customers will overcome the challenges and drive positive change in 2018 and beyond.

Thanks again to Geert and the whole team at ECHA for a very productive 2017 … and a truly memorable decade.

Jukka Malm
Deputy Executive Director

ECHA's legal mandate

The European Chemicals Agency (ECHA) is a European Union (EU) body established on 1 June 2007 by Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the 'Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)'.

ECHA was established for the purposes of managing and, in some cases, carrying out the technical, scientific and administrative aspects of the REACH Regulation and to ensure consistency at EU level. It was also established to manage tasks related to the classification and labelling of chemical substances which, since 2009, have been governed by the Regulation on 'Classification, Labelling and Packaging of substances and mixtures' (CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council).

In 2012, ECHA's mandate was expanded by Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products – the 'Biocidal Products Regulation' (BPR).

The recast of the Prior Informed Consent (PIC) Regulation (Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals) also entered into force in 2012. In 2014, certain tasks related to PIC were transferred from the European Commission's Joint Research Centre (JRC) to ECHA.

These legislative acts are applicable in all EU Member States (MSs) without the need for transposition into national law.

ECHA's mission, vision and values

ECHA's mission[1]

ECHA is the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness.
ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

ECHA's vision

ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.

ECHA's values

Transparent

We actively involve our regulatory partners and stakeholders in our activities and are transparent in our decision-making. We are easy to understand and to approach.

Independent

We are independent from all external interests and impartial in our decision-making. We consult members of the public openly before taking many of our decisions.

Trustworthy

Our decisions are science based and consistent. Accountability and the security of confidential information are cornerstones of all our actions.

Efficient

We are goal-oriented, committed and we always seek to use resources wisely. We apply high-quality standards and respect deadlines.

Committed to well-being

We stimulate the safe and sustainable use of chemicals to improve the quality of human life in Europe and to protect and improve the quality of the environment.

1 ECHA's mission, vision and values will be reviewed during the 1st half of 2018.

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
website visitors

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).

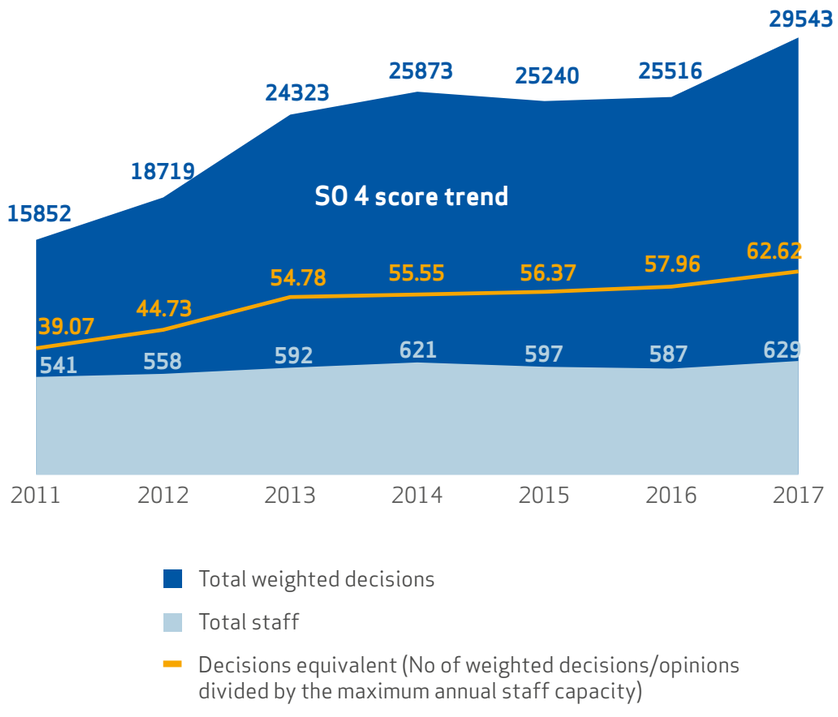
Since the publication of the second report on the operation of REACH and CLP (Article 117(2) REACH) in 2016, ECHA has integrated the commitments made in the report into its programming documents, so that progress can be monitored according to the usual annual cycle. The stakeholders surveyed in 2017 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 %

OPERATIONS

REACH dossier management and assessment

ECHA provides assistance and tools to companies for elaborating and submitting their registration dossiers through its helpdesk, guidance and communication activities. The Agency processes the dossiers and assigns registration numbers so that companies can manufacture, import or place their substances on the European market.

ECHA evaluates substance identity, hazard, use and exposure information as well as testing proposals (TPs) submitted by companies to improve the safety information and thereby risk management of chemicals, and to support the identification of candidates for regulatory risk management measures. The Member States evaluate substances to clarify whether a given substance may pose a risk to either human health or the environment.

Enforcement of the REACH Regulation is the responsibility of EU Member States. However, the Forum for Exchange of Information on Enforcement (the Forum) provides a network of Member State authorities responsible for enforcement with the aim of harmonising their approach to enforcing the REACH registration and evaluation provisions.

Year in numbers

510000
visits to REACH 2018 web pages since October 2014

3700
new subscribers to the IUCLID and Chesar websites

7914
helpdesk questions answered

64
data-sharing disputes handled

2170
inquiries concluded

Registration dossier preparation

Hurdles lowered for SMEs

SMEs can now prepare their registration dossiers directly online as ECHA provides IUCLID, the dossier preparation software, as a cloud service. The IUCLID Cloud relieves companies of the IT burden, as ECHA manages this aspect for them, including software installation, updates, data storage and back-ups.

As for fulfilling the information requirements of REACH, registrants need to improve their justifications when using alternatives to animal testing, reveals ECHA's report. Furthermore, scientists and regulators need to continue the work on non-animal methods for long-term effects. These methods are not yet scientifically solid enough to be used for regulatory purposes.

Main achievements

SMEs can now benefit from the International Uniform Chemical Information Database (IUCLID) – ECHA's IT tool for preparing registration dossiers – which is delivered as a cloud service. IUCLID Cloud helps SMEs to comply efficiently with their REACH obligations. Often, smaller companies cannot afford dedicated IT support to install and maintain IUCLID software and migrate data between versions. In addition to relieving companies of the need for IT support, IUCLID Cloud has many functionalities that guide them through dossier preparation. Furthermore, help texts on IUCLID functionalities will be available in 23 languages from early 2018.

As regards dossier preparation, less-experienced registrants will also benefit from new features added to the OECD (Q)SAR Toolbox in 2017. Completely automated predictions and standardised workflows, which include human decisions at predefined steps, simplify the correct use of the tool. Only potentially meaningful predictions are displayed to the user.

For those registrants who need to prepare a chemical safety report, Chesar – ECHA's tool for chemical safety assessment and reporting – now fully supports industry sectors that have generated use maps. The tool's usability has also been improved in many ways. Registrants are increasingly using Chesar: half of the chemical safety assessments in incoming registrations have been done with this tool.

IUCLID CLOUD – SIMPLER FOR SMALL COMPANIES

By using IUCLID Cloud, companies no longer have to install IUCLID – and its regular updates – locally on their computers. Rather, they have direct access to an online version in their web browser, any time, anywhere and at no charge. Those companies already using IUCLID can export their data from their local version to the online service.

The benefits of IUCLID Cloud:

- Work in a secure environment – an independent audit found ECHA's security management solid;
- Data are stored and backed up by ECHA
- Existing data are automatically transferred to match the requirements of the new system
- Work anywhere, at any time, as the service is available 24/7
- Collaborate and share files with colleagues or consultants to whom they have granted access without error-prone manual work
- Fewer resources to manage the installations and hardware to host and update IUCLID

The latest version of IUCLID Cloud, published in December 2017, contains a step-by-step guide for preparing a full REACH 2018 registration dossier from scratch. In addition, it contains the following useful online features:

- A validation assistant to check the completeness of the dossier and help solve certain inconsistencies
- View of what information from the registration will be published on ECHA's website
- Automatic generation of the chemical safety report
- Direct connection to REACH-IT to complete the submission to ECHA without a need to switch between IT systems
- Access to specific help texts for each task, available in 23 EU languages

Market study of SMEs

In order to make IUCLID Cloud as widely known as possible to SMEs, ECHA commissioned a market segmentation study of 2018 SME registrants [2]. The study gathered insights on the SME market structure and collected information on the SMEs' intentions to register by the last registration deadline on 31 May 2018. Besides possible IT difficulties, other issues that smaller companies face in the registration process were also analysed.

Alarmingly, the study's key finding was that a sizeable number of SMEs struggle with the high costs of registration, in particular, the costs for purchasing letters of access to the data and participating in the substance information exchange forums (SIEFs). As a result, a proportion of companies stated they were rationalising their substance portfolios and finding alternative solutions. For example, companies reported that they have reconsidered keeping their production and import volumes below the threshold of one tonne per year which triggers registration obligations.

This prompted ECHA to bring the issue of cost hurdles for SMEs to the attention of the Directors' Contact Group (DCG) [3]. This high-level group was set up in 2010 to monitor the progress of registration and find solutions to practical obstacles that companies may face during the process. The DCG issued a recommendation in December to allow companies registering small-volume substances and SME registrants which have not previously registered substances to access data and make joint submissions with a reasonable amount of effort.

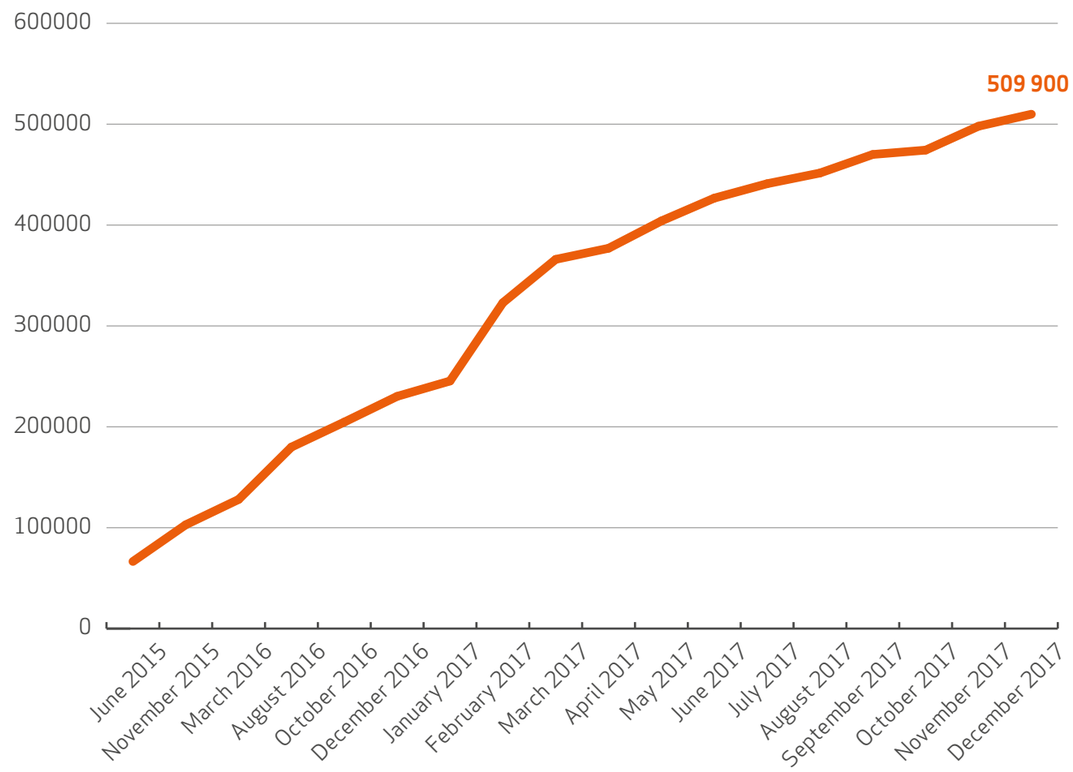
2 https://echa.europa.eu/documents/10162/22931011/sme_segmentation_study_report_en/

3 The DCG comprises representatives from two European Commission Directorates-General (Environment; Internal Market, Industry, Entrepreneurship and SMEs), ECHA, Cefic, Eurométaux, REACH Alliance, CONCAWE, FECC and UEAPME; and representatives of Orgalime (also representing the interests of ASD, ACEA and EuroCommerce) and DUCC (representing the interests of Downstream Users), along with a representative of the CheMI Platform. ECHA's Executive Director chairs the group.

Concrete advice for SMEs

The last registration deadline will concern many companies that have not yet prepared any registrations. To make the work related to the REACH registration process more concrete for these inexperienced registrants, a new section devoted to practical examples was added to ECHA's REACH 2018 web pages. It includes, for example, templates for planning the registration project and for conducting data-sharing negotiations. It also presents case studies on information gathering for different types of substances. ECHA's online information on REACH 2018, launched in autumn 2014, remains a recognised source of user-friendly support for SMEs, and reached the milestone of half a million unique visits by the end of 2017 (see figure 2).

FIGURE 2: Cumulative online visits to REACH 2018 web pages



Companies were also actively informed of the support material to make sure that no diligent company missed the deadline. ECHA reached out to the potential registrants via multilingual social media campaigns and targeted emails. Furthermore, national customs authorities were identified as important multipliers for REACH 2018 messages. They were invited to join the awareness-raising efforts to reach out to the many importers which may have registration obligations. ECHA's REACH 2018 Communicators' Network and its stakeholders enhanced awareness-raising at the national level, and the European Commission invited all EU delegations to remind their stakeholders of the deadline.

End of pre-registration period

In REACH, pre-registration was designed to put registrants of the same substance into contact with each other for data-sharing purposes. If companies pre-registered their substances, they could also benefit from the transitional scheme for registration. Since 1 June 2017, this option is no longer available. This means, in practice, that companies planning to manufacture or import existing substances – called phase-in substances under REACH – have to register the substances before they can start manufacturing or importing them.

Before registration, companies need to ask ECHA if there are already registrants for their substance. ECHA saw a significant increase in the number of inquiries in the second half of 2017; most were for substances subject to registration by the last registration deadline. The number of data-sharing disputes lodged with ECHA also increased, mainly as a result of companies no longer having the pre-registration option.

Another regulatory change put pressure on ECHA's data-sharing activities. Since the entry into force in January 2016 of the Commission Implementing Regulation on joint submission of data and data-sharing, it has been technically impossible to breach REACH's 'one substance, one registration' principle. At ECHA, this resulted in more data-sharing disputes, as companies could not circumvent their data-sharing obligations by submitting their dossiers outside of a joint registration.

Alternatives to animal testing

Registrants can benefit from two reports on the use of non-animal methods in fulfilling REACH information requirements. ECHA published a report on the use of alternatives to animal testing for the REACH Regulation[4] – the third of its kind – and an analysis of the current status of regulatory applicability of non-animal approaches under REACH, CLP and BPR[5]. Together, the two documents paint a clear picture of the current use of non-animal methods in the context of the EU's chemicals management scheme. More importantly, they also suggest actions that both companies and authorities should take to make further progress. It is evident from the analysis that while alternatives to animal testing are widely used in registrations (see figure 3), the argumentation and supporting evidence can and should be improved. All justifications must be solid from both the scientific and regulatory perspective.

Paradoxically, alternatives to animal testing are most widely used for long-term effects on human health and the environment, while the current stance is that they are most suitable for acute and local effects. The reports also reveal that more scientific development is needed to make alternatives to animal testing a valid choice for long-term effects, too.

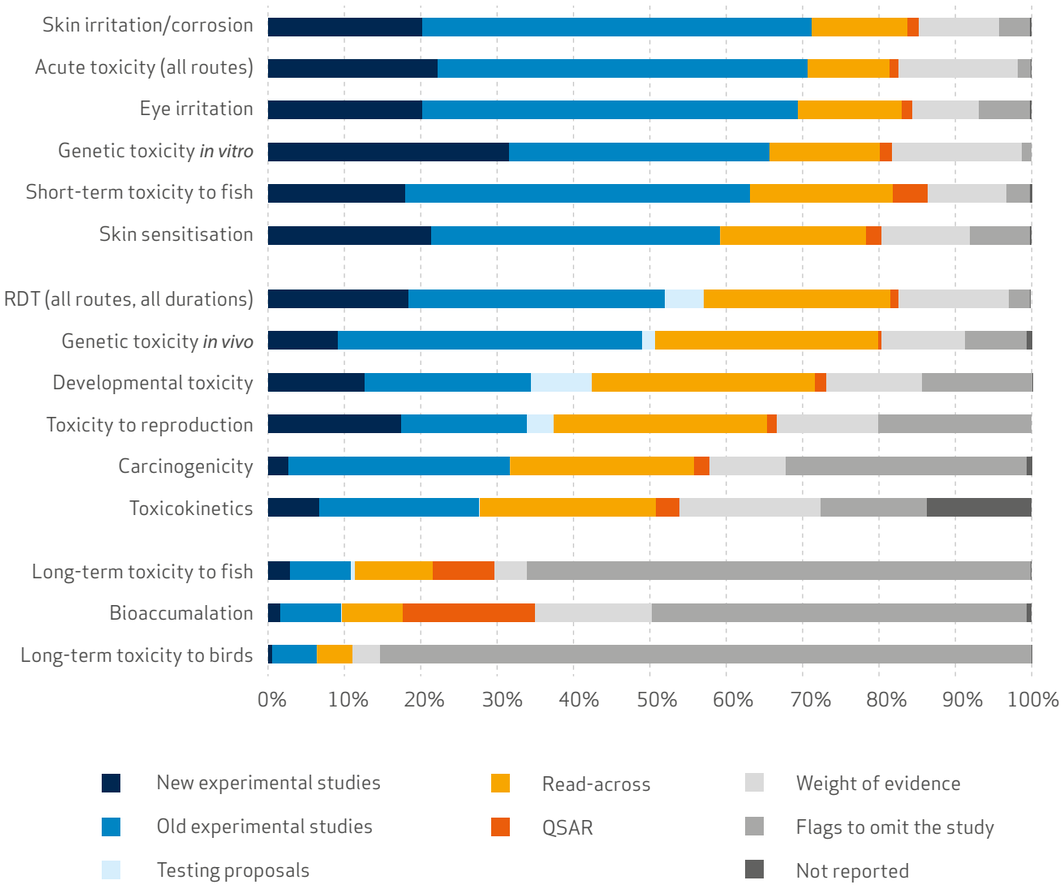
To this end, ECHA continued its cooperation with its regulatory peers in the area on new approach methodologies[6]. While this work is a long-term initiative, it is already feeding into ECHA's prioritisation of chemicals that matter. A key enabler for international cooperation in new approach methodologies is the use of common data-exchange formats. For this reason, regulatory authorities all over the world are increasing using IUCLID to store their data and share them with other authorities. In 2017, this happened in Canada and Australia, while Turkey also incorporated IUCLID as the format in which the dossiers for their new chemical regulation must be submitted. Besides enhanced data exchange between authorities, greater use of IUCLID worldwide will also bring efficiencies to companies that have already prepared dossiers for REACH, as they will be able to reuse the information for other jurisdictions.

4 https://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2017_en.pdf

5 https://echa.europa.eu/documents/10162/22931011/ non_animal_approcches_en.pdf

6 Broadly speaking, new approach methodologies include in-silico approaches, in-chemico and in-vitro assays, as well as the inclusion of information on the exposure of chemicals in the context of hazard assessment. They also include a variety of new testing tools, such as 'high-throughput screening' and 'high-content methods' – e.g. genomics, proteomics, metabolomics – as well as some 'conventional' methods that aim to enhance understanding of toxic effects, either by improving toxicokinetic or toxicodynamic knowledge of substances

FIGURE 3: Relative proportions of the options used by registrants to cover REACH information requirements



THE DCG RECOMMENDATIONS FOR 2018 REGISTRANTS

The cost of data remains the biggest registration hurdle for SMEs. To alleviate this, the Directors' Contact Group made a recommendation on actions to ease the cost burden for these companies, which includes four actions that should help SMEs join existing registrations.

First, registrants for the lowest tonnage band (1-10 tonnes/year) should explore whether they could benefit from an option to only submit physico-chemical information. This option is possible if their substance is a low-hazard, low-risk substance, as defined in Annex III of REACH, and should lead to reduced or no cost for the data.

Secondly, companies facing unresolvable difficulties in sharing data can lodge a data-sharing dispute with ECHA, which can also be done very close to the deadline. ECHA made a commitment to develop a process whereby the parties in dispute can submit their registrations despite an ongoing dispute, and the registration status of each party will be resolved once the outcome of the dispute is known.

Thirdly, the DCG suggested that lead registrants and SIEF managers should consider reducing the cost burden on SMEs by allowing payments for the letter of access to be made in instalments. Finally, DCG recommended that co-registrants could consider offering a low-cost affordable lump sum payment option for registrants for the 1-10 tonne band.

DCG also prompted registrants to be transparent when announcing their registration intentions to their customers in order to avoid abrupt breaks in the availability of critical substances in their supply chains. The effects of the DCG's actions will be analysed in detail once the outcome of the registration deadline of 31 May 2018 is made available.

Year in numbers

-15900
registration dossiers received (55 % new and 45 % updates)

2042
substances registered for the first time

76
companies made their first-ever registration

269
PPORD notifications

Registration and dossier submission

Ready for the last registration deadline

ECHA is ready to receive the peak number of submissions expected ahead of the last registration deadline. Many companies seem to have left it to the last minute to complete their joint submission negotiations and submit their registrations for the lowest tonnage bands, so the peak is likely to be a sharp one.

The enhanced completeness check process has stabilised and proved its worth. While almost one in ten registrations were initially considered incomplete by ECHA, the vast majority of these dossiers were updated and completed following ECHA's advice.

Around two-thirds of the registrations received since 2008 have never been updated. ECHA has identified the reasons for this, and authorities are now considering incentives for companies to see the registration dossier as a living document.

Main achievements

It is expected that up to 60 000 registration dossiers will be submitted for the last registration deadline of existing (phase-in) substances by May 2018. This concerns companies that manufacture substances between 1-10 or 10-100 tonnes/year. In 2017, ECHA made sure it was ready to receive such a high peak of submissions during spring 2018, and able to grant them a registration number within the deadlines and conditions set by REACH. The Agency also secured adequate staff to help companies with their submissions, as it expected a large proportion of registrants would be inexperienced with the registration process.

Staff typically handle around 10000 registration dossiers a year, which meant the workforce had to be increased significantly for the 2018 peak – the manual verification of dossier completeness is particularly labour intensive. The high number of dossiers also results in a greater workload for customer support and handling data-sharing disputes. Thus, recruitment and training of interim staff was one of the main activities during 2017. The internal preparations included extensive modelling of the dossier flux and arranging facilities for the growing workforce. Up to 110 external staff members will join ECHA to process registration dossier-related tasks and to give companies support.

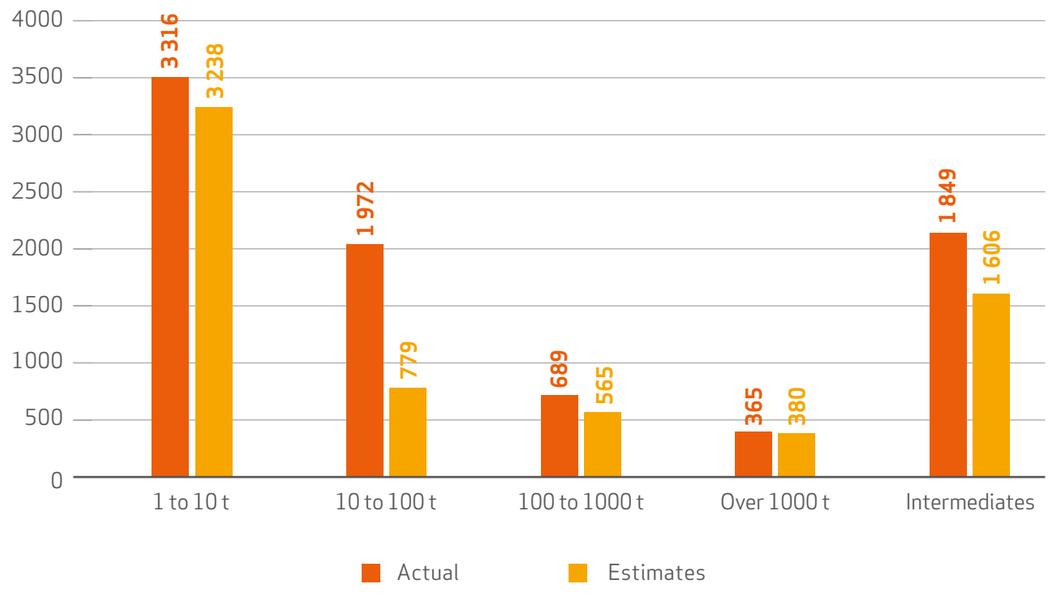
Most of the registration activities related to phase-in substances. In 2017, companies dealing with substances both in the lowest tonnage band of 1-10 tonnes per year and in quantities over 10 tonnes a year submitted more registrations than expected. However, these registrations mainly concerned substances that had already been registered. In total, only 1 813 phase-in substances not previously registered were registered in 2017, of which 871 were intermediates. Figure 4 shows the number of submissions received in 2017.

The share of registrations from SMEs remained low compared to the expected 40%, indicating that SMEs are leaving their registration decisions and preparations to the last minute. ECHA noted that this requires specific attention and has prompted suppliers to be open about their registration intentions and users of chemicals to be open about their requirements for certain substances to be available in the EU. ECHA has also repeatedly invited industry associations to identify their members' critical substances so that it can monitor their registration status. As a last resort, companies using chemicals may need to prepare for potential changes. For example, they can become importers if no registration has taken place or adjust their portfolios to the market situation after the deadline.

"Concrete support for SME registrants in the form of practical examples, templates, IUCLID Cloud and the DCG recommendations were in our focus this year.

Christel Musset, Director of Registration

FIGURE 4: Tonnages of 2017 initial phase-in submissions received (actual vs. estimate)



Enhanced completeness checks, including manual verifications at the time of submission, proved effective during the year. Companies managed to follow ECHA's advice and complete their registrations in the second and final round (see box).

Dossier type	Actual 2016	Actual 2017	WP 2017 estimates
Registrations	10660	15885	13000
Full registrations	8805	12868	-
Transported isolated intermediates	1352	2209	-
On-site isolated intermediates	503	808	-
Other type of dossiers			
PPORD notifications	203	269	300
Inquiries received	1218	2237	1700

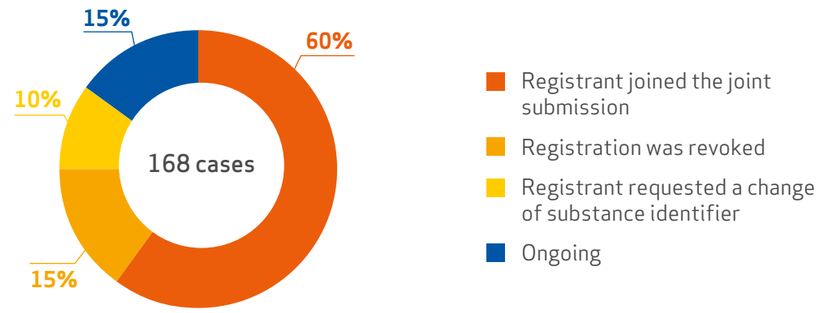
In 2017, ECHA published an enhanced version of the submission and communication tool, REACH-IT. It included online submission of substances in articles notifications and downstream user reports. This is an improvement towards giving companies one single point for submitting all their REACH dossiers. Furthermore, companies were given an increased visibility on the joint submission members. This feature has been requested by industry, as it helps to prevent the misuse of the token to the joint submission. Most new features were designed for ECHA to ensure its readiness for the deadline.

ECHA also continued its effort to level the playing field for companies. Specifically, the Agency addressed all situations where there were multiple registrations for the same substance. In practice, companies were put together to negotiate data – and cost-sharing issues with a view to merging all registrations under a single joint submission – a legal requirement of REACH. If, during the process, data sharing issues between the companies emerged, ECHA advised companies to raise a data sharing dispute with the Agency. In some cases, it turned out that registrants had used the wrong identifiers for their substances. If needed, ECHA could correct the identifiers.

CO-REGISTRANTS ON THE SAME PAGE

To minimise animal testing and reduce the cost of registration, REACH has a 'one-substance, one-registration' rule. Under this arrangement, co-registrants share their data, compensate data owners for their work, and submit information on hazards in a joint registration. In 2017, ECHA redoubled its efforts to retrospectively tackle cases where the one-for-one rule had not been respected.

FIGURE 5: Outcomes of requests to form a joint submission



For 147 substances, ECHA requested that one joint registration be formed. For 119 substances, there were individual registrations outside the joint registration; these involved a total of 169 registrants. For 28 substances, multiple joint submissions in place needed to be merged, involving 502 registrants. The latter action was initiated towards the end of the year, and the results will be available in 2018.

The biggest case related to charcoal and involved 118 registrants who had to join the existing joint registration. By the end of 2017, around 80 % of these companies had joined the joint submission, half of them even managing to complete their registrations. ECHA's SME Ambassador started to facilitate the discussions on data sharing for the remaining companies.

ENHANCED COMPLETENESS CHECK INCREASES DATA AVAILABILITY

To improve data availability in the registration dossiers, ECHA enhanced the completeness check process in 2016 by revising the automated checks and adding manual verification of certain information. Around a third of all dossiers were being picked up for a manual check after automated screening (see below), and of these around one in five were found to be incomplete after scrutiny. This meant that in total around 7 % of first-round submissions were found to be incomplete.

Type of information requested for dossiers that failed manual verification

	Dossiers checked	Dossiers failing manual TCC
Justification for data waiving	2690	425
Substance identity	2182	589
Testing proposals	523	85
Chemical safety reports	48	39

ECHA analysed the impact of the enhanced completeness check in 2017. The main findings were:

- Revision of the automatic completeness check means that more data is available at an earlier stage – 97 % of the dossiers in the database have the required information in the correct location. But improvement is still needed, especially in the identification of UVCB substances and the reporting of use description.
- Further quality analysis was performed on a sample of dossiers. In the majority of cases, the dossiers were significantly improved thanks to manual verification of substance identity information and cases where registrants had waived the standard information requirements. This increased the efficiency of subsequent regulatory processes.
- Following ECHA's instructions and indications of what data was missing, 95 % of incomplete registrations were successfully updated within the time specified.

ECHA monitors the reasons for incompleteness closely, and if any systematic errors are detected, advice for registrants is published on the ECHA website.

Finally, to improve the status of co-registrants in SIEFs where one company had unilaterally declared itself a lead registrant, ECHA put in place a process whereby companies could inform the Agency of such a situation. By the end of 2017, in eight cases, ECHA transferred the lead role in REACH-IT to a company working in agreement with the assenting co-registrants, based on the evidence provided by the SIEF. Although the number of actual cases is relatively low, it addresses feedback that operators have provided to ECHA. Having this process in place emphasises to the SIEFs the legal obligation lead registrants have to act with the agreement and consent of their co-registrants and provides a remedy for SIEFs where this may not be the case.

ECHA also continued to assess requests for confidentiality on certain parts of the registration dossiers. Altogether, 270 decisions were taken during 2017 (20 % of which rejected the request, leading to information being published on the ECHA website).

COMPANIES NEED INCENTIVES TO UPDATE THEIR REGISTRATIONS

Since the entry into force of REACH, around two-thirds of the registration dossiers have not been updated. This is a concern as registration dossiers are supposed to be living documents capturing increased knowledge on the substance, the volumes manufactured or imported by the registrant, and various uses in the supply chain. REACH requires companies to update their registrations on their own initiative should they become aware of new information on the substance. Dossier updates can also be prompted by authorities, for example in the evaluation process.

Wanting to know more about company challenges and incentives to update REACH and CLP dossiers, ECHA commissioned a study on the topic[7]. There are several issues affect companies' updating behaviour. First, many companies have the wrong perception that submitting the registration is the end of the process and no additional work is needed afterwards. Secondly, the obligations are not well understood: it is unclear what needs to be updated, when and by whom. Finally, limited resources, especially for SMEs, affect the approach to registration dossier updates.

The report proposed improvements and incentives structured around four steps addressed to ECHA, trade associations and policymakers:

1. Clear definition of what needs to be updated.
2. Clear definition of who is responsible for the updates – clarifying the roles of the lead and co-registrants.
3. Better understanding of why updates are important – i.e. they have an impact on protecting human health and the environment.
4. Implementing Act to clarify the update requirement of Article 22 of REACH, including well-defined circumstances and fixed intervals when dossiers need to be updated.

ECHA plans to take up the results when it designs the material for the remaining phase 7 ('Keep your dossier up to date') of its REACH 2018 Roadmap. ECHA also sent the report to the European Commission for its consideration under the REACH review.

7 Study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers, July 2017: https://echa.europa.eu/-/study-finds-companies-lack-incentives-for-updating-their-reach-registrations

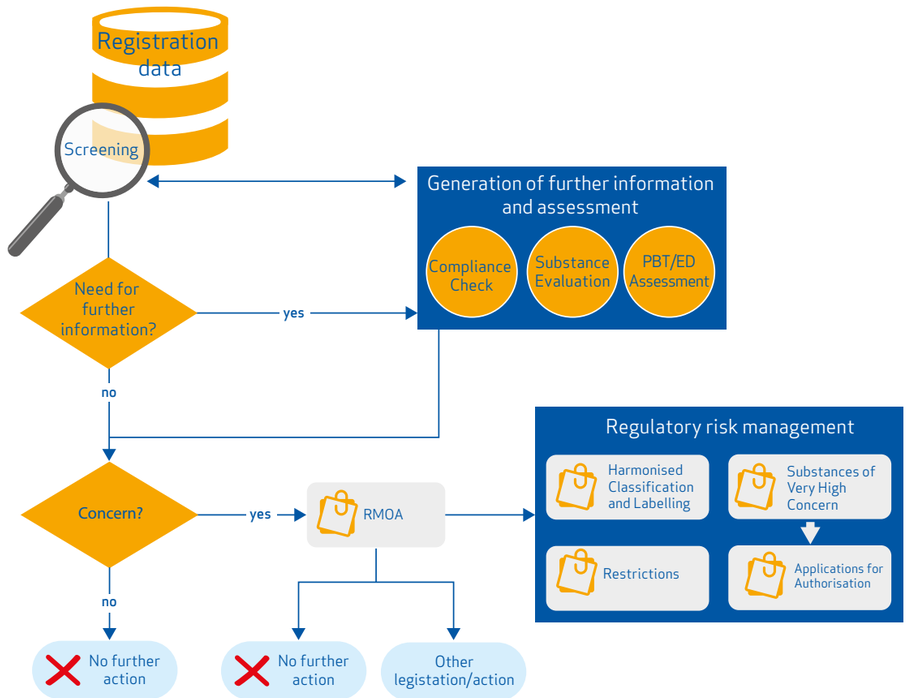
INTEGRATED REGULATORY STRATEGY FOR REACH AND CLP PROCESSES

Learning from its previous experience of trying to implement REACH and CLP regulatory processes separately, ECHA decided to develop an Integrated Regulatory Strategy (IRS). The IRS brings all the processes together to achieve these regulations' aims, as well as contributing to meeting the 2020 goals of the World Summit on Sustainable Development.

Today, the IRS is an inherent part of most REACH and CLP processes. REACH registrations provide the basis for all activities. Several activities address the quality of dossiers before submission, at the completeness check phase, and after a submission has been approved.

Together with the Member States, ECHA developed a common screening process which identifies substances with the greatest potential for adverse impacts on human health and the environment. This screening enables a conclusion to be reached on which substances need a further compliance check (CCH) and/or substance evaluation, and which substances can be directly earmarked for EU-level risk management measures.

Under the CCH process, priority is given to full registrations of chemicals produced in volumes of over 100 tonnes per year, and with potential concern that may require substance evaluation or risk management measures. The main focus is on the higher tier (Annex IX and X) human health and environment endpoints which are relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic) and PBT/vPvB ((very) persistent, bioaccumulative and toxic) substances.



If the evaluation confirms the concern, a risk management option analysis (RMOA) process usually follows to check which risk management process is the most suitable. The generation of new information can also lead to the conclusion that a substance is currently of no, or low, concern.

Universe of substances

ECHA's ambition is, by 2020, to have mapped the 'universe of registered substances' above 100 tonnes through a number of actions. These actions help to reduce the pool of substances of potential concern and conclude, for as many as possible, whether specific action is required or that they are currently of low priority.

The work is carried out in collaboration with industry sectors, and companies can proactively contribute by updating their dossiers when informed of the results of the common screening and providing better use and exposure information. This level of coordination is also instrumental in making sure that all relevant currently known substances of very high concern (SVHC) are on the candidate list by 2020, with the best risk management options identified (as provided by the SVHC Roadmap).

The IRS works towards three main goals:

1. Provide confidence amongst stakeholders and the public that registrants meet REACH information requirements, followed up by improved communication on safe use in the supply chain.
2. Efficiently select substances that raise potential concern, generating the necessary information for assessing their safety through a CCH or other means so that any remaining concerns can be addressed through the most suitable regulatory risk management instrument.
3. Ensure appropriate and timely intervention from all actors (ECHA, Member States, industry and the European Commission) within the different REACH and CLP processes so that chemicals of concern are addressed as soon as possible through the regulatory risk management measures.

Year in numbers

222
new compliance checks concluded

72
testing proposals examined

327
follow-up evaluations concluded

39
new substance evaluations performed

56
substance evaluations finalised

Evaluation

Piloting evaluation of groups of substances

Year 2017 saw good progress in closing many of the identified data gaps while the missing key information on high-volume priority substances continued to be requested through compliance check decisions.

In addition, a few pilots were launched in 2017 to address dossier non-compliance and groups of substances under evaluation in a more collaborative manner, with the early involvement of registrants and Member State authorities. These actions can complement existing evaluation tools, help improve efficiency and facilitate progress on the Integrated Regulatory Strategy.

Main achievements[8]

Progress on dossier evaluation

In line with the Integrated Regulatory Strategy (IRS), ECHA performed a further 185 priority compliance checks (CCH) on substances of potential concern, finding relevant data gaps in a significant number (75%) of cases. The gaps identified were addressed with draft decisions sent for the registrant's comments ahead of a formal decision-making procedure. These results demonstrate that there are still important data gaps which registrants are required to fill in to ensure the safe use of their substances. To support and help speed up this process, ECHA introduced new ways to deal with non-compliance in the substance identity area and to address more complex categories of substances that apply a read-across approach (see boxes below).

For the evaluation of testing proposals (TP), an important milestone was reached when the European Commission took a decision on the 216 testing proposal and compliance check cases addressing reproduction toxicity, which had previously been referred to the Commission following stalemate in the Member State Committee. In most of these cases, the registrants were asked to update their dossiers within 90 days to provide either a new TP for 'extended one generation reproductive toxicity' or a valid adaptation. Late resubmission of these TPs at the end of 2017 meant the overall number of TPs examined during the year was lower than originally planned.

The impact of dossier evaluation can be seen in the follow-up evaluation – an important step for the IRS – where ECHA examines whether or not registrants have provided the requested data, thereby rendering their dossiers compliant. ECHA also assesses if the information provided causes concern and prompts further regulatory risk management measures. The outcome of the 2017 follow-up evaluations shows that 85% (639) of the endpoints originally identified as non-compliant were later deemed compliant as a result of dossier evaluation. This high rate of compliance demonstrates the effectiveness of the process in generating fit-for-purpose information on registered substances. Furthermore, 20% of all follow-up cases evaluated in 2017 were flagged as candidates for further regulatory processes, i.e. classification and labelling, substance evaluation or a new compliance check.

The majority (83%) of the follow-up examinations performed in 2017 resulted in a positive conclusion (see figure 7) communicated to both Member States and registrants. In the remaining cases, the registrants had either not submitted any information, or the information was inadequate. Consequently, ECHA informed Member State authorities, inviting them to consider enforcement action. Furthermore, a new consultation, as per Articles 50 and 51 of REACH, may be initiated in specific cases where – in response to a decision – a registrant submits information that is substantial and new but still not sufficient to meet the initial request. This new element has been added to the follow-up process in response to the Board of Appeal decision in case A-019-2013.

"Addressing substances in groups, rather than one by one, was the main theme for evaluation in 2017. Moving to this approach is not without challenges but it is motivated both by longer-term efficiency gains, the need to conclude on all high-tonnage substances in the next years and to ensure animal testing is done only as a last resort. It will also increase consistency and predictability of regulatory risk management, helping to avoid regrettable substitution.

Leena Ylä-Mononen, Director of Evaluation

SOLVING SID ISSUES INFORMALLY HELPS SPEED UP EVALUATION

Until 2016, finding substance identity (SID) issues during dossier or substance evaluation usually triggered a SID-targeted compliance check. This significantly delayed the original process as a formal dossier update request, with its inherent decision-making and follow-up procedures, could take up to a year. However, some of those SID issues could have been resolved efficiently by informally requesting a fast-track dossier update when, for example, no generation of new data was actually required. By mid-2016, ECHA had started piloting a new approach to gradually solving more complex SID issues through informal contacts with the registrants. That led to much faster provision of the necessary data and enabled smoother evaluation of dossiers and substances. Following the successful pilot project, this informal call procedure was adopted as a first step towards solving SID issues. If, however, the registrant fails to address the issues discussed informally with ECHA, a draft decision is issued. The new approach avoids unnecessary delays in dossier and substance evaluation and gives registrants a better chance to clarify issues and influence the agreement.

8 The annual progress report on evaluation provides a more detailed description of ECHA's evaluation and related activities in 2017. The report is available at: https://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_en.pdf

Progress on substance evaluation

Substance evaluation plays an important role in ECHA's Integrated Regulatory Strategy as it concludes whether risks are sufficiently controlled under existing measures or EU-wide risk management measures are needed.

As a result of earlier annual rounds of evaluation, ECHA adopted 31 substance evaluation decisions requesting further information from registrants to clarify the suspected concerns. Moreover, 25 substance evaluation conclusion documents prepared by the evaluating Member States were published in 2017. In 12 of these cases, the conclusion was that EU-wide risk management measures were necessary.

Following adoption of the updated Community Rolling Action Plan (CoRAP) 2017-2019 in March 2017, evaluating Member States started the evaluation of 22 new substances. At the same time, they concluded their evaluation of 39 substances from the previous round. As a result, registrants of 28 substances received draft decisions which, after adoption, will require them to provide additional information.

To further improve the effectiveness and efficiency of the substance evaluation process, a workshop on substance evaluation in the context of the Integrated Regulatory Strategy was organised in October 2017. One of its aims was to strengthen the follow-up and conclusion phases of the substance evaluation as well as the interface with regulatory risk management measures. The growing importance of the reliable follow-up process was also emphasised in the internal audit on the substance evaluation process earlier in the year.

NEW APPROACH TO CATEGORIES UNDER DOSSIER EVALUATION

Many of the registered substances are grouped by their registrants into categories based on structural similarity, using read-across approaches. To explore how to evaluate such groups of substances and dossiers most effectively and ensure their compliance with REACH information requirements, ECHA set up a pilot project in 2017 to evaluate a category of 14 substances. The novelty in the tested approach was to involve the registrants in a discussion on shortcomings and data gaps, and to agree on the best testing strategy before a formal compliance check is initiated and a decision is drafted. The draft decision itself is also different from a standard case as it addresses all the substances in the category in one single document. The first such combined draft decision was sent for registrants' comments in December 2017. The formal decision-making that follows will show the true value of this approach, although we can expect it to help bring category dossiers to compliance faster, potentially using fewer resources and fewer tests with vertebrate animals.

COLLABORATIVE APPROACH TO ADDRESS GROUPS OF SUBSTANCES UNDER EVALUATION

The latest ECHA report on the operation of REACH and CLP 2016 found that a significant proportion of registration dossiers are still not up to standard, hampering progress of the Integrated Regulatory Strategy. With this in mind, ECHA started pilot projects on a new collaborative approach to address groups of substances under evaluation (COLLA). The idea behind the pilot was to address substances in structurally- or use-related groups rather than one by one, and to do so in close collaboration between ECHA, the Member States and registrants. The approach is intended to be a complementary measure to support, not replace, the regulatory evaluation processes.

In the first phases of the pilot, seven Member States volunteered to screen five groups of substances and interact with their registrants to discuss the issues, testing strategies and potential regulatory plans for addressing identified concerns that may lead to the initiation of a compliance check, substance evaluation or risk management option analysis. The initial results indicate that registrants appreciate the opportunity to discuss the concerns raised on their substances early in the process, and to provide additional supporting information to the authorities. All actors have a better picture of their roles and further information needs to achieve a conclusion on the whole group. By the end of 2017, registrants of all five substance groups submitted further information and proposals for testing strategies. The experience and impact of early collaboration observed to date will be reviewed following completion of the pilots in March 2018, when the regulatory plans are finalised.

FIGURE 6: Final decisions sent to registrants in 2017 per dossier evaluation type

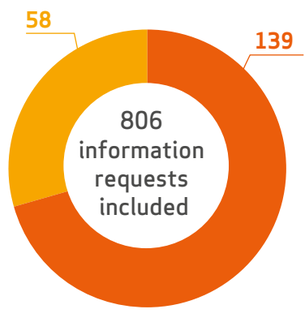


FIGURE 7: Follow-up evaluations concluded (327) in 2017 per type of outcome

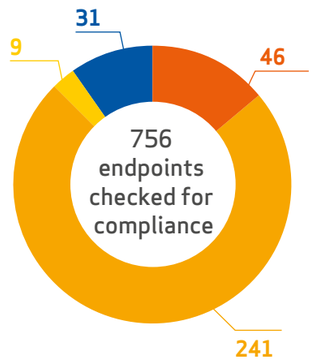
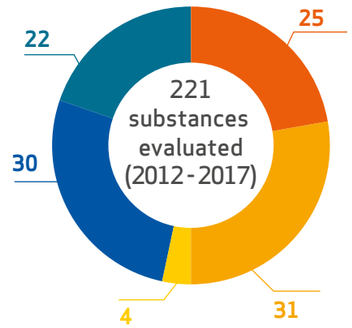


FIGURE 8: Status of substance evaluations in 2017



NANOMATERIALS

MORE INFORMATION AND GUIDANCE

ECHA achieved two important milestones in 2017: the launch of the European Union Observatory for Nanomaterials (EUON) and updates of four existing ECHA guidance documents for nanomaterials, providing more clarity for registrants ahead of the 2018 registration deadline. These achievements would not have been possible without active support from Member States and stakeholders.

EUON launch

ECHA successfully launched the EU Observatory for Nanomaterials (EUON) in June. ECHA was entrusted with the task of hosting EUON through a delegation agreement with the European Commission. EUON will systematically collect available information on nanomaterials with a specific focus on their markets and how they are used, their hazards and risks, and ongoing nano-safety research activities and their main results. ECHA will use various information sources to develop the content of the observatory. These include ECHA's own regulatory activities (e.g. dissemination of registration data, evaluation decisions or risk management processes), information from implementation of other EU legislation, national inventories or registers, market studies and/or related databases, and EU-funded research activities.

The observatory partly creates edited content adapted for various audiences (consumers, workers, authorities and researchers), and partly links to other relevant data sources. ECHA is setting up the observatory in three phases with the second and third phase being released in 2018 and 2019, respectively.

Although the observatory already contains a broad range of information, it will continue to grow in the years to come with the support of stakeholders, sister agencies and policymakers. In particular, integration with external databases – such as those for research data – will be one of the important next steps in expanding EUON. For example, through EUON, research data on the safety of nanomaterials can be made more accessible to regulators and other interested users.

While EUON cannot request the submission of new data by industry or other actors, the web platform further strengthens and complements the information that is currently in the public domain. Of particular importance is EUON's link to information on the safe use of nanomaterials submitted under REACH by industry and available via ECHA's dissemination website.

Updated guidance for nanomaterials under REACH

An assessment of the need for additional support for registrants on how to register nanoforms of substances led ECHA to publish updates on four different guidance documents ahead of the 2018 registration deadline. This was based on the significant progress in regulatory science and the experience gained in implementing REACH for these materials over the past 10 years.

Despite efforts to clarify existing REACH information requirements via the improved guidance, it is evident that efficient implementation of REACH for nanomaterials also demands revision of the legal text itself, especially to enable efficient use of compliance checks. This is the clear conclusion from the two decisions by ECHA's Board of Appeal published in 2017. Seven more substances with nanoforms are scheduled for ECHA's substance evaluation process and the Agency will continue to support Member States in carrying out these evaluations.

ECHA's Nanomaterials Expert Group played a key role in both the process of amending the guidance documents and in discussions with the OECD on how to ensure the applicability of its existing test guidelines to nanomaterials.

More information: https://euon.echa.europa.eu

Year in numbers

6
sector use maps

~12 000
file downloads from use map library

2
Chesar releases

12
model exposure scenarios for communication created for inspectors (in REF-5 project)

35
related news pieces in ECHA

Communication of risk management advice through the supply chain

Better information flow to improve safety

Companies now have a suite of tools and guidance to enable them to improve the information they must provide on chemical use and exposure for the 2018 registration deadline. As a result, downstream users will receive more helpful and consistent advice on the safe use of chemicals and mixtures.

Main achievements

In November 2017, the European Chemical Industry Council (Cefic), the Downstream Users of Chemicals Co-ordination group (DUCC), Concawe and ECHA introduced proposals for a new work programme to 2020 to the stakeholder network, the Exchange Network on Exposure Scenarios (ENES), to improve communication in the supply chain. The programme sets out a series of actions directed at the way registrants, formulators and end-users generate or apply recommendations for the safe use of substances and mixtures along the supply chain. The new programme follows up on recommendations from a 2016 evaluation on the CSR/ES Roadmap and ENES activities. The programme is expected to be published in spring 2018.

During the year, six industry associations published (or contributed elements to) a 'sector-use map', thereby supporting the efficient generation and communication of information on use from downstream sectors to registrants. A further seven sector organisations began reviewing their information with the intention of publishing use maps, too. In particular, sectors that developed generic exposure scenarios (GES) for the registration deadlines in 2010 and 2013 mapped or compared their data to identify where closer alignment with the ENES format was needed. A series of pilot exercises and workshops organised in conjunction with industry helped registrants and formulators to understand how the use maps package can be applied.

ECHA's Chesar team collaborated with many sectors to help them convert their sector material into a file suitable for registrants to generate their REACH chemical safety assessment at the click of a button. Furthermore, training events were held for both beginners and advanced users of Chesar. They demonstrated how supply chain communication tools, like use maps and the standard phrase package ESCom, can function within the chemical safety assessment framework to provide clear and consistent exposure scenarios. Updated examples of the chemical safety report and exposure scenarios also served as training material.

Throughout 2017, ECHA gave advice to downstream users in its newsletter (35 news snippets published), as well as in fact sheets. ECHA also made downstream user information more accessible via the web, adapting its supply chain communication pages, and providing information on topical issues through social media and other communication channels. Research has started to promote a better understanding of companies' actual needs regarding safe-use information, with collaboration in a few Member States. The findings will help inform the actions under the ENES work programme mentioned above.

ECHA supported the fieldwork carried out by EU national enforcement authorities in 2017 as part of the Forum's fifth European Enforcement Project (REF-5). This project checked the consistency of exposure scenarios with the safety data sheets and the chemical safety report. ECHA completed the profiles for 42 substances registered in its database, identified by Member States for inspection at the manufacturer's site – 50% of these profiles were of substances of concern[9]. In addition, 12 model exposure scenarios for communication were created for inspectors to use in comparison with those generated by industry.

> *"Companies now have a suite of tools and guidance to enable them to improve the information.*

9 In this context, substances of concern mean those restricted under REACH, placed on the authorisation list, on the candidate list, with a RMOA (risk-management option analysis) concluded with a need for REACH regulatory action, or a RMOA in progress (no conclusion published yet).

Risk management

ECHA supports the implementation of the restrictions and authorisation titles under REACH.

The authorisation procedure aims to ensure that the risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternatives whilst assuring the functioning of the EU's internal market.

Restrictions are designed to address unacceptable risks from chemicals at the EU level. They limit or ban the manufacture, placing on the market or use of certain substances within the EU. Through its Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC), ECHA provides opinions for the Commission on authorisation applications and proposals for restrictions.

The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through the classification and labelling of chemicals. ECHA manages the process with regard to harmonised classifications and, through RAC, provides opinions for the Commission on proposals for harmonised classification and labelling of substances. ECHA maintains a classification and labelling inventory and also decides on alternative name requests where a company wishes to keep the real name of a substance used in a mixture confidential.

ECHA updates duty holders and national helpdesks on developments through its helpdesk, communications and HelpNet as well as through its guidance activities.

ECHA maintains contacts with peer agencies in Australia, Canada, Japan and the United States to exchange knowledge and experience, particularly on risk identification and risk management topics.

Year in numbers

31
substance evaluation decisions

25
substance evaluation conclusions

12
substance evaluation conclusions suggesting EU-wide regulatory action

98
RMOAs concluded

191
substances listed in fourth screening round

Identifying needs for regulatory risk management

In 2017, good progress was made with the further implementation of the common screening approach which drives the implementation of the IRS. Grouping approaches are increasingly being used to tackle related substances in one go, which ensures fairness and consistency and helps to avoid regrettable substitutions. Substances with potential PBT or endocrine disruptor (ED) properties are increasingly being brought for advice to the relevant expert groups supporting Member States in their regulatory work.

Main achievements

Together with the Member States and the Commission, ECHA has set up a common screening process to identify substances of potential concern and guide them towards the appropriate REACH and CLP processes. Between 2014 and 2016, the first three screening rounds focused on individual substances and used screening algorithms to identify potential hazards and relevant uses that would lead to concerns. All of these substances give indications of the potential exposure of workers, consumers or the environment due to wide dispersive uses. The potential hazards identified cover all classes that are regarded as of highest concern – CMRs, sensitisers, EDs, and PBTs.

In the fourth screening round, ECHA has also applied a grouping approach whereby related substances are grouped together using read-across or category arguments proposed by registrants in their dossiers and structural similarity. This means that when a substance of potential concern is shortlisted, related substances are included and assessed together with the substance. This ensures fairness and consistency when scrutinising related substances and helps to avoid regrettable substitution by industry.

The fourth round resulted in the listing of 191 substances. The follow-up processes identified after manual verification vary: CCH, substance evaluation, further assessment of PBT/ED properties, RMOA, and dossier preparation for harmonised classification and labelling or for other risk management measures.

The PBT and ED expert groups continued their work to support those Member States assessing substances either to conclude on PBT and ED properties based on the available data, or to define whether further information should be requested – and if so what – to conclude on these properties. Currently, evaluating Member States bring the majority of the substances they consider under substance evaluation and SVHC identification to the expert groups.

ECHA published PBT-assessment-related REACH guidance updates on its website in June 2017. The PBT expert group was the main contributor to these updates.

RMOA is a voluntary step which aims to enable early exchange among authorities on the selection of the most appropriate regulatory action to address identified concerns. In 2017, the number of new RMOAs initiated increased compared to last year with 36 new intentions published on ECHA's website, five of which were concluded in 2017. The number of concluded RMOAs rose significantly to 98.

In 2017, ECHA continued to support the RMOA process and reviewed it in the context of reviewing the implementation of the SVHC Roadmap to 2020. Authorities felt that the RMOA process is functioning adequately and should be continued.

The 2017 SVHC Roadmap implementation report provides further insight into common screening and how it serves the different evaluation and regulatory risk management steps[10].

> *When a substance of potential concern is shortlisted, related substances are included and assessed together with the substance.*

SECTOR APPROACH FOR PLASTIC ADDITIVES

A sector approach for plastic additives was started in November 2016 in cooperation with manufacturers of plastic additives (Cefic sector groups, Eurocolour, Eurometaux, BSEF), and plastics compounders and converters (EuPC and PlasticsEurope). The aim of this project is to promote registration dossier updates by generating a better understanding of the uses and exposure potential of substances used as plastic additives, and to improve the quality and compliance of hazard information and the way chemical safety aspects are covered in registration dossiers.

10 https://echa.europa.eu/svhc-roadmap-to-2020-implementation

FIGURE 9: Manual screening outcome per property

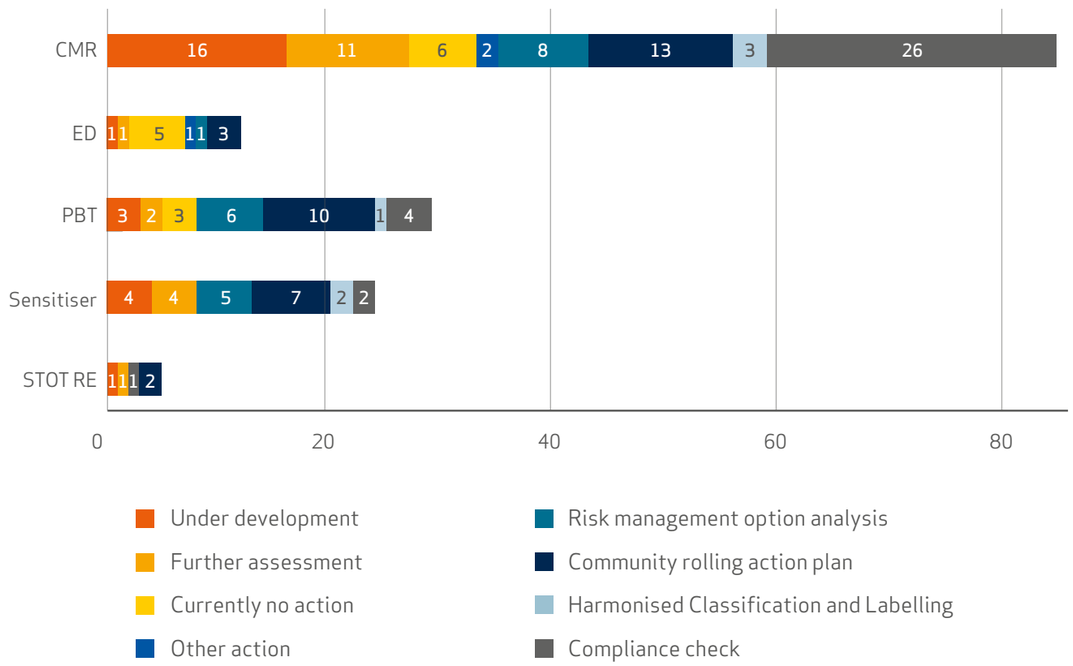
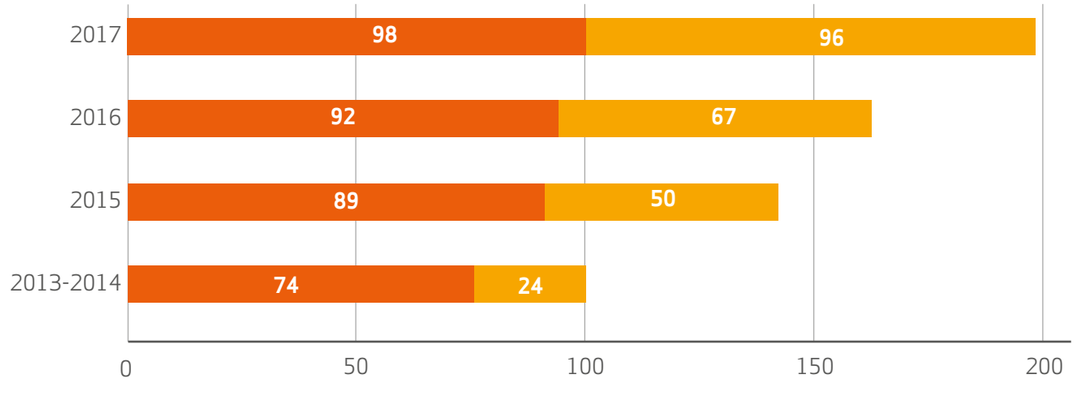


FIGURE 10: Overview of substances in RMOA (cumulative)



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Year in numbers

8
new SVHCs added to the candidate list and one entry updated twice (BPA)

7
SVHCs prioritised for the authorisation list

8
pre-submission information sessions for authorisation applicants

58
combined opinions on AfAs by RAC and SEAC

10
applications for authorisation

2
review reports

1
comprehensive update of the guide to develop use descriptions

14
notifications of SVHCs in articles

Authorisation

Authorisation promotes substitution

ECHA continued to include SVHCs on the candidate list for authorisation and to make recommendations to the European Commission on priority substances to be added to the authorisation list. These lists serve as advance notice to companies as to when they need to substitute. ECHA's scientific committees managed the second year of a peak workload in giving opinions on applications for authorisation. The Agency also published its strategy on substitution for the years to come.

Main achievements

Based on proposals submitted by Member States, eight SVHCs were added to the candidate list in July 2017 and five entries were updated (Bisphenol A, DEHP, DBP, BBP and DIBP, the last four as a result of a Commission decision). Two substances were identified because of their endocrine disrupting properties and three because they are PBTs. A total of 181 SVHCs have been included in the candidate list.

ECHA continued to prioritise substances from the candidate list for inclusion in the authorisation list. The draft eighth priority substances recommendation included seven substances[11]. These were prioritised because of their high volume and widespread uses, which may pose a threat to the environment (five of them have PBT/vPvB properties) or to human health, or because they may be used to replace other substances already on the authorisation list. ECHA's recommendations, the MSC opinion, comments received during the public consultation and ECHA's responses to them, as well as all other background documentation are publicly available on the Agency's website.

ECHA and its scientific committees continued to work on a peak number of applications related to chromium compounds, 1,2-dichloroethane and diglyme. The main achievement was that it concluded 58 opinions on applications for authorisation and sent them to the European Commission. The efficiency gains achieved since the Agency started processing opinions were maintained.

11 The final Recommendation was adopted by ECHA on 5 February 2018. It contains the same substances as proposed in the draft Recommendation.

With the help of the Task Force on the Workability of Applications for Authorisation, the Agency and the European Commission organised a stocktaking conference on the implementation of REACH authorisation. The task force also helped to revise a guide called 'How to develop use descriptions in applications for authorisation'. The revisions aim to help applicants better determine how to describe and scope the uses applied for in applications for authorisation.

The stocktaking conference concluded that the authorisation system achieved its objectives by encouraging substitution and improvements in the way SVHCs are used (i.e. risk reduction). Participants also recognised that two key challenges remain: how to describe uses in applications for authorisation by upstream actors, and how to further involve alternative providers in the process. ECHA, the European Commission and the task force will continue working to meet these challenges.

"I am pleased to see that the Commission's recent study substantiates our earlier observations: authorisation has indeed promoted substitution.

Jack De Bruijn,
Director of Risk Management

CANDIDATE LIST ENABLES FORMAL IDENTIFICATION OF ED AND PBT PROPERTIES

Inclusion in the candidate list is the first step of the authorisation process under REACH. In addition, inclusion makes it possible to officially confirm that a substance has PBT or ED properties. This is an important additional benefit of this list as there are no classification criteria at the global or EU level for these properties.

Table 3 . 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
2017	10 (13)	16	58	74	46
Total	**121 (208)**	**196**	**177**	**337**	**110**

ESTIMATES OF BENEFITS AND RISKS IN APPLICATIONS FOR AUTHORISATION

By the end of 2016, ECHA's scientific committees had evaluated the benefits and risks of 118 continued uses of SVHCs which had gone through the REACH opinion-forming process. ECHA carried out a meta-analysis of the socio-economic impacts of REACH authorisations and published the outcome in a report in September 2017[12]. In the report, it is concluded that the aggregate monetised risks to human health were estimated at EUR 281 million per year while the aggregate benefits of continued use were estimated to be at least EUR 4.2 billion per year, i.e. 15 times higher.

12 https://echa.europa.eu/documents/10162/13637/tecch_report_socioeconomic_impact_reach_authorisations_en.pdf

Review reports

Holders of authorisations can submit a Review Report to ECHA requesting an extension of the period during which they can continue to use a substance. In 2017 ECHA received the first two reports, which both came from recyclers of DEHP-containing PVC. One recycler ceased this operation and thus did not submit a Review Report.

In 2017, ECHA received and disseminated information on almost 500 notifications of uses of SVHCs from 129 downstream users. To date ECHA has received over 600 notifications of uses from 231 companies. This information helps authorisation holders better understand how their substances are used. It also informs authorities who carry out enforcement actions and stakeholders who want to increase their knowledge of the implications of the authorisation system.

Overall, the authorisation system has encouraged more and more companies to take innovative approaches to finding safer alternatives and to improve the way they use SVHCs. ECHA has also started to further improve the application process based on the experience gained so far. It is also preparing for new submissions of substances that the Commission added in 2017 to the Authorisation List (Annex XIV of the REACH Regulation) . For the first time, these include endocrine disruptors.

In 2017, ECHA developed its substitution strategy in collaboration with the Commission, Member States and stakeholders. Its Management Board took note and welcomed the strategy in its December meeting (see box).

ECHA continued to co-chair the OECD Ad Hoc Group on Substitution of Harmful Chemicals and held webinars and published articles on substitution.

STRATEGY TO SUPPORT SUBSTITUTION

ECHA has developed a strategy to encourage substitution in a business-friendly manner. It needs to be implemented and further developed in a stepwise approach based on the lessons learnt from the implementation of the strategic action areas in 2018.

The following four action areas underpin ECHA's substitution strategy:

1. Capacity building through supply chain interaction workshops;
2. Facilitating access to additional funding and technical support;
3. Facilitating the use of registration, classification and risk management data for sustainable substitution;
4. Development of networks related to substitution of chemicals of concern.

SUBSTANCES IN ARTICLES

ECHA's activities relating to substances in articles aim to promote the safer use of articles by enhancing industry knowledge on their current obligations. These activities also support the development of approaches and tools that will improve knowledge transfer on substances in often complex supply chains.

Ultimately, this approach should substantially improve the amount of information available to ECHA and the Member States on which substances are present in articles in Europe, which is a prerequisite for establishing a non-toxic environment and developing a circular economy.

On 10 September 2015, the European Court of Justice (ECJ) clarified how to calculate the 0.1 % threshold for candidate list substances in articles. Based on this, in June 2017, ECHA published an update of its 'Guidance on requirements for substances in articles'. The main aim was to give producers and importers of articles practical approaches they can apply to identify and communicate relevant information on the safe use of their products, during all life-cycle stages, in the most efficient way. ECHA published the related 'Guidance in a nutshell' document in December 2017.

To further support companies, the Agency ran a webinar in November 2017 – Communicating on substances in articles – what you need to know. Around 500 online participants attended the webinar, which triggered more than 150 questions. The recorded webinar is available on ECHA's website[13].

In November 2017, ECHA provided a new tool in REACH-IT for online submissions of REACH Article 7(2) notifications of substances in articles. The tool aims to make it easier for companies to make notifications on the development and submission of substances in articles.

In 2017, a dedicated working group of the Forum – supported by the ECHA Secretariat – developed the necessary documentation to start the operational phase of a pilot enforcement project on substances in articles.

These actions, as well as several other ECHA's activities, can be used to address the challenges identified in the Commission's Communication on the interface between chemical, product and waste legislation. These other activities include defining the substances that should be traced in article streams, and identifying what information is needed by the different actors in the related supply chains. ECHA has also supported development of the technical and scientific requirements needed to demonstrate that substances in matrixes are not bio-available under the CLP Regulation.

13 https://echa.europa.eu/-/communicating-about-substances-in-articles-what-you-need-to-know

I was glad to see how ECHA was able to consult different stakeholders when it was preparing the restrictions in lead in shots and in tattoo inks.

Matti Vainio, Head of the Risk Management Implementation Unit

Year in numbers

2
opinions adopted for restrictions

5
proposals for restriction under scientific evaluation

8
dossiers possibly leading to proposals for restriction

1
workshop on restrictions

2
workshops on socio-economic analysis

Restrictions

Major decision on plastic softeners

ECHA's scientific committees recommended to the European Commission an important restriction on the placing on the market of articles containing four phthalate substances that make plastics flexible. ECHA also proposed a noteworthy restriction on lead in shot used over wetlands, which harms wildlife and the environment. ECHA continues to encourage Member States to be active on restrictions and worked with four (Denmark, Germany, Italy and Norway) to restrict the use of harmful substances in tattoo inks.

Main achievements

Based on ECHA's proposal, its scientific committees recommended to the Commission that certain articles containing four classified phthalates, including bis (2-ethylhexyl) phthalate (DEHP), should be restricted due to their harmful effects on human fertility.

Meanwhile, ongoing work to improve the restriction process aims to encourage Member States to make new proposals on substances that matter. Four Member States worked with ECHA to propose the first EU-wide legislation on harmful substances in tattoo inks to make sure they are safe for use.

ECHA's workload in terms of processing restriction opinions was lower than expected in 2017 as only one new dossier was received from a Member State. ECHA's scientific committees evaluated this dossier, namely C9-C14 Perfluoralkylcarboxilic acids (PFCAs)[14], as well as a previously submitted dossier on di-isocyanates[15]. During 2017, the Agency submitted three restriction proposals for opinion by its scientific committees:

- One proposal concerned restricting lead in shot used over wetlands to fulfil the EU's commitment under the 2009 Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA). It has been estimated that this proposal reduces the risk to between 0.4 and 1.2 million birds that die every year due to consuming lead shot that is indiscriminately spread in wetlands.
- The second proposal concerned reducing the risks caused by hazardous substances in some tattoo inks. These include some substances already banned in cosmetics as well as additional ones. ECHA prepared this restriction proposal in cooperation with Denmark, Germany, Italy and Norway. The aim was not to ban tattoo inks or tattooing but to regulate specific hazardous substances present in tattoo inks so that they are safe to use on people.
- The third proposal was to restrict the use of lead used as a stabiliser in PVC. This restriction is estimated to have only a small impact as European industry has already taken voluntary steps to use safer substitutes. Thus, this restriction will essentially ensure that the remaining minor uses would cease in the EU and imported articles will become subject to the same rules.

ECHA also prepared several review reports and continued work on guidelines on polycyclic aromatic hydrocarbons (PAHs) and nickel restrictions to support stakeholders and enforcement authorities in understanding the scope of the restriction. Overall, the restriction activity increased in 2017 and will further intensify in 2018-19.

14 Submitted by Germany in cooperation with Sweden
15 Submitted by Germany

ARE RECYCLED RUBBER GRANULES SAFE TO PLAY ON?

In February 2017, ECHA concluded its report on the risk of substances in recycled rubber used on artificial sports pitches. Based on the evidence available, it concluded that the concern for players on these pitches, including children and workers who install and maintain them is very low. In autumn 2017, the Netherlands started work with ECHA to prepare a restriction proposal to ensure that plastic and rubber granulate is only supplied with very low concentrations of PAHs. The proposal will be submitted by July 2018.

HOW DO RESTRICTIONS WORK IN REACH?

Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals in the EU. Restrictions may limit or ban the manufacture, placing on the market or use of a substance. A restriction can apply to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.

At the request of the Commission, a Member State or ECHA can propose restrictions if they find that a risk needs to be addressed on an EU-wide basis. ECHA can also propose a restriction on articles containing substances that are in the Authorisation List (Annex XIV), based on Article 69(2).

Anyone can comment on a proposal to restrict a substance both in the EU and beyond. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities. ECHA's committees on risk assessment and socio-economic analysis provide scientific opinions on all proposed restrictions. The opinions take into account the advice on enforceability provided by the Forum.

The committees' chairpersons are from ECHA while the members come from Member States but are independent of any influence. Stakeholders observe the work of the committees. The committees' opinions help the Commission, together with the Member States, to take the final decision if a restriction is needed.

ECHA IS WORKING ACTIVELY ON RESTRICTIONS

ECHA's risk assessment and socio-economic analysis committees gave opinions on two restrictions and formulated opinions on five more:

Adopted opinions:

- Four phthalates making plastics flexible
- TDFA[16] waterproofing sprays used by the general public

Under scientific evaluation:

- Lead used as a stabiliser in PVC (ECHA)
- Diisocyanates used in the workplace (Germany)
- Lead in shot fired in or over wetlands (ECHA)
- Tattoo inks and permanent make-up containing hazardous substances (ECHA in cooperation with Denmark, Germany, Italy and Norway)
- C9-C14 Perfluoralkylcarboxilic acids (Germany and Sweden)

ECHA is working on several dossiers which may lead to proposals for restriction:

- Calcium cyanamide as a fertiliser
- Five soluble cobalt salts in industrial and consumer uses
- Formaldehyde in consumer articles and mixtures
- Lead chromates in articles
- Flame retardants TCEP, TCPP and TDCP in polyurethane foams (with Denmark)[16]
- Rubber infill in sports fields (with the Netherlands)
- Plastics: microplastics and oxo-degradable plastics added intentionally to consumer and professional products
- Siloxanes D4, D5 and D6 used in leave-on cosmetics

16 TDFA = (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives; TCPP= tris(2-chloro-1-methylethyl) phosphate; TDCP = tris[2-chloro- 1-(chloromethyl)ethyl] phosphate; and TCEP = tris(2-chloroethyl) phosphate.

Table 4. Status of received restrictions per year

	Received intentions	Restriction dossiers submitted by Member States	Restrictions prepared by ECHA	RAC-SEAC opinions	Commission decisions
2009	4	0	0	0	0
2010	1	3	1	0	0
2011	2	1	0	4	0
2012	2	1	1	1	4
2013	7	3	1	2	0
2014	4	4	2	4	3
2015	4	3	0	6	2
2016	2	2	2	2	5
2017	5	1	2	2	2
Total	**31**	**18**	**9**	**21**	**16**

SOCIO-ECONOMIC ANALYSIS SUPPORTS RISK MANAGEMENT OF CHEMICALS

ECHA has worked with the Commission, the OECD and the Member States to improve the understanding of how socio-economic analysis (SEA) is used in regulatory decision-making, in particular in restrictions and applications for authorisation. In 2017, two workshops related to SEA were held in Ottawa and Helsinki, respectively.

- In August, ECHA participated in a workshop in Ottawa organised by Health Canada and Environment and Climate Change Canada together with the OECD on 'Best practices in assessing the social costs of selected chemicals. Back-to-back, ECHA co-organised a workshop on the willingness to pay for health and environmental endpoints. As a result, in February 2018, the OECD secretariat recommended that the OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology conducted a coordinated valuation study on various health outcomes associated with exposure to harmful chemicals. ECHA is intensively involved in this work, which includes the European Commission and some Member States. The aim is that, in a couple of years, willingness-to-pay values for chemical-related health and environmental endpoints would be made available and would help in the impact assessment of regulating chemicals.
- In May, ECHA hosted the sixth meeting of the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) in Helsinki. The focus was on improving assessments of how chemicals impact humans via the environment, and on analysing alternatives and thus the cost of substitution. In 2018, the work will continue by ECHA, Member States and also applicants for REACH authorisation on both human impacts via the environment and analysis of alternatives.
- In September, ECHA published its study on the socio-economic impacts of REACH authorisations based on the first 100 applications for authorisation. This study gave an aggregate view on the health and environmental impacts and costs of the applications. Based on the assessments of RAC and SEAC, it found that the aggregate benefit of continued use was around 15 times larger than the aggregate cost. The study underpinned the Commission study on the impacts of REACH authorisation.

Year in numbers

33
opinions on proposals for CLH

11
dossiers for PPP and BP active substances

22
CLH dossiers for industrial chemicals

2
updated guidance documents

C&L inventory:
130 000
substances

Classification and labelling

Ensuring predictability and transparency

Half of the REACH substances, biocides and pesticides entered or updated for classification and labelling during the year pose long-term health hazards to humans. Harmonised classification and labelling is expected to significantly reduce the risk of these substances to humans and the environment. ECHA has continued to ensure that the classification and labelling process is predictable and transparent for national authorities, industry and civil society.

Main achievements

The Agency's RAC provided opinions on 33 proposals for harmonised classification and labelling (CLH) in 2017. Half of these concerned substances for which the classification had not been harmonised, and half were reviews of existing CLP entries. Finalisation of the important opinion on glyphosate, a widely used active substance in herbicides, was one of the key activities in 2017, which created a significant amount of work for RAC and the ECHA secretariat, in particular in explaining to the outside world how the CLH process functions and what ECHA's role and remit is.

The predictability and transparency of the CLH process is critical due to its importance for both the safe use of chemicals and other 'downstream' legal obligations. Therefore, industry and other stakeholders – such as trade unions, NGOs and academia – should be aware of which substances are being proposed for harmonised classification and be prepared to comment during public consultations. Companies must be ready to comply with potentially new obligations. ECHA has continued to ensure consistent and robust implementation of the CLH process.

The new and revised harmonised classification of substances requires industry to check whether their registrations and safety data sheets need to be updated and whether new regulatory requirements apply under other legislation. The process also gives authorities a basis upon which to take action – for instance, to identify a substance as an SVHC because of its CMR properties.

Half of the new or updated entries in CLP are for substances with CMR hazard properties. For some other entries, the RAC assessed the available information in detail and concluded that it did not support classification as CMR. Confirmed classification as CMR category 1A or B results in non-approval as plant protection products (PPPs) and biocidal products (BPs) active substances, and a ban on supplying the substance to the general public in its pure form or in mixtures requiring its substitution. When such options are not currently feasible, companies must apply severe risk management measures. The harmonisation of other hazards, such as skin sensitisation and environmental hazards, also requires industry to take action that includes giving workers and consumers more information on the substance.

Despite the importance of a harmonised classification for the safe use of chemicals, ECHA does not receive CLH dossiers for all active substances in PPPs which have already been approved in the EU and are in the process of renewal under the PPP Regulation. The total number of CLH dossiers for PPP and BP active substances continued to fall, reaching just 11 dossiers in 2017, the same number as in 2011.

The number of CLH dossiers for industrial chemicals remained at a similar level to previous years, reaching 22 in total. In line with the IRS, there is still a need to increase the number of CLHs for industrial substances and to focus on substances that matter for safe use. These concern substances for which harmonising their classification and labelling is expected to have a substantial effect on their safety. Therefore, the identification of candidates for CLH is part of the common screening approach that identifies substances of potential concern.

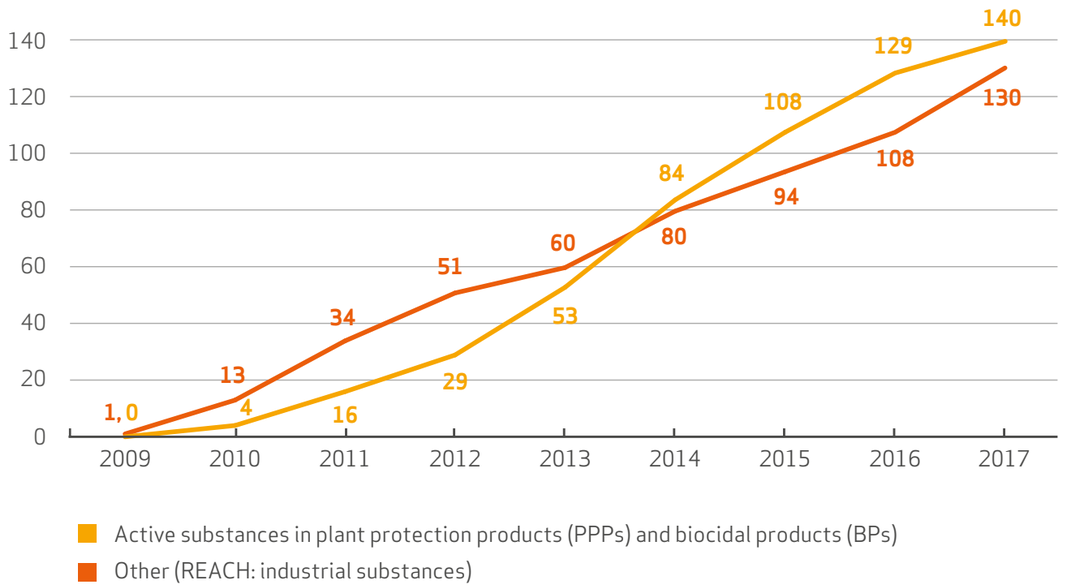
Industry is obliged to self-classify substances for hazards that do not have harmonised classification under CLP, and to notify ECHA accordingly.

ECHA's classification and labelling inventory is a comprehensive source of information on all harmonised and self-classifications which covers over 130 000 substances. In 2017, ECHA speeded up dissemination of the new harmonised and self-classifications and aligned the inventory with the latest changes in the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). In preparation for the 2018 registration deadline, ECHA included additional automated quality checks in the C&L notification tools (Reach-IT and IUCLID) to reduce the possibility of industry introducing inherently inconsistent notifications.

The CLP Regulation implements the GHS in the EU. ECHA is actively involved in the UN's scientific and technical work to refine and complement the criteria. Revisions of the GHS criteria will be implemented in the CLP. In 2017, ECHA contributed to the review of the human health hazard criteria regarding non-animal testing methods, e.g. in-vitro and in-silico methods, focusing on skin corrosion/irritation. The Agency also continued to support the discussion on the potential to develop a global harmonised classification list. Furthermore, ECHA continued its contribution to practical classification issues by, for instance, suggesting changes to the GHS criteria to allow additivity to be applied in the classification of a mixture for any hazard including CMR.

> *"Predictability and transparency of the CLH process is critical due to its importance for both the safe use of chemicals and other 'downstream' legal obligations.*

FIGURE 11: Total number of CLH opinions adopted by RAC since 2009



GLYPHOSATE OPINION AND TRANSPARENCY

One adopted CLH opinion was on glyphosate, a widely used active substance in herbicides. Based on a thorough assessment of the information included in the proposal made by Germany and submitted via public consultation, RAC recommended not to change the existing harmonised classification for glyphosate. This included the conclusion that current scientific evidence does not support the classification of glyphosate for carcinogenicity.

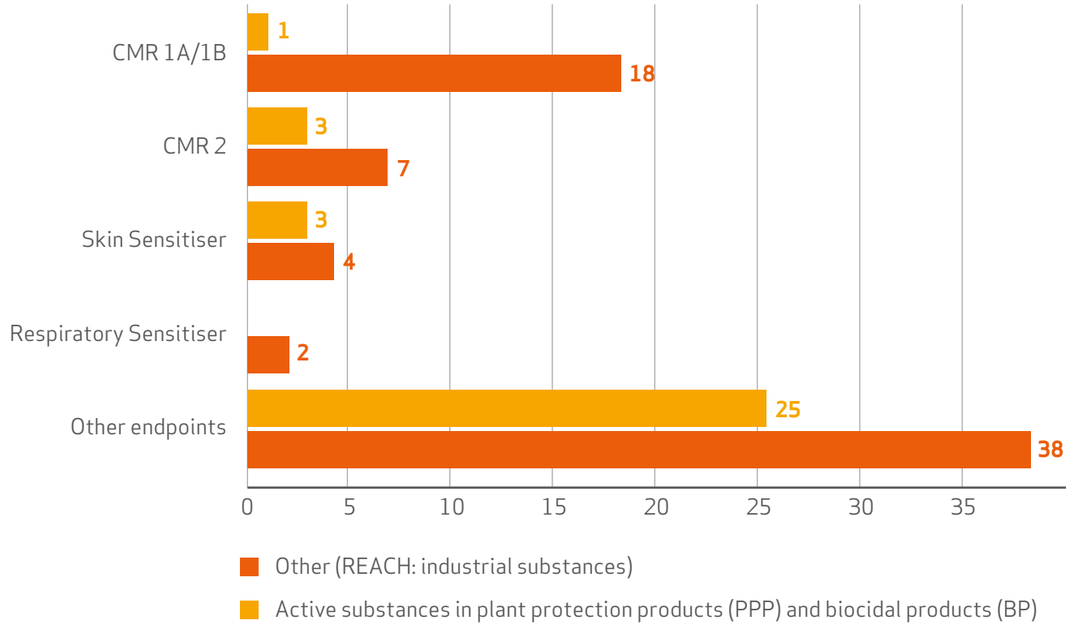
The RAC's consideration of the dossier was divided into two parts. First, interested parties[17] were invited to provide their views to the Committee on the scientific studies on glyphosate. Then, at its next meeting, RAC discussed the classification based on all available information. It had access to the original study reports on carcinogenicity and carried out its independent evaluation on that basis, also acknowledging later reviews and opinions. It made its handling of the case open to public scrutiny. The ECHA secretariat answered numerous enquiries, including those from the European Parliament, the press and individuals.

17 Health and Environment Alliance (HEAL), IARC, WHO/FAO JMPR, EFSA, Germany as dossier submitter and the Glyphosate Task Force

Harmonised classification and labelling

Brings benefits to industry	Plays a central role in the integrated regulatory strategy and beyond
CLH provides a solid basis for industry to carry out safety assessments and to communicate hazards to users, including consumers.	Dossier and substance evaluation can be used to generate new information that Member States need in order to propose harmonised classifications.
CLH has a major impact on the obligations of companies manufacturing and importing chemicals. These obligations apply regardless of volumes involved, i.e. also to actors that do not need to register under REACH due to the low volumes they manufacture or imported.	When REACH's authorisation or restriction processes are needed for substances due to their CMR properties, their classification needs to be harmonised first.
CLH also enhances the level playing field for industry, and triggers more consistent risk management advice to downstream users of substances and mixtures. These effects are important as the alignment of self-classifications is proceeding very slowly.	CLH also triggers obligations under other legislation. These include a ban on using CMR substances in toys. Furthermore, CLH enables authorities to take action under other legislation, such as legal requirements that define which substances require emission limit values under the Industrial Emissions Directive.

FIGURE 12: Number of hazards classified by RAC in 2017



Biocides

The Biocidal Products Regulation (BPR) concerns the placing on the market and use of biocidal active substances and products. These are typically used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, through the action of the active substances in the biocidal product. Via its Biocidal Products Committee (BPC), ECHA delivers opinions for the European Commission to support decision-making on biocidal active substances and products. The Agency is not only coordinating the evaluation of active substances and the Union-wide authorisation of biocidal products but is also the central hub for all national and EU applications. Furthermore, ECHA's role includes establishing technical equivalence, assessment of applications for alternative suppliers, resolution of data-sharing disputes, dissemination, preparation of guidance, and communication. It keeps duty holders and national authorities abreast of developments via its communications, helpdesk and HelpNet activities.

Year in numbers

39
BPC opinions on active substances (30 on existing and 9 on new active substances)

2
BPC opinions on Union authorisations

5
other opinions addressing European Commission requests

2 new and **6** revised guidance documents

28 WG meetings (24 permanent WGs and 4 ad-hoc WGs)

247
active substances – product type combinations have already been evaluated in the Review Programme (167 since ECHA took over responsibility in 2014)

618
active substances – total product type combinations in the Review Programme

5744
submissions received via R4BP 3

Active support for BPC delivers solid results

For the first time, support to Member States' competent authorities and the Biocidal Products Committee helped to implement a new way of authorising biocidal products, Union authorisation which gives companies global access to the EU market at reduced cost, and the overall workload of the competent authorities.

ECHA also helped the Biocidal Products Committee to progress towards the target of the Review Programme for active substances, and further developed the biocides IT tools and guidance supporting companies and Member States.

Main achievements

ECHA's active support towards the competent authorities, the BPC and its working groups resulted in the first two opinions on Union authorisation in December 2017. The Agency was instrumental in coordinating the evaluating authorities and helping to ensure companies received consistent and fair treatment.

It also helped the BPC and its working groups to make significant progress in assessing the active substances that were already on the EU market in 2000. ECHA supported Member States during their evaluation and organised and chaired 28 working group meetings and five BPC meetings. However, the number of opinions on active substances adopted in 2017 (39 in total, 31 of which were for the Review Programme) is lower than in previous years, illustrating the resources issues Member States are currently facing. This means that regularisation of the biocidal products already on the market will take more time than foreseen and that if this trend continues the Review Programme might not be finalised by the end of 2024.

ECHA has also supported the Coordination Group's increasing workload resulting from the rise in mutual recognition referrals and the need to clarify important technical and policy issues for product authorisations, such as interpreting key parameters for biocidal product families. The duration of the meetings has increased to 1.5 days on average and one meeting of the working parties has been organised.

Improved tools for companies and authorities

ECHA has continued to develop the biocides IT tools, R4BP 3 and the SPC editor: two new versions were released in 2017, making them more flexible and user-friendly to help companies and competent authorities address their legal obligations. In particular, a technical constraint was lifted so that several similar products can now be linked to the same reference product. Search tools were also improved considerably. Additional work was done to enhance the efficiency of the submission process, including a number of improvements to R4BP, which also ensured that competent authorities receive the applications more quickly than in the past.

A joint effort by the Member States and ECHA led to significant progress in terms of guidance: several important gaps in the biocides scientific guidance were filled and recommendations for in-situ generated active substances were published. This will help companies to prepare their applications and Member States to assess them.

The criteria for ED substances for biocides and pesticides were agreed in 2017. As requested by the Commission, ECHA and the European Food Safety Authority (EFSA) drafted the Guidance for ED identification, which is scheduled for publication by the time the ED criteria become applicable (mid-2018).

Extending the scope of ECHA's Forum constitutes a major step towards the coordination of national enforcement activities for biocides. A dedicated subgroup of the Forum was created and started working on coordinating and harmonising their actions to ensure the safety of consumers and the environment.

"We welcome the first two opinions of the BPC on Union authorisation. This is a major milestone in the implementation of the BPR with an efficient way to have biocidal products authorised in Europe.

Hugues Kenigswald, Head of the Biocides Assessment Unit

FIGURE 13: BPC opinions in 2017

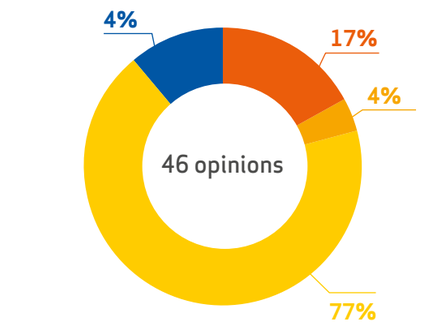


FIGURE 14: BPC and WG meetings in 2017

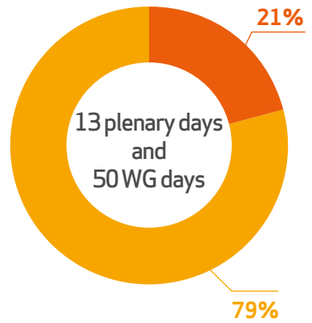
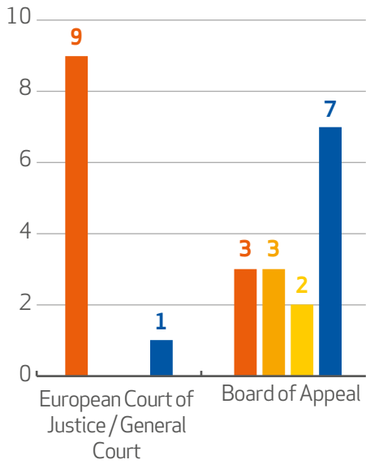


FIGURE 15: Outcome of decisions of the Board of Appeal and judgements of the EU Courts (excluding decisions and judgments limited to procedural issues, such as confirmation of an appeal withdrawal)

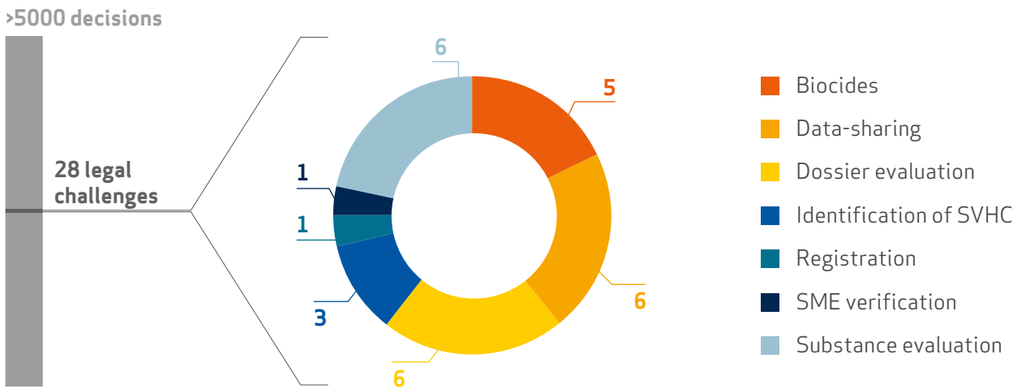


PREDICTABLE, CONSISTENT REACH REGULATORY PROCESSES

In view of the intricacies of REACH, CLP, BPR and PIC Regulations and the high number of decisions issued each year, ECHA is aiming for an efficient, consistent and transparent approach, paying particular attention to SMEs. These efforts have resulted in a high level of acceptability regarding ECHA's decision-making (see figures 15 and 16). The Court of Justice of the European Union and the ECHA's Board of Appeal have further increased the predictability of ECHA's processes through various rulings on new issues, including the inclusion of endocrine disrupter on the candidate list.

Litigation cases routinely raise complex legal and scientific issues and impose a significant workload on in-house legal and scientific experts within short, and sometimes competing, deadlines.

FIGURE 16: Comparison between the number of decisions made by ECHA with the number of legal challenges[1] in 2017



PIC Regulation

ECHA contributes to the implementation of the Prior Informed Consent (PIC) Regulation which administers the export/import of certain hazardous chemicals to/from the EU.

Year in numbers

7843
export notifications for 2017

230
helpdesk questions from companies answered

-2 100
scientific/technical questions answered

Cooperating on overseeing international trade in hazardous chemicals

The first report on the operation of the PIC Regulation covers 2014 to 2016. It shows that ECHA is helping to promote cooperation in the international trade in hazardous chemicals –protecting human health and the environment. In addition, ECHA published a report on the actual exports and imports of PIC chemicals in the year following the reporting period. In 2016, ethylene dichloride was the EU's most exported PIC chemical by volume.

Main achievements

According to the first report on operation of the regulation, ECHA has established a close working relationship with stakeholders and has offered high-quality support on PIC. The report relies on ECHA's experience in implementation from 2014 to 2016.

During these first three years of operation, ECHA published information on the export and import of PIC chemicals in an accessible format on its website. The Agency has invested in developing related reporting information. The report found that ECHA's EU and international stakeholders recognise its contribution to the implementation of PIC and to the Rotterdam Convention on the PIC procedure.

The report also discusses potential areas for development and suggests how ECHA can better cooperate with the European Commission in implementing PIC. The report highlights such topics as distributing or reallocating certain tasks, estimating workload, managing amendments to the regulation, and proposing potential changes to the legal text.

The report emphasises the constant rise in PIC-related activities. Over the three-year period, the number of companies rose from 390 to 1177 and annual export notifications increased by 74% – from 4500 in 2014 to nearly 8000 in 2016. This figure, which is far beyond the original estimate of a 10% annual increase, is mainly due to new chemicals becoming subject to PIC as well as companies' overall growing awareness of their obligations under this regulation.

ECHA emphasised its concern about the rapidly increasing workload and the resources needed to continue implementing PIC provisions at the same quality level in the coming years. In 2017, there was no increase in the number of notifications as the expected amendment to the regulation was delayed and no new substances were added to the list. Nevertheless, ECHA continued to give stakeholders a high level of support: over 2000 requests for scientific, technical and administrative support from national authorities in EU and non-EU countries and from the Commission were answered. In 2018, the number of notifications is expected to surge again, as two amendments are foreseen adding substances within the scope of PIC.

ECHA also published a non-confidential report on the actual exports and imports of PIC chemicals in 2016. Improvements to both the IT tool (ePIC) and the dedicated data-aggregation tool developed by the Agency enabled it to process the trade data faster than in the past.

Ethylene dichloride was the EU's most exported PIC chemical in 2016, while the most imported PIC chemical was benzene. PIC-relevant exports and imports occurred in 19 of the 28 Member States.

ECHA attended the 8th Conference of the Parties (COP) to the Rotterdam Convention. At the event, it provided five training sessions for non-EU countries on the specific provisions of the EU's PIC Regulation, with support from a number of Member States. Representatives from 50 countries attended the training and expressed their interest in and appreciation of the opportunity.

The reporting functionality for exporters and importers of PIC chemicals as well as other features requested by the users were implemented in the new version of ePIC, the PIC Regulation submission tool. In addition, the Agency conducted a preliminary assessment of the potential impact on PIC processes of the UK's withdrawal from the EU. In 2018, it will be necessary to implement substantial changes in the ePIC tool.

In addition, ECHA also helped the Commission with tasks related to implementation of the Rotterdam Convention. It drafted four notifications for final regulatory action for pesticide active substances, and also provided an expert for the Rotterdam Convention's Chemical

> *"ECHA is helping to promote cooperation in the international trade in hazardous chemicals – protecting human health and the environment.*

Data management and dissemination

Tasks covered in this area include four legislations on: data governance, data harmonisation, data architecture, data security, data warehousing and business intelligence, computational methods for data mining as well as data dissemination to stakeholders and the public at large.

Since early 2016, the Dissemination Portal has provided the world's largest public database on the properties of industrial chemicals in a tiered format – with InfoCards for laypersons and more detailed information for experts drawn from a multitude of ECHA's databases – and is expected to attract ever-increasing attention from interested readers.

Year in numbers

69
data and service requests from external parties

~1.3
million views of infocards

Information from
7 961
registration dossiers added to the dissemination websites

From regulatory information to knowledge

EU chemical management is based on seamless collaboration between companies, ECHA and other authorities. To streamline shared activities, the Agency developed a tool where up-to-date information on all substance-specific activities – planned, ongoing or completed – by ECHA and/or Member States is visible to all authorities.

As from 2020, companies making hazardous mixtures available in the EU will have to notify them to poison centres. In anticipation of this, the first tools have become available, and important groundwork has also been done in analysing ECHA's future potential as a major data holder on chemicals.

Main achievements

To improve efficiency, ECHA's Integrated Regulatory Strategy (see pages 36 to 37) requires solid data-management practices. These result in better data integrity, standardisation, integration and accessibility, which can be partly automated. In 2017, one specific focus area concerned enhancing the IT interfaces through which Member State competent authorities (MSCA) access data on ECHA's regulatory activities.

The activities coordination tool (ACT), which was published in a revised format in 2017, provides both ECHA and MSCAs with a holistic overview of regulatory work carried out on a substance or group of substances. Planned, ongoing and completed activities are now visible to all actors which helps to minimise duplication of work on the same or similar substances. It covers a total of 10 regulatory processes, such as dossier evaluation, substance screening, PBT assessment and risk management option analysis. The enhanced ACT also serves as a basis for the public version, PACT, which has been available on the ECHA website since 2014, providing transparency to all stakeholders on regulatory activities on substances.

To further support efficient decision-making, ECHA conducted a pilot whereby RAC and SEAC rapporteurs were given direct access to ECHA's systems. The impact of this work is explained under the 'Committees' section of this report.

Mapping all chemicals on the EU market

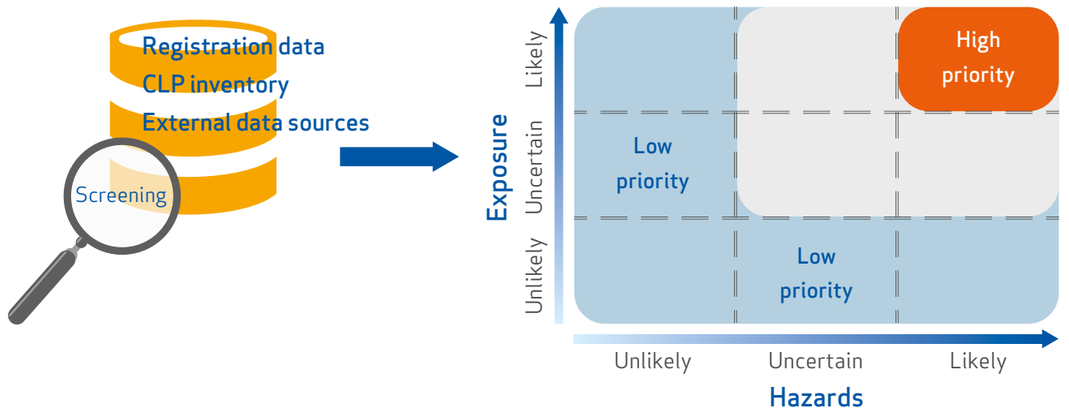
Companies need to improve the quality and compliance of information in their registration dossiers. ECHA started a project to systematically capture and represent its knowledge on regulatory concerns (such as the outcome of scientific assessment carried out in ECHA's regulatory processes in pursuit of a detected concern on a chemical) and detected data deficiencies (such as the outcome of a CCH on a given dossier) (see figure 17).

The aim of this work is to have a fully automated and consistent way of presenting all registered substances in the EU in an easy-to-read format or graph plotting 'hazards' and 'exposure'. In this graph, it will be possible to locate those substances for which regulatory risk management is needed, those where there is low priority for further action, those whose exposure levels need to be monitored, and those for which more information is required.

In practice, this means that each scientific assessment made by ECHA staff will be recorded in a time-stamped, harmonised way, enabling coherent monitoring of the progress.

ECHA's roadmap towards having a fully operational system by 2020 identified several milestones: modelling and standardisation of assessment data recording; aligning key ECHA assessment recording IT systems to the model and harmonising the assessment recording practices (2018-2019); and mapping assessment data over the past 10 years to the model as cost-efficiently as possible.

FIGURE 17: Mapping of chemicals of priority for further regulatory work



Poison centres: a central notification portal would be feasible.

Tools and support for companies with reporting obligations on information on hazardous mixtures to be used by national poison centres

For companies dealing with mixtures, a major obligation will be the forthcoming notification of hazardous mixtures to national poison centres which starts from 2020. The new CLP annex describing this obligation was published in March 2017. Shortly afterwards, ECHA published draft versions of the notification format and product category editor so that companies could orientate themselves around the new tools and obligations. ECHA also published the draft product categorisation system on its website.

ECHA offered webinars (for about 1 000 participants) to explain the basic concepts behind the harmonisation of information submitted to poison centres. The Agency also gave recommendations on how to prepare for new notifications. In this context, the European Commission asked ECHA to analyse the feasibility of developing a central notification portal, where companies could benefit from a single submission point. The portal would subsequently dispatch notifications to the relevant national bodies. The study, commissioned by ECHA, concluded that building such a central portal would be feasible. Work on an initial basic version of the portal starts in 2018. The Commission and ECHA are still working on the sustainability of the initiative beyond 2018 and, specifically, on a proposal to further develop the portal to offer a searchable central notification database for Member States which cannot develop their own IT systems.

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VALUE OF ECHA'S DATA ON CHEMICALS DISCOVERED

ECHA surveyed stakeholders and analysed long-term options for maximising the value of the Agency's unique database of information on chemicals. The study presented three different ways to enhance the value of the data for: 1) ECHA and EU institutions, 2) trusted partners, and 3) a broader audience such as academia, industry and society at large.

These options correspond to different future ambition levels and all comply with ECHA's mission. Each option creates additional benefits by using ECHA data and generating knowledge from it.

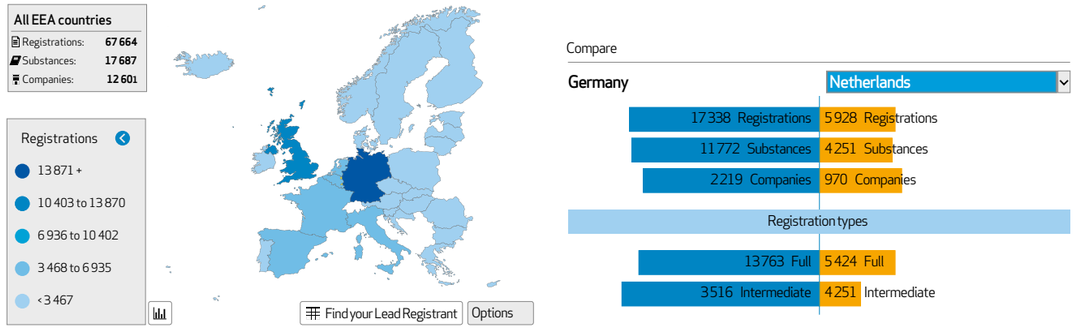
Option 1: Steward – the focus is on improving internal operations and reducing costs while continuing to provide better advice on chemicals safety. ECHA continues to interact mainly with its current stakeholders.

Option 2: Incubator – ECHA experiments, innovates and develops knowledge on chemicals safety, for example by sharing data or trying new technologies such as machine learning. ECHA opens up its data and know-how to trusted partners who bring their own information and knowledge to the benefit of all by identifying and exploring synergies.

Option 3: Hub – ECHA is becoming the main source of knowledge and advice on chemicals in its organisational environment. As far as possible, ECHA opens up its data and know-how to a broader audience so that information can be reused to benefit human health and environmental protection.

ECHA will consider these results in formulating the Agency's strategic priorities for 2019-2023.

FIGURE 18: Interactive map on registration statistics to compare, for example, countries or results over a given week, month or year



Dissemination of information to the general public: visualisation of registration progress

The public, as the ultimate beneficiary of ECHA's work, should be able to follow the progress made under the EU's chemical management regime. To this end, in 2017, ECHA made an effort to present the outcome of the registration process in a new, more visual format, helping journalists and non-specialists to better understand its core work.

The interactive tool displays statistical data about the registrations received from the 28 EU Member States and the European Economic Area countries – Norway, Iceland and Liechtenstein. An interactive map, easily toggled from graph view to table view, presents the data. On the map, information is available on unique substances, registration dossiers and the companies that have registered the chemicals. Options are available to view data per country and covering a desired time frame (week, month or year) (see figure 18).

In addition, important groundwork was done to prepare for disseminating information on biocides and will become available on ECHA's website in 2018.

EU Chemicals Legislation Finder

A given chemical substance can be subject to several EU legislations pursuing different objectives (REACH, biocides, pesticides, cosmetics, fertilisers, drug precursors, explosives, pyrotechnics, detergents, worker protection, toy safety etc.). This information is, however, not accessible from one single entry point. This renders the access to information burdensome and costly, in particular for SMEs that have to deal with chemical substances as producers or downstream users. The creation of an EU chemicals legislation finder would address this issue.

Considering that compliance with EU legislations is often mandatory in order to sell and distribute substances, this initiative can facilitate access to markets for SMEs.

Decision pending on legislation finder

It is feasible to build an EU chemicals legislation finder – a proposed website with information on how a chemical substance is regulated in the EU. This is a task delegated to the Agency. However, further details must be clarified before ECHA can make a decision to start developing the online portal.

Main achievements

An EU chemicals legislation finder website would help provide companies, especially SMEs, with a comprehensive picture on how chemicals are regulated in the EU. Union and national authorities would also benefit from a regulatory overview on each chemical substance, as both overlaps and regulatory gaps could be identified more easily.

In response to this perceived need, ECHA commissioned a feasibility study on whether it would be possible, both technically and organisationally, to develop such a service. The study concluded that it is feasible. Altogether, 55 pieces of EU legislation were found to be relevant to be included within the scope of such a website. In addition, the companies and industry associations surveyed considered that national occupational exposure limits (OELs) and emission values were highly relevant. Industry associations, the European Commission and ECHA agreed that these should be included in the EU chemicals legislation finder as a second priority.

The study identified ECHA as the most suitable body to host the website because of synergies with its tasks in managing and processing data arising from the implementation of REACH, CLP, BPR and PIC legislation. In addition, ECHA already has relevant expertise in informing the public about chemical substances for which it has developed effective IT tools and a user-friendly and well-known dissemination portal.

However, the study identified certain elements that need further investigation and refinement before starting to develop the website. These comprise a detailed analysis of the IT implications of integrating the elements related to legislation on ECHA's dissemination portal (architectural study), and validating and detailing the substance-based information concerning the 55 pieces of European legislation agreed as being within the scope of the finder's first phase (business analysis).

Based on the outcome of the above-mentioned analysis, ECHA will make its final decision on whether to pursue this initiative in 2018.

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GOVERNANCE AND SUPPORT

Management of ECHA bodies and networks

The Committees – Member State Committee (MSC), Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) and the Biocidal Products Committee (BPC) – form an integral part of ECHA. They play a crucial role by providing independent scientific and technical advice (i.e. agreements and opinions) for ECHA and Commission decision-making.

The Forum for Exchange of Information on Enforcement provides a network of Member State authorities responsible for the enforcement of the REACH, CLP, PIC and BPR regulations, with the goal of harmonising their approach to enforcement.

ECHA and the national BPR, CLP and REACH helpdesks operate a network of helpdesks (HelpNet) with the aim of exchanging information and cooperating, particularly with a view to providing consistent and harmonised advice. HelpNet is governed by the HelpNet Steering Group comprising ECHA, the national BPR, CLP and REACH helpdesks, the Commission and observers from the European Enterprise Network, candidate countries/other third countries, and/or ASOs.

The Security Officers' Network (SON) is a network of experts from MSCAs, mandated national institutions, the European Commission and CEFIC.

The Board of Appeal was established by the REACH Regulation to give interested parties the possibility of an administrative legal review of certain ECHA's decisions.

It should be noted that in order to achieve all the operational activities' objectives, other informal bodies and expert groups function alongside those mentioned above.

Year in numbers

22
plenary meetings

97%
unanimous MSC decisions

96%
RAC and SEAC opinions adopted by consensus

RAC: **54**
members (including 4 co-opted members)

SEAC: **38**
members (including 3 co-opted members)

MSC: **29** members and 25 alternate members

BPC: **27** members and 26 alternate members

BPC WGs: **35** core members and 18 alternate members

Committees

Committees' work is more efficient

The four committees – the Member State Committee (MSC), the Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC) and the Biocidal Products Committee (BPC) – continued to provide valuable opinions and agreements to support ECHA and the European Commission's decision-making processes. Each committee's workload was successfully managed thanks to the high level of commitment and dedication of the members and experts supporting them in the Member States, and the coordination provided by the Secretariat.

Main achievements

In 2017, RAC and SEAC issued 99 and 60 opinions, respectively, while MSC issued 126 agreements and 2 opinions; BPC adopted 46 opinions. The scale and degree of difficulty of these dossiers varies widely.

ECHA reviewed the work flow across all the processes for all the committees, which resulted in improvements to several administrative processes. For example, the management of all committees' related declarations was made more efficient.

RAC and SEAC successfully managed the peak workload on chromate and process solvent applications for authorisations. In addition to authorisations and restrictions, RAC's workload was high because of the introduction of carcinogens- and mutagens-related work on OELs, i.e. in addition to the above and the usual workload from classification and labelling.

Bisphenol A and glyphosate

ECHA's committees also dealt with other substances of public interest. These included the identification by the MSC of bisphenol A, as a substance of very high concern based on its endocrine-disrupting properties for both human health and environment, while the RAC adopted its opinion on the harmonised classification of glyphosate, proposing that under the CLP regulation criteria this substance is not considered to cause cancer. The issue of glyphosate drew significant media and stakeholder interest throughout 2017.

The MSC continued to resolve diverging views among Member States on the state of compliance of registration dossiers, testing proposals by industry, and substance evaluation outcomes enabling ECHA to issue decisions on these topics to registrants.

In 2017, the BPC met five times and 28 BPC WG meetings were held, with six meetings for each of the four permanent BPC WGs (human health, analytical methods and physico-chemical properties, efficacy, and environment).

In December, the BPC adopted its first opinions supporting applications for Union authorisation for two iodine-containing biocidal products which are used for the disinfection of teats of milk-producing animals like dairy cows, sheep and goats.

Committee members and experts contributed extensively to the evaluation of the safe use of chemicals from different processes within REACH, CLP and the BPR, channelled through their plenary meetings and decision-making structures.

ECHA managed the committees' memberships, including the application of ECHA's conflict of interest policy and timely membership renewal, and encouraged the competent authorities to ensure the committees had adequate capacity.

> *"Committee members and experts contributed extensively to the evaluation of the safe use of chemicals from different processes within REACH, CLP and the BPR.*

The committees benefited from a broad range of other smaller-scale meetings, including working groups and preparatory meetings organised by ECHA to facilitate the assessment work. Written consultations and procedures were used to a large extent to achieve the necessary efficiency, and preparatory work at many levels and in different ways was successfully used to build consensus on important issues.

All these measures allowed the committees to dedicate all the available discussion time to the most challenging topics during their meetings, and to deliver high-quality outcomes and opinions with a sound scientific basis. Active participation by stakeholder observers continued and contributed to the transparency of the committees' work.

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FIGURE 19: RAC plenary meetings in 2017
Time spent

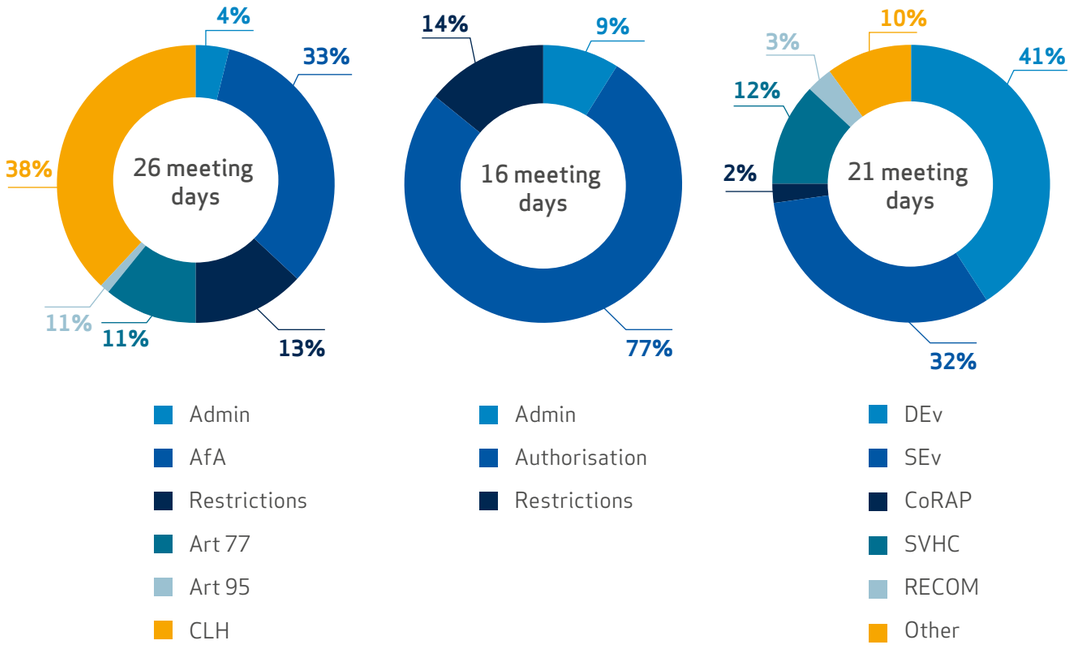


FIGURE 20: SEAC plenary meetings in 2017
Time spent

FIGURE 21: MSC plenary meetings in 2017
Time spent

SCIENTIFIC EVALUATION OF OCCUPATIONAL EXPOSURE LIMITS

At the request of the Commission, a joint task force between ECHA-RAC and DG Employment's Scientific Committee on Occupational Exposure Limits (SCOEL) was formed to investigate the scientific aspects and methodologies related to assessing exposure to hazardous chemicals in the workplace. The task force finalised two reports in 2017, endorsed by SCOEL and RAC:

1. Comparative critical assessment of REACH-derived no-effect levels and occupational exposure limit methodologies, including the dermal route of exposure;
2. Comparative critical assessment of ECHA and SCOEL methodologies in relation to 'non-threshold' substances.

Within this collaboration, mutual understanding of the different approaches used has increased and common scientific approaches, in particular for genotoxic carcinogens, have been identified. In parallel, RAC evaluated the setting of occupational exposure limits for five substances, three of which were ongoing at the end of 2017. This work supports the Commission in developing binding OELs under the third and fourth amendment to Directive 2004/37/EC on the protection of workers from risks related to exposure to carcinogens and mutagens at work.

Year in numbers

4
REACH enforcement projects

4
pilot projects

23
active WGs

3
Forum plenary meetings

3
plenary BPRS meetings

1
Accredited Stakeholder Organisations open session

Forum

Enforcement projects continue at a steady pace

The seamless collaboration between all actors – the Forum, national enforcement authorities, MSCAs and the ECHA Secretariat – in designing, preparing and executing numerous enforcement projects has brought the Forum's operations to maturity. The Forum intensified its collaboration with stakeholders by launching joint actions with Accredited Stakeholder Organisations aimed at improving the quality of safety data sheets.

Main achievements

At the end of the first decade of the Agency's operations, the Forum's work towards a 'level playing field' through harmonised enforcement actions has moved further to the forefront. This has given the Forum enhanced weight and visibility as part of ECHA. In 2017, the Forum increased its output of regular and pilot enforcement projects.

To tackle this workload, Forum members convened in 23 topical WGs (19 in 2016) to design and steer these projects. To this end, the secretariat also made use of tele- and video-conferences. ECHA's web pages contain more detail on the topics the current WGs are addressing (https://echa.europa.eu/about-us/who-we-are/enforcement-forum).

Given the nature of the Forum's mandate to harmonise enforcement projects at EU level, the individual members appointed by each EU Member State have the task of ensuring that new projects complement national enforcement strategies. Some Member States even conduct such actions at a sub-national level.

ECHA's Secretariat also contributed topical proposals for enforcement projects, drawing on the Agency's observations of managing its regulatory work. The Forum considered these in its plenary meetings when deciding on the content of its harmonised projects. Ultimately, it is the combined efforts of harmonised EU enforcement projects conducted by ECHA's Forum and all national enforcement activities that contribute to levelling the playing field, which the authorities and stakeholders seek to achieve.

Companies placing chemical substances on the market experienced enforcement actions that targeted a variety of obligations at the core of handling chemicals safely. The published reports on the Forum's fourth coordinated enforcement project (REF-4) related to REACH restrictions and on its second project on authorisation-related obligations revealed the remaining gaps that need to be bridged to achieve full compliance.

During 2017, inspectors completed their operations on the REF-5 project addressing risk management throughout the supply chain. A CLP pilot project focused on internet sales of chemicals. The Forum will publish reports on the projects in 2018.

Companies also experienced enforcement actions through a pilot project on substances in articles. The Forum prepared a pilot project on PIC obligations as well as the REF-6 project on the classification and labelling of mixtures, for which inspections will take place in 2018.

In their work, inspectors were able to make use of a newly upgraded version of the portal dashboard for national enforcement authorities. This digital tool provides them with access to data held by ECHA which they need for their inspection activities. Due to resource constraints, the Agency decided to postpone until 2019 the development of this tool to include inspections of BPR obligations.

Training

The Forum dedicated its annual training for trainers of inspectors to familiarise them with developments regarding REACH authorisations, classification and labelling. For the third time, this 'train-the-trainers' programme benefited from the participation of national helpdesk experts.

The Forum's sub-group handling BPR matters (BPRS) saw its first full year of operations. In 2017, the Forum introduced new ways of working, including creating registered substance summary profiles to facilitate inspections of company practice in communicating in the supply chain; and a first-time joint action with ASOs dedicated to improving the quality of safety data sheets.

With the aim of providing more transparency on the Forum's activities, the ECHA Secretariat launched redesigned dedicated web pages (see link above). It also included enforcement in the agenda of its annual accredited stakeholder workshop for Brussels-based organisations, in addition to organising the Forum's traditional open day during its third annual meeting.

More information on specific enforcement projects is available in the respective operational chapters of this report and on ECHA's web pages.

> *"The Forum intensified its collaboration with stakeholders by launching joint actions with Accredited Stakeholder Organisations aimed at improving the quality of safety data sheets.*

Year in numbers

4
'HelpNet Updates' issued

3
REACH workshops

2 CLP workshops + **1** 'train the trainers' parallel activity

80
SON officers from **63** organisations in 31 EU/EEA countries

HelpNet and Security Officers' Network

Valuable boost for helpdesks and IT security

HelpNet focused on preparing national helpdesks and companies to meet their 2018 REACH registration obligations.

The Security Officer's Network devised a security model that embraces modern ways of working and innovative IT solutions against sophisticated security threats.

Main achievements

HelpNet

HelpNet correspondents from the national helpdesks of 28 EU Member States and the three EEA countries benefited from a wide variety of events organised by ECHA's HelpNet Secretariat. These involved observers from Serbia and Turkey as well as industry associations' helpdesks.

During 2017, the HelpNet welcomed three new observers: the Only Representatives Organisation (ORO), the European Association of Chemical Distributors (FECC), and the Swiss Federal Office of Public Health (FOPH) as the national Notification Authority for Chemicals, thereby expanding the range of HelpNet's outreach. Granting Switzerland observer status followed a favourable decision by ECHA's Management Board.

In the run-up to the third REACH registration deadline of May 2018, the annual agenda included numerous updates in support of national helpdesks' interactions with registrants preparing their dossier submissions. The ECHA Secretariat gave correspondents intensive briefings at three REACH workshops, which allowed them to keep pace with ECHA's 'REACH 2018' information and the latest developments in registration-related procedures, such as the introduction of enhanced technical completeness checks.

IT tools' training for REACH and CLP correspondents on IUCLID, REACH-IT, Chesar and ECHA's new cloud services complemented these presentations and discussion workshops.

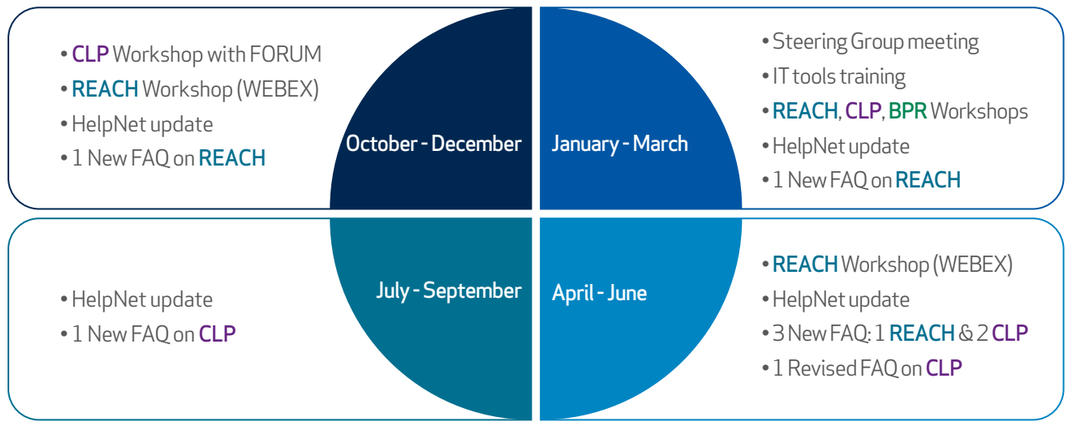
The workshops also provided opportunities for national helpdesks to share experiences drawn from their own awareness-raising and information activities. Sharing their knowledge and insights with communication professionals, a group of HelpNet members contributed to the Agency's 'REACH 2018' communicators' network.

Correspondents from national BPR helpdesks took part in a workshop and an IT training event on R4BP 3 and IUCLID. The CLP HelpNet members met for two workshops, one of which took place alongside the Forum's 'train the trainers' event.

During 2017, the HelpNet Secretariat kept members abreast of developments through four 'HelpNet Updates'. For companies, HelpNet published three new 'frequently asked questions' and updated another four as an outcome of consultations between its members, using the HelpEx tool.

In March 2017, all national helpdesk correspondents – representing BPR, CLP and REACH national helpdesks – convened for the annual HelpNet steering group meeting, which covered a wide range of topics.

FIGURE 22: HelpNet activities



This meeting was the occasion for ECHA and participants to celebrate the 10th anniversary of the HelpNet, which was launched as the very first collective ECHA activity in February 2007, even before the Agency itself became operational. At the time, the HelpNet still operated under the name of REHCORN (REACH Helpdesk Correspondents Network). The minutes of the steering group meeting include a photograph documenting this celebration[18].

Security Officers' Network

The The Security Officers' Network advised ECHA on the secure exchange of information pertaining to the REACH, CLP, PIC and Biocidal Products Regulations, between ECHA, MSCAs, mandated national institutions and the Commission.

In 2016, they reflected critically on the security model, and mirroring the experience they had gained over the last five years, they appointed a task force group with the aim of having the new security model in place in 2017.

In April, 42 security officers representing 40 national authorities in EU/EEA Member States gathered at ECHA for their 14th meeting and approved the reform of the security model. The reformed model is streamlined and better aligned with the current status of IT systems and remote-access solutions. Furthermore, it recognises that the key to ensure security is to raise awareness among those individuals using the systems.

Midway through the year, ECHA's Management Board endorsed the reformed security model which – after a six-month transition period – was scheduled for launch on 1 January 2018.

18 Steering Group minutes, as well as those of the HelpNet regulatory workshops, are accessible at: https://echa.europa.eu/about-us/partners-and-networks/helpnet

ABOUT HELPNET

National helpdesks provide advice and assistance to companies established in the 31 EU and EEA countries on fulfilling their obligations under the EU chemicals legislation. HelpNet supplies updated information on regulatory developments, as well as the guidance and tools available to duty holders. Candidate country and industry association helpdesks are involved as observers.

ABOUT SON

The Security Officers' Network (SON) is a grouping of experts appointed by the Member State Competent Authorities (MSCAs), Mandated National Institutions (MNIs), the European Commission and the accredited industrial association CEFIC to represent industry. SON ensures that a solid and shared security model is applied when the organisations represented are granted internet access to restricted or highly restricted data in ECHA's databases. ECHA's Management Board has given SON a formal role in reviewing security requirements, agreeing on any deviations and in preparing security-related audit guidelines. SON provides advice to ECHA on security issues related to accessing to the Agency's IT systems, and on the exchange of information pertaining to the REACH, CLP, BPR and PIC Regulations, between ECHA, MSCAs, MNIs and the European Commission. It also advises on security issues related to scientific IT tools (such as REACH-IT, R4BP 3, ePIC, IUCLID, portal dashboard) and the external collaboration platform S-CIRCABC.

The Network consists of 80 Security Officers from 63 organisations in 31 EU/EEA countries and meets once a year.

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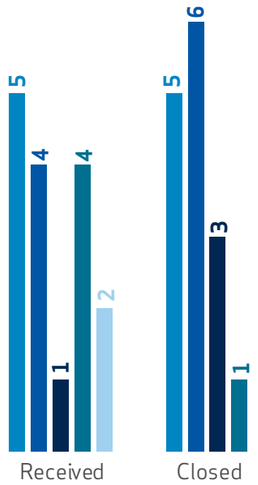
Year in numbers

16
new appeals

15
final decisions

FIGURE 23: Appeals in 2017



Board of Appeal

Decisions clarifying key issues

In 2017, the Board of Appeal (BoA) decided on appeals related to important aspects of REACH. For example, its decisions clarified how REACH applies to nanomaterials and in particular the information required for the registration and evaluation of nanoforms; the interaction between REACH and other EU legislation, such as the Cosmetics Regulation, and the consequences of legal certainty; the 'relevant conditions' under which ECHA can request further persistence testing; the correct choice of REACH process for requesting standard information; and under what conditions 'standard information' can be requested under substance evaluation. The Board of Appeal also further clarified the 'every effort' criterion for data sharing under the Biocidal Products Regulation.

Main achievements

The Board of Appeal adopted 15 final decisions in 2017. During this period, 16 new appeals were received and 20 cases were pending at the end of 2017 (16 under REACH and 4 under BPR). Measures taken to ensure procedural efficiency are proving effective. Appellants increasingly file cases jointly (the 15 cases closed in 2017 involved 62 companies). On average, the cases closed in 2017 lasted a little over a year. The more legally and scientifically complex cases that reached a full decision in 2017, in particular several substance evaluation cases, took between one and two years to complete.

Nanoforms

The application of REACH to nanoforms was an important issue in cases decided in 2017. As regards substance evaluation, the Board of Appeal highlighted that ECHA can request further information on nanoforms if there is a potential risk that requires clarification. However, a substance does not automatically present a potential risk simply because it is a nanoform[19].

As regards registration/dossier evaluation, the Board of Appeal decided a case in which ECHA had requested detailed substance identity information on the nanoforms covered by a registration for titanium dioxide[20]. The Board held that the information requirements for registration purposes concerning substance identity are clear and precise and cannot be extended by ECHA. Information on the size, shape and surface treatment of nanoforms is not required for registration.

However, it also held that giving a broad substance definition, such as including the bulk form and nanoforms of a substance under a single registration, has consequences: the human health and environmental hazards posed by all forms of the substance covered by the registration must be addressed by the data in the registration dossier. ECHA can verify this through a compliance check.

Relationship of REACH and the Cosmetics Regulation[21]

REACH includes obligations that may require substances to be tested on vertebrate animals, whilst the Cosmetics Regulation provides for a marketing ban on cosmetics containing ingredients tested on vertebrate animals. The Board of Appeal held that if ECHA requires a registrant to test a substance used only as a cosmetic ingredient on vertebrate animals, it must examine the implications this may have with regard to the Cosmetics Regulation and a possible marketing ban and address this point in its decision[22].

Substance evaluation

Despite the growing body of decisions, aspects of the substance evaluation procedure are still the subject of appeals. For example, the Board of Appeal examined requests for further information that can also constitute standard information for registration purposes. It held that standard information can be requested under substance evaluation provided that the request is based on a potential risk, the requested information will help to clarify the potential risk, and the registrants' rights are respected as they would be in the CCH procedure[23].

In one case, the Board also examined the rights and obligations of downstream users. It concluded that companies do not have the standing to file an appeal against a substance evaluation decision solely because they are downstream users of that substance[24].

In another decision, the BoA found that ECHA must establish that a required test can provide results which will help clarify the concern being investigated, although this is not always simple. When drafting its decisions, ECHA should take this issue into account[25].

"2017 has been a productive year for the Board of Appeal and its Registry. Most of the 'hard' issues under REACH end up before us eventually, and we have shown that we are up to the task. We are proud of our achievements and look forward to the first judgments from the General Court on our decisions.

Mercedes Ortuño,
Chairman of the Board of Appeal

19 Case A-014-2015, Grace and Advanced Refining Technologies, and Case A-015-2015, Evonik Degussa and Others
20 Case A-011-2014, Huntsman P&A UK and others
21 Regulation (EC) No 1223/2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)
22 A-013-2016, BASF Personal Care and Nutrition
23 Case A-023-2015, Akzo Nobel and Others
24 Case A-022-2015, Michelin
25 Case A-026-2015, Envigo Consulting and DJChem Chemicals Poland

Biocidal Products Regulation

The Board of Appeal examined various aspects of the data-sharing procedure under the BPR and further interpreted what the requirement to make 'every effort' to share data and costs means[26]. In particular, it held that ECHA must examine the efforts made by both parties in order to determine whether a data claimant made 'every effort'.

Other developments

Two actions for annulment were filed before the General Court against Board of Appeal decisions[27]: both concern the scope and/or intensity of review by the Board.

26 Case A-001-2016, Troy Chemical Company
27 Case T-125/17, BASF Grenzach v ECHA; Case T-755/17, Germany v ECHA

Management

ECHA is governed by a 36-member Management Board. The Board appoints the Executive Director who is in charge of the Agency's day-to-day management and administration. The Executive Director is also a legal representative of the Agency and reports to the Management Board. The Executive Director is supported by the senior management team.

Year in numbers

103
accredited stakeholder organisations

1800
general enquiries

57
decisions on access to documents

First decade prepares ECHA for the next

In 2017, ECHA celebrated its 10th anniversary. It was a moment to reflect on developments in the Agency and its management of chemicals in Europe, also in light of the EU's commitments to the UN sustainable development goals. It also marked the end of an era under the pioneering leadership of ECHA's founding Executive Director Geert Dancet. His successor, Bjorn Hansen, will continue the good work in what has become a dynamic and challenging regulatory environment. The Agency has prepared the basis of a strategic approach to this phase.

Main achievements

Working towards the United Nations World Summit on Sustainable Development Goals

The 2020 goals for chemicals management, as defined by the United Nations World Summit on Sustainable Development (WSSD), remain the key driver for ECHA's strategic direction. In 2017, the Agency further strengthened its commitment towards successful implementation of these goals which have become an integral part of ECHA's activities.

Together with the Management Board and Member States, ECHA continued to develop a strategic plan for managing chemicals beyond 2020 – in the context of the WSSD goals and the EU's next multi-annual financial framework. This provides clarity and direction not only for the Agency but also for industry, consumers, regulators and other stakeholders.

On request, the Agency provided input to the European Commission's ongoing review of chemicals legislation. The outcome of this exercise will also be relevant to ECHA's future regulatory work.

ECHA's new strategic plan will be implemented under the leadership of Bjorn Hansen, its new Executive Director, who was elected to the post by the Management Board at its September meeting. As part of the process, he was invited to the responsible European Parliament committee and replied to questions from the Members of Parliament. Bjorn Hansen signed his contract in December and the Secretariat ensured a smooth handover for business continuity.

Transparency of ECHA's work

Throughout 2017, the Agency lived up to its values of transparency and independence. These values were demonstrated during ECHA's contribution to the controversial public debate about glyphosate. During these discussions, the Agency brought in its scientific expertise and explained its well-established practices to the public in an open and proactive way.

As a result, ECHA's process for providing scientific opinions through the RAC stood up to intense scrutiny from stakeholders and the public. In a dedicated hearing at the European Parliament, the Agency assured MEPs that transparency and independence are indispensable pillars of its work on chemicals – even though there may be different points of view on how to interpret scientific information. This experience reinforced confidence in ECHA's procedures for ensuring transparency and how it deals with perceived conflicts of interest. Both elements are key to public and stakeholder trust in ECHA's impartial and objective work.

In terms of its own staff, the Agency also reviewed its post-employment rules to ensure transparency and independence. These rules aim to achieve a fair balance between public and individual interests (see box).

"When I look back, what do I see as the achievements of ECHA? The first thing is the progress we have made towards our ultimate goal – safer chemicals in Europe, and protecting human health and the environment from their toxic effects – in line with the UN sustainability goals for 2020. What could be more important than that?"

Geert Dancet, ECHA Executive Director 2007–2017 at the 10-year anniversary conference, 7 June 2017

MORE TRANSPARENCY ON POST-EMPLOYMENT RULES

The handover from ECHA's first Executive Director, Geert Dancet, to his successor led to a review of how post-employment rules apply to the head of the Agency. Under Article 16 of the EU Staff Regulations, all staff have a duty to request authorisation for new occupational activities for the first two years after leaving the Agency. ECHA can either forbid the new activity or impose conditions.

Post-employment rules aim to prevent former staff members from using their positions to gain special advantages from their new clients or employers. They also seek to provide staff with a reasonable freedom of choice regarding employment, while promoting trust in public service.

For senior managers, specific provisions prohibit them for 12 months from engaging in "lobbying or advocacy" towards the Agency's staff on matters for which they were responsible during their last three years in the service. The provisions also require ECHA to publish information each year on the post-employment activities of senior managers.

As a result of the review, ECHA will also publish an overview of the post-employment decisions on former senior managers, including their names, date of departure, positions, their foreseen new occupational activities, and the outcomes of ECHA's assessments. This additional transparency will start with the conclusion of the first Executive Director's mandate.

Hot topics in the media

- 2018 REACH registration deadline
- Classification of glyphosate
- Endocrine disrupting chemicals
- Impact on REACH due to the UK withdrawal from the EU
- Safety of:
  - rubber crumbs used on artificial pitches
  - tattooing inks
  - titanium dioxide
  - Bisphenol A

ECHA's 10th anniversary

The Agency's 10th anniversary celebration highlighted its achievements as an agile and modern regulatory organisation during the tenure of the first Executive Director. It brought together key people, including those who had contributed to establishing the Agency and those who are currently shaping its future.

Finland, ECHA's host state, celebrated its centenary as an independent country in 2017, which provided an opportunity for participants to reflect more widely on European integration and the role of decentralised agencies. Such a reflection also revealed the challenges for chemicals regulation in the coming decade.

An exhibition at the European Parliament focused on the benefits of REACH and its associated legislation, and highlighted the complex nature of ECHA's work based on science.

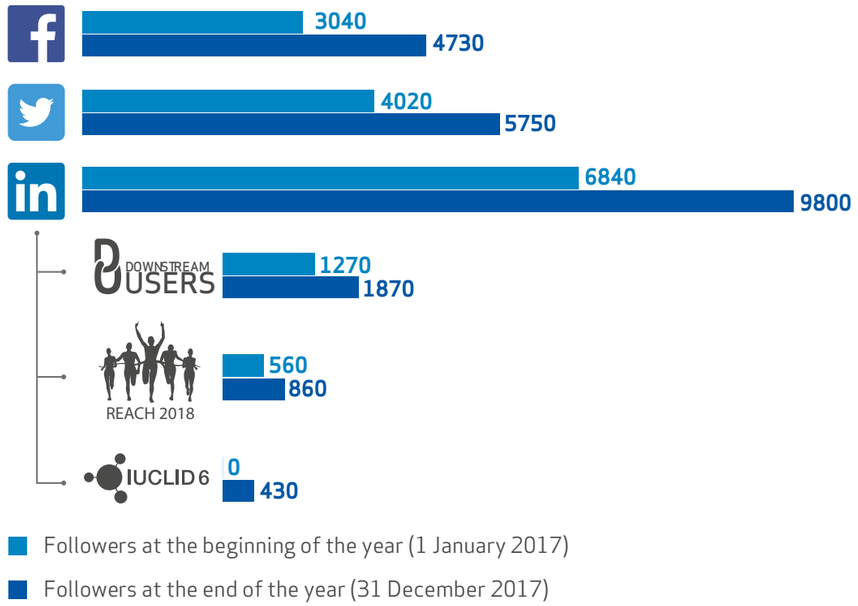
In a new initiative, ECHA together with its Board of Appeal brought together judges, legal advisors from other agencies and Member States as well as other legal experts in a litigation seminar to discuss the similarities and differences of the European Courts and Boards of Appeal. The Court of Justice of the European Union and ECHA's Board of Appeal clarified a number of questions related to the Agency's area of responsibility, while other issues are still being debated. An exchange of different legal viewpoints in a more open forum helps to provide further clarity and resolve issues as they arise.

Communications tailored to reach target audiences

ECHA continued to pay attention to the sensitivities around risk communication. The Agency improved the readability and accessibility of online information by introducing a new layout on its website. It also launched and further expanded topical web pages, such as those on the EU Observatory for Nanomaterials and on communication in the supply chain. The number of people following ECHA on social media increased significantly, widening the audiences directed towards news and support available on the website. ECHA maintained its commitment to reach out to smaller companies and interested members of the public.

Following the United Kingdom's notification to the EU on 29 March 2017 of its intention to withdraw from the Union, ECHA intensified its preparations to address the consequences. One of ECHA's senior managers took on the role of coordinating these preparations, which include modifying IT tools to address the new circumstances. The Agency also launched dedicated web pages to inform chemical operators about the expected impact of the UK withdrawal on all duty holders. The European Commission and many stakeholders appreciated the clarity this information provides at a time when uncertainties still abound.

FIGURE 24: Uptake of ECHA's content though social media



INTERNATIONAL ACTIVITIES

ECHA's main international activities focus on collaborating with the OECD as this creates direct synergies with the Agency's operational work. It advanced the work on IUCLID, including the collection and prioritisation of user requirements for further developing the tool. Similar collaboration led to the release of a new version of the QSAR toolbox and use descriptions of articles. The Agency also contributed to the development and updating of test guidelines and alternatives to animal testing, to nanomaterial activities at the OECD, as well as to various risk management activities.

ECHA shares experience and knowledge with an increasing number of regulatory authorities in countries adopting chemicals safety legislation similar to that in the EU. The activities contribute to improving the quality of data, classification and labelling, enabling the safe manufacture and use of chemicals. They also enable third-country actors to identify and address chemicals of concern.

In 2017, raising awareness of the upcoming 2018 registration deadline was the focus of ECHA's international activities. For example, the Executive Director visited China and India, two major exporting countries to the EU, to explain to exporters and their associations Europe's regulatory needs – in particular, addressing SMEs not yet familiar with their duties under REACH and CLP. This facilitates the registration process for operators in such countries. In addition, ECHA concluded an exchange of letters with Switzerland for future cooperation.

It also provided scientific and technical support to EU candidate countries preparing to implement REACH, CLP and BPR. This work is being carried out under the European Union's Instrument for Pre-accession Assistance (IPA) funded by the Commission.

General management activities: focus on quality, efficiency and data

ECHA's stakeholders demand the efficient use of the Agency's resources, compliance with its founding regulation and applicable rules, as well as transparent operations and decision-making. It has invested in meeting these requirements by improving its Integrated Management System (IMS).

In 2017, ECHA's environmental management system, which aims to achieve an environmentally friendly workplace, received ISO 14001:2015 certification. Its certification under the latest quality standard ISO 9001:2015 was also successfully renewed. All quality-related information can now be accessed and handled in one place via a new integrated IT tool.

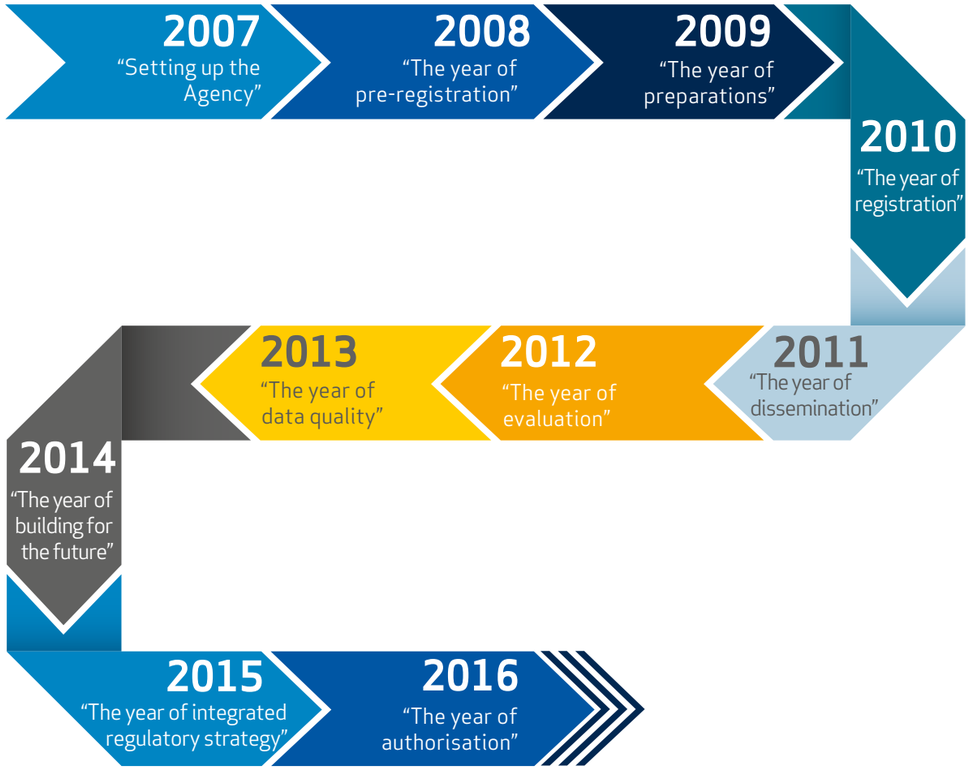
The Agency continued to improve efficiency and process coordination in 2017. The focus was on substance evaluation, the review programme under BPR, and the work of the ECHA committees. These processes were scrutinised for possible improvements by using alternative approaches and better coordinating administrative support.

The data held on chemicals is one of the Agency's most valuable assets – enhancing the accessibility and usability of such data is of interest to all EU regulatory agencies. As part of a European Parliament initiative, ECHA, the European Food Safety Authority and the European Medicines Agency started to consider how to handle data in a common way, thereby intensifying their existing cooperation. Ultimately, the rather technical work on harmonised data standards which enables ease of access, search, analysis and reuse – revealing cross-sectoral relationships of possible chemicals of concern and identifying gaps in knowledge that require further work – will help to achieve the main goal of ECHA's legislation, i.e. protecting human health and the environment.

The Agency digitised its paper files for archiving and made them more available for internal use. When ECHA started operations in 2007, it inherited documents used under predecessor legislation to REACH, including those drawn up under the old Directive 67/548/ EEC – these are now digital. They remain relevant to ECHA's regulatory strategy as background information for substance assessment and for mapping the chemical universe. Digitising historical archives containing relevant information on chemicals further strengthens ECHA's core underpinning as the EU's hub for knowledge and information on chemicals.

In 2017, the Agency received and followed up on 13 external complaints in accordance with its certified quality management system, with a reply to the complainants.

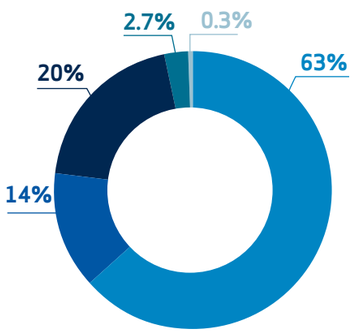
FIGURE 25: Achievements 2007-2016 – ECHA's General Report titles



Resources

Finance, human resources, corporate services, communications and information and communications technology (ICT) functions are needed for an organisation with stable and reliable funding, services, competences and a place of work.

FIGURE 26: Expenditure committed in 2017



Financial resources

Financial targets met

The mixed financing regime – a combination of EU subsidy and income from fees – continued to be challenging. This was primarily due to the difficulty associated with accurately anticipating fee levels from incoming registrations and applications. ECHA reacted swiftly to this variability by adjusting the budget throughout the year, while continuously maintaining high standards of financial governance.

Main achievements

With the REACH 2018 registration deadline approaching, the precise level and scheduling of fee-based financing was difficult to foresee. The chemicals market is extremely dynamic and opaque. Companies decide on their registration approach independently following their individual business decisions and undisclosed strategies.

The total fee income amounted to around EUR 42 million, of which EUR 34 million came from REACH/CLP fees and EUR 8.1 million came from biocides. This was higher than anticipated for the year and, as a result, the total fee income covered 39% of ECHA's 2017 budget.

The more favourable fee-income receipts during the year meant that ECHA was able to reduce the EU subsidy claim by 7% (EUR 5.2 million) for the REACH/CLP budget and 12% (EUR 0.6 million) for the biocides budget.

The Agency's total spending budget reached the same level as the previous year: the REACH/CLP budget decreased slightly and was balanced by an increased biocides budget. The PIC budget remained unchanged.

Sound financial governance

There were no findings from the 2017 audits conducted by the European Court of Auditors. This achievement is evidence of ECHA's sound financial governance and solid internal controls. In addition, the Agency was able to meet all of its financial targets while maintaining high standards of income and expenditure monitoring. Furthermore, it continued its efforts to improve the efficiency of its financial operations by introducing new tools and initiating measures to upgrade its financial information management system.

Financing details

Total revenue received under ECHA's REACH/CLP Regulation, including the EU subsidy, amounted to EUR 101.1 million. Consequently, EUR 4.5 million will be returned to the Commission, based on the positive annual financial result. Compared to 2016, income from fees and charges rose by 2% to EUR 34 million. As observed in the past, the majority of fee income originated from the registration of substances in the highest tonnage band, over 1 000 tonnes.

Total revenue received under the Biocidal Products Regulation, including the EU subsidy, amounted to EUR 12.2 million. This sum included a biocidal fee revenue of EUR 8.1 million which is 5% lower than the previous year but higher than initially budgeted, mainly due to more applications for Union authorisation. However, this surplus in income was largely absorbed by the need for more IT development expenditure.

ECHA received a EUR 1.2 million contribution from the EU for the PIC Regulation.

The Agency's financing exceeded the targets for its commitment and payment rates (key performance indicators), with 98% (95% target) and 88% (80% target) achieved respectively.

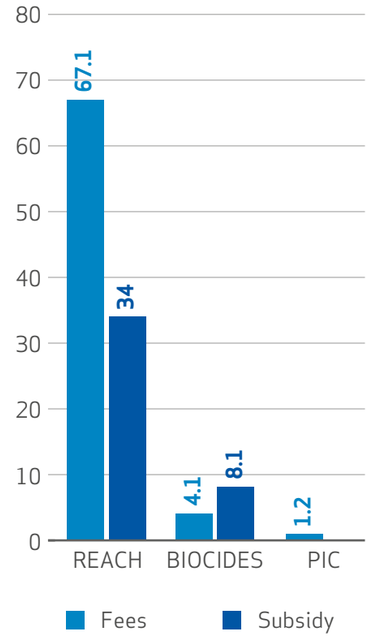
SME status checks

The Agency continued its systematic verification of the status of those companies which previously registered as SMEs and thus benefited from SME fee reductions. As a result, 332 companies which registered under the REACH/CLP regulation as SMEs were checked and the status of 50% was changed. This robust verification effort brought in an additional EUR 3 million in fees and charges resulting from the identification of wrongly declared company sizes. In addition, ECHA completed an ex-ante verification of company size for 28 companies under the Biocidal Products Regulation.

Going digital to improve operational efficiency

In 2017, the Agency enacted several measures to improve financial operational efficiency. These improvements included a new digital work-flow tool for the internal verification of registrants' SME size, and use of the existing REACH-IT system as the sole means of official communication with SMEs. The Agency also started using a new web-based system to conduct low-value procurements in a more cost-effective manner. It signed an agreement with the Commission to achieve greater efficiency by moving to electronic invoicing and the electronic submission of tenders, which will start in 2018.

FIGURE 27 : Financing per regulation in 2017 (in EUR m)



Year in numbers

561
total staff

98 %
of posts filled by year end for REACH/CLP, PIC and BPR

86 %
response rate in 2017 staff survey

Human resources

Committed people to achieve our tasks

By maintaining a proactive approach to human resources, HR management was able to fill all of ECHA's available establishment plan posts for REACH/CLP, the BPR and PIC in 2017. In addition, the turnover rate of statutory staff remained very low. Together with a balanced learning and development plan which combined directorate, unit and individual learning needs, HR contributed to ensuring that the Agency has the necessary number of motivated and skilled staff at its disposal.

Main achievements

The Agency's recruitment target was achieved with 98.26 % of posts filled at the end of the year for REACH/CLP, PIC and the BPR. This result is in line with the 2018 establishment plan, as of 1 January 2018 – i.e. six fewer posts to comply with overall staff reductions of 2 %, as communicated in COM (2013)519 final) for REACH/ CLP.

Overall, ECHA's staff planning is becoming increasingly demanding due to the ongoing need to take into account the cutting of posts which has been imposed on the Agency. ECHA fully implemented the reductions foreseen in 2017 for authorised staff numbers in REACH/ CLP. In the absence of a corresponding decrease in the Agency's workload, it had to focus on workload prioritisation (related staff allocation) and efficiency gains. At the end of 2017, ECHA's turnover rate was 6.1 % for contract agents and 2.9 % for temporary agents.

The performance management and contract renewal processes were more closely aligned with the general requirement to deliver all of the Agency's tasks and objectives using fewer human resources. Achieving the same output with fewer resources requires highly motivated and committed staff members who are able to demonstrate efficiency and initiative in their respective roles within ECHA

Staff survey

In 2017, a staff engagement survey was conducted and achieved an 86 % response rate, which is comparable to the previous survey in 2015. In accordance with international benchmarking data provided by the service provider, the current overall staff engagement score categorises ECHA as an organisation demonstrating "strength" in this important area. Based on the survey results, each unit and directorate has formulated specific action plans to best respond to their needs. In parallel, the corporate-level action plan focuses on developing three priority areas: organisation efficiency, working culture and motivation.

The new HR portal was further developed in 2017 to integrate different HR procedures into a single IT tool while improving the efficiency of the underlying processes. For instance, implementation of an electronic payslip system contributed to ECHA's internal efficiency and commitment to become a more environmentally friendly workplace.

Furthermore, in 2017, ECHA continued to implement decisions and clarifications related to staff entitlements upon recruitment and during their service at the Agency, resulting in a number of gains in both efficiency and savings for the organisation.

Planning for the 2018 peak

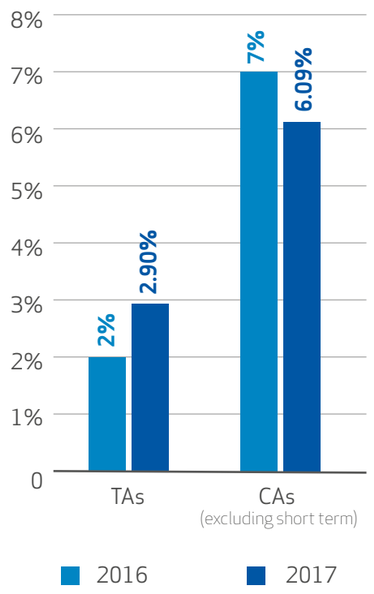
A screening/benchmarking exercise was conducted at the end of 2017 and confirmed the increase in operational staff, while the number of staff working on horizontal activities fell.

HR also participated in the Agency's preparatory group for the 2018 registration deadline and designed a staffing plan to meet temporary additional workforce requirements for 2017 and 2018. This plan has been implemented by recruiting additional short-term contract agents, interim staff and trainees, as well as redeploying a number of internal staff for these activities.

In 2017, ECHA significantly increased teleworking possibilities (structural and occasional) for staff as a further step in developing the Agency's modern ways of working agenda. This helps staff plan their working days more independently whilst being managed according to deliverables rather than their physical presence in the building. The first review of the new teleworking policy showed a high level of acceptance and delivered positive feedback from both staff members and managers.

In the area of staff well-being, ECHA introduced an early support policy that follows the practice under Finnish occupational health care. In practice, ECHA managers are required to address any signs of physical or psychological distress among their staff as early as possible to ensure staff well-being and avoid prolonged periods of sick leave.

FIGURE 28 : Turnover of statutory staff



Year in numbers

1 822
meeting supported by audio-visual team

10 300
visits by external participants

Corporate Services

Demand for an increase in services

The unit met the demands of a challenging year with increased activity in all areas of work. One significant organisational achievement was the key role the corporate services unit played in establishing a new leasing contract for modern and safe premises when the Agency's current lease expires on 31 December 2019.

Main achievements

As the lease on the current premises expires at the end of 2019, a number of important preparatory activities relating to the selection of the Agency's future building were undertaken during 2017. These included an extensive procurement procedure and evaluation.

A proposal based on ECHA's specific requirements was prepared, sent to the budgetary authority and was approved in November 2017. The lease contract for ECHA's new premises was signed in December 2017. The new building will provide a modern and safe working environment while striving to minimise the environmental impact of the Agency's activities. It will include modern conference and meeting facilities and provide office space for around 650 people.

ECHA's conference and meeting facilities hosted 10 030 visits from external participants (an increase of 0.5 % on 2016). In parallel, 11 890 people participated in virtual meetings or webinars over the year (an increase of 48 % on 2016), with many of the webinars related to the REACH-2018 registration programme. Since 2015, the number of virtual participants has grown by 80 % (from 6 600 to 11 890), enhancing collaboration and widening horizons for disseminating information and training. During 2017, the audio-visual team supported 1 822 meetings and events (up 15.3 % on 2016). In addition, the audio-visual infrastructure in ECHA's BoA hearing room was significantly upgraded during 2017 to support the digital transmission of images and give participants an enhanced viewing experience.

Following on from the above, the event logistics management tool was launched in November 2017. The aim of the tool is to improve ECHA's approach to the organisation of meetings and events through more automation, to facilitate better reporting and, in general, to streamline the overall process.

There was further demand on the corporate services unit to provide a working area for the additional office space required for the 2018 registration deadline. As part of the planning for the deadline, the unit arranged for some of the conference facilities to be used during the registration deadline period, including the procurement and delivery of tables, chairs and other physical facilities. Consequently, this has put additional pressure on the availability of meeting facilities in the conference centre.

During 2017, a number of air-quality issues were addressed with the landlord and an air-quality survey was carried out by the Finnish Institute of Occupational Health.

In 2017, a new contract was drawn up for the provision of cleaning, security and reception services, which enabled the Agency to secure the required services at a lower cost. The project to install ergonomic electric work desks for all staff members was completed and a crisis management exercise for ECHA's strategic and operational groups was held in November 2017.

Finally, the corporate services unit was instrumental in the organisation and success of several additional events held to commemorate ECHA's 10th anniversary.

> *"The lease contract for ECHA's new premises was signed in December 2017.*

iTEX

The external IT service provides valuable support to industry and the MSCAs. In 2017, iTex resolved 5 049 incidents.

ICT

ICT gears up for REACH deadline

With the expected increase in workload due to the approaching REACH registration deadline in 2018, ECHA's IT department reviewed and updated key IT tools for industry and strengthened IT support and business continuity. In addition, the Agency has been promoting environmental awareness by adopting new technology and practices, getting closer and closer to achieving green IT.

Main achievements

Thanks to improvements in key tools, such as the ECHA Cloud Services, smaller businesses now have faster and simpler ways to prepare dossiers for the registration deadline.

To deal with the increased workload, services directed at the Agency's stakeholders have been strengthened: temporary external staff has been contracted and ECHA staff redeployed as required, for example, in the external IT (iTex) support team.

To help SMEs meet the deadline and reduce their administrative and financial burden, IUCLID Cloud Services was released during summer 2017. Since then, the number of SMEs using the service has grown steadily in parallel with the registrations received for the 2018 deadline. By using the service, SMEs no longer need to download and install the IUCLID application – and its regular updates – on their own computers or IT servers. Data is securely stored and backed up by ECHA. The cloud solution is completely private, as user data cannot be accessed by anyone else or lost. Securely sharing data is now easier and SMEs need fewer resources to manage the installations and hardware to host and update IUCLID. Furthermore, they can now benefit from faster responses to questions and 24/7 service availability.

'Greening' up our act

ECHA has taken vital steps towards achieving its green IT targets while, at the same time, supporting mobile and location-independent work.

The new facilities include a new generation of printing services, lightweight devices and replacing landline phones with mobiles. This has resulted in a noticeable increase in teleworking, while the new "follow-me" printing devices have helped to reduce the Agency's environmental footprint.

REGISTRATIONS FOR BIOCIDAL PRODUCTS (R4BP)

Companies planning to bring to the market biocidal products in EU Member States use the R4BP system for the registration process. The system was launched in September 2013.

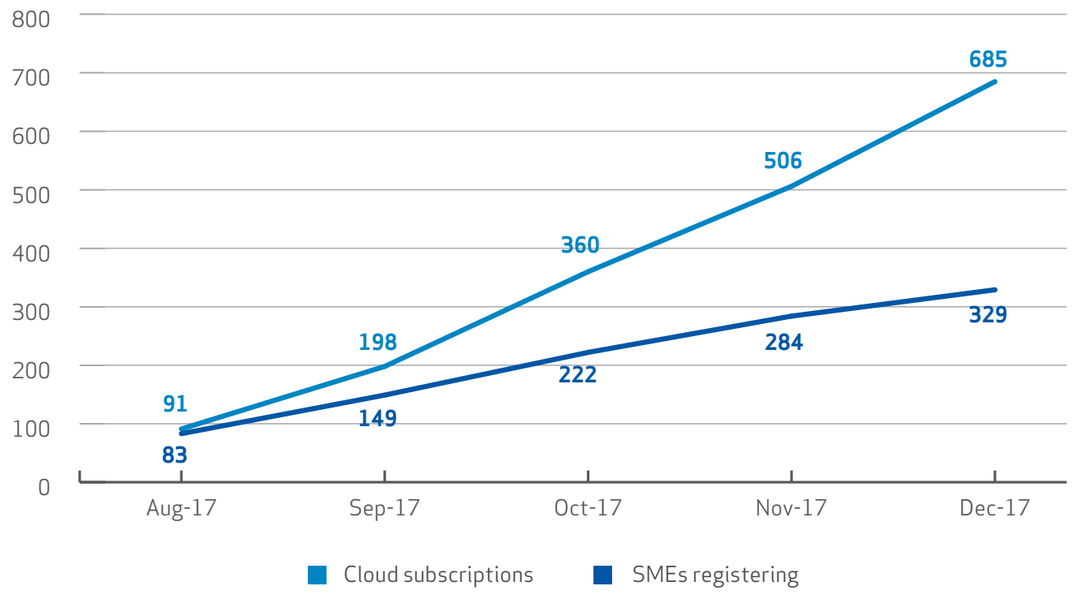
A steady increase in the number of R4BP submissions was observed during 2017. The following metrics illustrate 2017 growth in the use of the R4BP3 system:

	Total end 2016	New 2017	Total end 2017	% change
Cases[28]	20 923	7 600	28 523	+36 %
Assets[29]	9 182	403	9 585	+4 %

28 A case relates to an application by industry users and is created with a unique case number in R4BP after the successful submission. It includes all the steps in the application process which lead to the creation of, or update of, an asset (the regulatory decision). The purpose of a case is to manage and view progress of the submission by both industry and authority users.

29 In the R4BP context, an asset is a regulatory decision on an application with a unique asset number related to either an active substance (e.g. a decision on technical equivalence or the Article 95 list) or a biocidal product (e.g. a national authorisation or EU authorisation).

FIGURE 29: IUCLID Cloud Services



Agency risks

ECHA conducts an annual risk assessment exercise to identify, assess and manage the potential events that could put at risk the achievement of the objectives defined in the annual work programme. Senior management followed up the implementation and reviewed the effectiveness of the risk mitigation measures on a quarterly basis during 2017.

Based on this assessment, ECHA's management identified eight main risks which were included in the corporate risk register. Senior management also agreed that four of the risks should be reduced by specific actions described in the action plan relating to the risk register and four should be accepted provided that they are due to external factors on which ECHA has no or limited influence. The risks for which an 'accept' response was chosen were strictly monitored throughout the year to determine whether the triggers of their likelihood and impact increased or decreased.

Senior management followed up the implementation and reviewed the effectiveness of the risk mitigation measures twice during the year (T1, January to April and T2, May to August). The final review of the risk register is carried out after the year end (T3 follow-up) and the analysis of the risks and mitigation measures taken is included in the Agency's Consolidated Annual Activity Report for that year.

In the last follow-up at the beginning of 2017, management concluded that the actions taken to mitigate the risks had been implemented according to the plan, had proved effective and had not lead to major secondary risks.

In 2017, one of the risks with highest impact, which materialised as of 31 December 2017, was related to achievement of the Biocides Review Programme target set at 50 opinions per year. Even though ECHA undertook mitigating actions both in 2016 and 2017 – such as creating guide templates, supporting the quality of the assessment reports, and using scenario planning to be able to respond to different market situations – the review programme target was not met in two consecutive years (31 of the foreseen 50 opinions were adopted in 2017 and 41 in 2016). This was mainly due to a number of MSCA deliverables being postponed.

None of the other risks impacted the execution of the 2017 Work Programme, and some will remain relevant in the future.

The risk ranked highest by the directors when the initial risk assessment was made concerns the smooth processing of registration dossiers for the 2018 deadlines. In particular, this refers to the smooth functioning of and capacity development in the OSOR (one substance, one registration) and enhanced technical completeness check (TCC) projects during a period of insufficient resources. The risk has been managed correctly for years by proper recruitment planning and good cross-unit cooperation. The stable submission rate has also been beneficial, reducing the likelihood of the risk in 2017. However, the risk will remain high in 2018, due to the uncertainty surrounding the submission rate during this year and its potential mismatch with the planned recruitment.

Another risk related to the 2018 registration deadline is the potential delay in implementing new functionalities and efficiencies in the REACH-IT software. This has been managed through holistic planning, proper scope management and extensive staff training. The risk is relevant and must be properly managed in 2018, too, through early (re-)deployment of resources, training and good cooperation with the contractor.

The risk concerning the lack of a financial balancing mechanism, which also existed previously, did not materialise in 2017. Due to the higher than expected income received for 2017, ECHA was able to cover its expenditure. Thus, the financial risk did not materialise last year but remains high for the years to come.

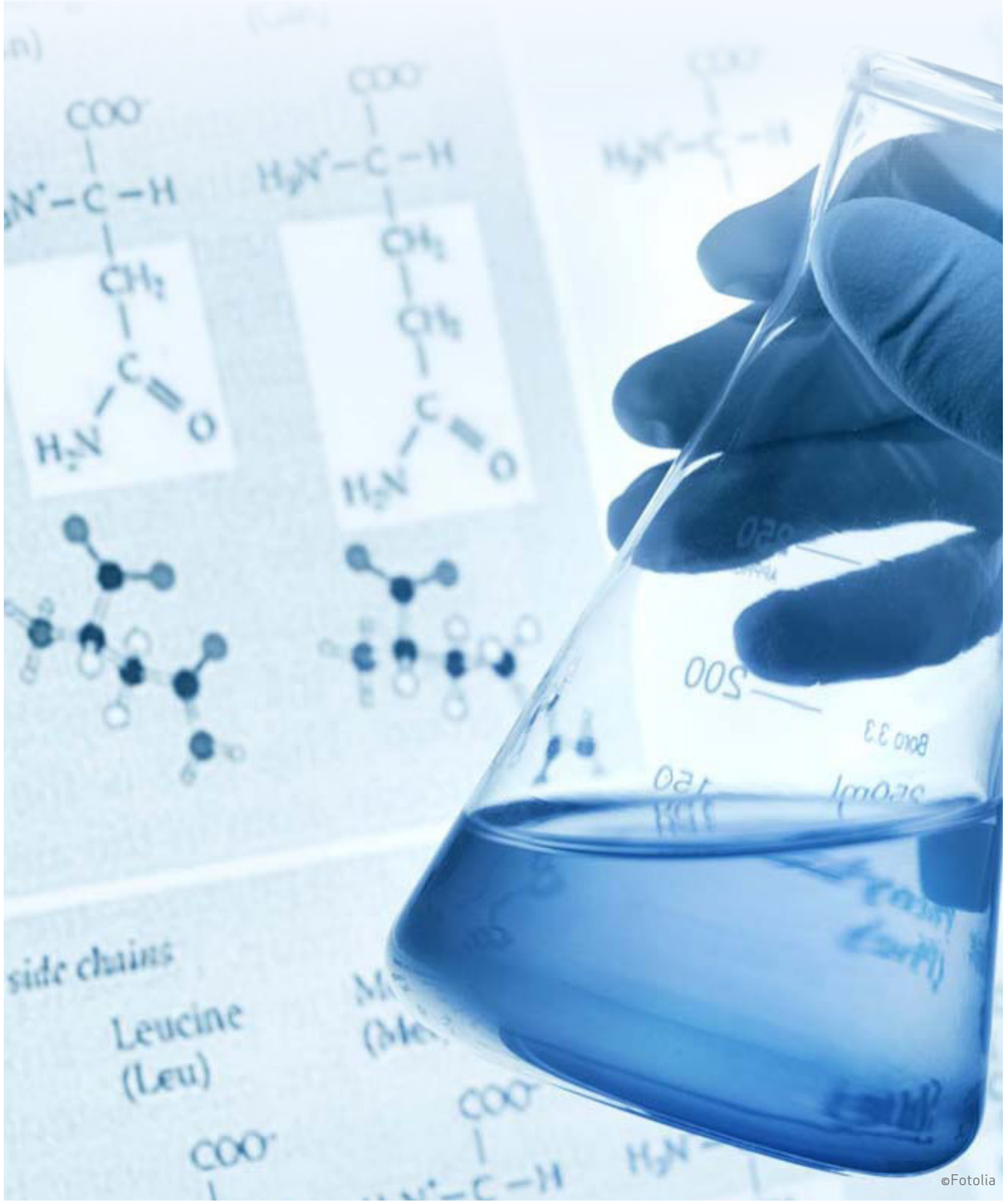
One risk was related to the IRS, in particular not making sufficient progress in the characterisation of substances and regulatory actions around substances that matter. This was mitigated mainly through a clear annual and multi-annual plan for triggering action by industry, tracking and tracing outcomes, informal interaction with certain priority category cases, and close monitoring and communication of SVHC roadmap activities to the MSCAs. This risk is also relevant for 2018 and work on the above-mentioned aspects will continue.

The risk with regard to ECHA's inadequate resources to provide the new and complex technical Cloud service solution, resulting in delays in the planned timetable, had not materialised as of 31 December 2017. The release of the Cloud service went according to plan, by the end of July 2017. A secondary risk concerning the actual use of the tool by the SMEs appeared during the year, thereby rendering the promotion of the tool a key for its success. The target number of SMEs registering was around 40 % or 2 000 subscriptions, while the actual number was considerably lower.

The risks related to the malfunctioning of ECHA's current premises, and in particular to air-quality issues, have been mitigated through specific short-term measures such as testing, measuring and improving the air quality, as well as through long-term measures, such as selecting a new building for the future ECHA premises as of January 2020.

The market risk for the authorisation applications, concerning a potential peak in applications, was successfully mitigated. The RAC and SEAC opinions are being processed with the expected level of quality and are meeting their deadlines despite a peak in the number of authorisation applications received.

APPENDICES



Appendix 1: Achievements of Work Programme 2017 by activity

1.1.1 Registration dossier preparation

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Implement ECHA's REACH 2018 roadmap, which outlines ECHA's plans for improving registration process, tools and support for the last registration deadline of phase-in substances, in dialogue with industry stakeholders, Commission and national authorities and specifically:		
(1) Monitor, via the various stakeholder networks, the need for specific support for SME registrants, and based on assessed demand arrange e.g. webinars, best practices or workshops on specific issues.	**Yes**	
(2) Provide advice to industry sectors that may face specific difficulties and develop registration guidelines suitable to their sector (similar to the essential oils sector in 2015-2016) with the aim of also improving data quality and compliance.	**Yes**	
(3) Provide support to registrants and downstream users via the Agency's SME Ambassador, in view of the expectation that companies will take their business decisions on continuing placing specific phase-in substances due for registration in 2018 onto the market only during 2017.	**Yes**	
(4) To further facilitate dossier preparation for SMEs that have comparatively less technical resources than the large companies do, ECHA intends to launch a centrally hosted and managed Cloud platform that will be accessible on-line, without any need for local installation and local data storage. According to this delivery model, companies will manage their data and prepare their registration dossiers online, on an ECHA hosted and supported service. It is estimated that using this option the SMEs segment of the chemical Industry could save approximately 5.4 Million Euros per year.	**Yes**	
(5) Improve the usability of IT tools for dossier preparation through releases of IUCLID and Chesar.	**Yes**	
(6) Revise ECHA's model for servicing users, to rely more on the national helpdesks as first point of contact particularly for SMEs to better cope with the presumably very high level of requests for end users' support on the IT tools. Special training, second level support and dedicated IT environments for the national helpdesk will be considered in order to enable local support to the use of the IT tools.	**Yes**	
(7) Intensify coordinated communication activities via various networks (such as the REACH Communicators' network), and using multiple communication channels (online, audio-visual, documentation, events and social media) in order to raise awareness among registrants.	**Yes**	
Support the fulfilment of information requirements:		
(1) Maintain the list of substances for which there is evidence that one or more Annex III criteria might be met and in which case all information requirements according to Article 12(1)(a) should be provided, unless evidence to the contrary is included in the registration dossier; provide support to registrants to make use of this list as needed.	**Yes**	
(2) Encourage downstream users, via awareness actions, to benefit from the harmonised means to communicate uses for registration purposes, and registrants to document the results of their chemical safety assessments in harmonised formats.	**Yes**	
(3) Maintain and improve tools for generating and communicating use and exposure information from downstream users to registrants, and promote the uptake of use map packages by registrants for their 2018 registrations and updates.	**Yes**	
(4) Promote the use of newly released QSAR Toolbox 4.0 for filling data gaps in 2018 registrations by giving trainings and publishing examples. Initiate the second part of the Phase III implementation of the QSAR Toolbox which includes both scientific and technical improvements.	**Yes**	
(5) Keep the amendments of published guidance on information requirements for REACH, to a minimum, in line with the Guidance Moratorium of 2016, and limit them to those necessary to accommodate legal developments, to ensure as much guidance stability as possible in the two years ahead of the 2018 REACH registration deadline. At the same time start reviewing the potential need for updating the guidance to scientific developments post 2018.	**Yes**	
(6) Promote Chesar and provide training to increase the number of users. Support to sectors for developing assessment inputs to registrants in Chesar format. Further development of the tool.	**Yes**	

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
ECHA will develop a strategy on the future development of exposure estimation tools and their relation to Chesar, as the quality of the CSA/CSR are to some extent dependent on them. The role of ECHA regarding these tools should be clarified. Future activities will depend on the decision on ECHA's role.	**Partially**	The vision document on the further development of Chesar referred to a potential ECHA strategy. However, it was not elaborated because 1) the topic is part of the programming document 2019-2021 for which MB agreement was needed; and 2) resources constraints. A workshop is planned in April 2018 to discuss stakeholders' expectations, scope and resources needs.
Continue communicating about correct use of alternative methods and approaches to replace animal testing. Increase transparency of ECHA's criteria and judgements in accepting or rejecting justifications for adapting standard information requirements and the use of weight of evidence.	**Yes**	
Report on the alternatives to testing on animals for the REACH Regulation (Article 117(3) report). ECHA will also publish a report on regulatory applicability of alternative and non-animal approaches.	**Yes**	
Continue activities of the Nanomaterials Working Group including the organisation of two workshops.	**Yes**	
Pre-registration and SIEF management		
(1) In order to optimise data sharing after closure of the possibility to pre-register mid 2017, adapt the inquiry process to be able to handle a large number of inquiries and ensure that potential new registrants of phase-in substances (newcomers on the European market) are put in contact with SIEF members of the last deadline.	**Yes**	
(2) Manage the increasing number of data-sharing disputes arising from the reinforcement of the OSOR principle in REACH-IT.	**Yes**	

1.1.2 Registration and dossier submission

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Process an increasing number of registrations (preliminary estimates up to ca. 7000 new registrations and 6000 updates). This may have an impact on the follow-up activities such as assessment of confidentiality requests and SME status verification. A majority of the new registrations are expected to be submitted for the 2018 deadline.	**Yes**	
Further develop the process and support for manual verification of completeness of information based on experience gathered in 2016, also targeting retroactively existing registrations to verify that the information provided is meaningful.	**Partially**	Assessment of the first year of the enhanced completeness check, including on existing registrations that were verified retrospectively, showed a positive outcome. The process and support for manual verification were refined based on experience. Two retrospective completeness check campaigns initiated in 2016 were concluded in 2017. Preparations for a new campaign started but could not be launched in 2017 due to resource constraints. This is planned to take place in 2018.
Ensure that all legacy cases of registrations submitted outside of the joint registration are addressed in 2017.	**Yes**	
Ensure the internal readiness of the IT tools and related IT services for handling the incoming peak of registration dossiers for the 2018 registration deadline; in particular those necessary for users access management, for processing dossiers, inquiries and confidentiality claims, for invoicing and for reporting.	**Yes**	
As part of implementing ECHA's regulatory strategy, continue to stimulate dossier updates through the publication of the list of substances to be potentially addressed under compliance check, targeted letter campaigns e.g. to inform registrants that their dossiers may be targeted for dossier evaluation, verify the intermediate status of substances of very high concern, and other measures so that the quality of registration information is further enhanced.	**Yes**	

1.1.3 Evaluation

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Continue compliance checks addressing relevant higher tier hazard endpoints for substances of potential concern over 1000 tn dossiers and 100-1000 tn dossiers, in line with the regulatory strategy set in 2015. The selection of dossiers for compliance check will continue to be based on the common screening that also serves substance evaluation and regulatory risk management.	**Yes**	
Address 2-3 selected groups of priority substances on which registrants are using read-across or grouping approaches for the key endpoints and initiate informal interaction to try out how to most effectively address such groups of substances and dossiers and ensure their compliance with information requirements.	**Yes**	
Continue providing improved visibility to content and outcome of compliance checks through the dissemination platform and the improved annual evaluation report (Article 54) as an important part of implementation of the compliance check strategy.	**Yes**	
Examine any testing proposals within the set legal deadlines, giving priority to non-phase-in testing proposals and to the resubmitted 2010 testing proposals for reproduction toxicity.	**Yes**	
In line with the follow-up evaluation approach reviewed in 2016 and agreed with the Member States, examine any information submitted in consequence of ECHA's dossier evaluation decisions and communicate to the Commission and Member States the information obtained and any conclusions made as well as inform the concerned national authorities in case no or not sufficient information is submitted. Where appropriate, draft follow-up decisions. Ensure that, where relevant, the information obtained and any conclusions made are fed back into screening and regulatory risk management processes.	**Yes**	
Ensure, together with Member States, that substance evaluation supports and contributes to the regulatory risk management processes in an effective and efficient manner based on the review of the process in 2015. This entails the effective interplay with dossier evaluation and risk management processes in the annual CoRAP updating and ECHA's seamless coordination of and support to substance evaluation decision-making and conclusion.	**Yes**	
Continue addressing the lack of information on the safe use of substances in nanoforms under both dossier and substance evaluation.	**Partially**	Requiring legislative amendments to enable regulatory work.
Complete the full migration and decommissioning of case management tool for dossier evaluation (ECM-DEP) depending on the outcomes of its migration to Dynamic Case initiated in 2016.	**Yes**	

1.1.4 Communication of risk management advice through the supply chain

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Subject to the outcome of the evaluation of the CSR/SE Roadmap and ENES activities carried out in 2016, support downstream user industry's utilisation of tools, formats and methodologies developed under the CSR/ES Roadmap. Specifically, promote development of use maps in new downstream user sectors.	**Yes**	
Provide targeted support for downstream users to support their adoption and uptake of the risk reduction measures in REACH exposure scenarios.	**Yes**	
Support to enforcement authorities, including support to the operational phase of the Forum's fifth harmonised enforcement project (REF-5) on extended safety data sheets, exposure scenarios, risk management measures and operational conditions.	**Yes**	
Continue to broaden the exemplification of REACH information useful/needed to comply with other legislation, and the benefits of REACH.	**No**	Deprioritised because of resource constraints.
Further promote companies' awareness of their obligations for sharing information in the supply chain through communication activities based on a set of downstream user-oriented information material published on the ECHA website in 2016. This may trigger a certain increase also in questions to the ECHA and national helpdesks during the subsequent year that the HelpNet will need to address.	**Yes**	

1.2.1 Identifying needs for Regulatory Risk Management

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Adapt common screening methods to address newly registered substances with lower information levels, including complementary approaches, using other than REACH/CLP data as its basis.	**Partially**	Low tonnage substances are integrated (e.g. via grouping approaches), but there is no specific strategy for low-tonne substances has been developed yet.
Ensure maturity of the common screening approach for all REACH/CLP processes with the focus on enhancing its use (e.g. initiating the CLH process for substances that matter) and improving the system based on lessons learned.	**Yes**	
Use the RMOA approach to identify appropriate risk management needs based on the information generated through CCH and SEv and their respective follow-up, leading up to development of a 'common follow-up approach'.	**Yes**	
Continue preparation of RMOA's, upon request by the Commission, and providing coordination and support to Member States in their preparation. Ensure well-functioning informal assessment of PBT and ED properties. Adapt as needed guidance and advice on ED identification based on the criteria set out by the Commission.	**Yes**	
Continue developing article service-life exposure assessment approaches based on the gap analysis done in 2016 and supporting industry in improving service-life parts of their CSA/ESs thus using REACH data to contribute to the implementation of circular economy. Moreover, explore further how CSAs and ESs can cover the waste stage.	**Partially**	While the development of the service-life exposure assessment approaches has continued in the framework of plastic additives work, the further exploration of the waste stage has been postponed.
Maintain high level of efforts for co-operation and co-ordination with all authorities of the work on SVHC roadmap implementation and beyond. Effective use of a combination of meetings, including RiME and concern related expert and co-ordination groups, and IT tools. The implementation of the approach used for the petroleum and coal stream sector is integrated to the extent necessary into the other co-operation work.	**Yes**	
Continue the review of the SVHC roadmap implementation initiated in 2016 and report as part of the annual report on the first elements of this review (relevance of impurities, sensitisers). Progress the review of other elements together with Member States Competent Authorities.	**Yes**	
Develop the third SVHC roadmap progress report and identify actions for further improvement.	**Yes**	
Continue updating the information on ECHA's website on screening and assessments thus providing industry with better predictability on which substances will be under authorities' attention and consequently allowing more time to plan for substitution and improving safety.	**Yes**	

1.2.2 Authorisation

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Handle the increased workload on SVHC dossiers, in particular those pertaining to PBTs, EDs and other substances of equivalent concern by ensuring involvement of the relevant expert groups, and sufficient capacity of the MSC.	**Yes**	
Continue to raise awareness of and support the implementation of obligations to communicate in the supply chains and to notify to ECHA SVHCs in articles. This work will in particular consider the update of the Guidance on requirements for substances in articles launched in 2016, which will be based on the court judgement on the 0,1 % limit and experiences so far.	**Yes**	
Implement a further streamlined and focussed application process taking account of the experience gained, including the "Lessons Learnt" conference and "Streamlined Applications" workshop held in 2015, as well as the recommendations of the "Task Force on Applications for Authorisation", possibly indicating good examples of applications.	**Yes**	
Establish the "reference" DNELs and dose-response relationships for substances that have been placed on the Authorisation List in 2016.	**Yes**	
Continue to improve and adapt communication through ECHA's website to facilitate the preparation of "fit-for-purpose" applications for authorisation.	**Yes**	
Conclude the work related to applications, mostly relating to the use of chromium compounds, submitted in the end of 2015 and early 2016, including the opinion forming by ECHA's Committees for Risk Assessment and Socio-economic Analysis and the support to the Commission in finalising the commission implementing decisions.	**Yes**	
Organise with the Commission a second "Lessons Learnt"	**Yes**	
Ensure full availability of information about notifications of companies covered by the authorisation decisions to enforcement authorities in the Portal Dashboard - NEA.	**Yes**	
Publish the report from Forum's second pilot project on authorisation-related obligations.	**Yes**	
Develop a strategy on how to further encourage and support industry in their efforts in substituting SVHCs and other substances of concern.	**Yes**	
Contribute to a feasibility study on the different systems in place for tracking of chemicals from article production and import through the service-life until waste and recovery.	**Yes**	

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
First draft developed of a framework to carry out socio-economic assessments of recycling and waste recovery practices	**No**	Due to a lack of socio-economic assessment resources and conflicting priorities, this was not feasible. In the context of the further discussions on the chemicals-products-waste interface, the work may be re-initiated.
Initiate and prepare a Forum pilot project on substances in articles	**Yes**	

1.2.3 Restrictions

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Provide support to the Member States during their preparation of restriction dossiers, e.g. in the Pre-Restriction Information Meetings and continue to improve the efficiency of the process.	**Yes**	
Initiate further development of methodologies (including valuation) for carrying out socio-economic analysis.	**Yes**	
Further develop and implement a capacity building programme for Member States and members of the SEA Committee on regulatory impact assessment, in particular on methods used in socio-economic analysis.	**Yes**	
Report from the Forum's fourth coordinated enforcement project on restrictions (REF-4)	**Yes**	

1.2.4 Classification and Labelling

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Aim to reduce the overlapping work for the CLH process with the assessment processes for pesticides and biocides in MSCAs, committees and agencies by further development and support to the use of integrated assessment templates to reduce the workload of dossier submitters and increase efficiency of the processes.	**Yes**	
Efficiently manage the development of CLH opinions for biocides and pesticides, which are expected to increase in number in the coming years. The selection of industrial chemicals is based, to an increasing extent, on common screening.	**Yes**	
Publish updates to the guidance on the application of the CLP criteria and on labelling and packaging in accordance with CLP to take into account the 8th Adaptation to Progress (ATP) of the CLP Regulation during 2017.	**Yes**	
Update CLP guidance, as necessary, to reflect changes in information requirement. Depending on the further clarification of the applicability and development of the test methods, ECHA will work on the use of bioelution in C&L, with the aim of publication of new guidance during 2018.	**Yes**	
Develop support on the use of read-across in CLP based on work done in 2016.	**Partially**	While the use of read-across has continued to develop in the framework of CLP and RAC, further support was de-prioritised in 2017.
Continue monitoring the convergence of self-classifications and where appropriate carry out focussed actions encouraging industry to agree on classifications and to update notifications accordingly.	**Partially**	Monitoring continued. The C&L inventory available on the website improved further, which supports its notifiers and users.
Provide scientific and technical support to the European Commission in the context of the further development of the United Nations Global Harmonised System of classification and labelling of chemicals (UNGHS).Continue to raise awareness amongst the public of the CLP pictograms. The European Commission intends to include questions on the use and recognition of CLP pictograms and understanding cautionary statements into a Eurobarometer study to be launched in late 2016, and the Agency will adapt its communication to the public on these matters in accordance with the survey's results.	**Yes**	
ECHA's HelpNet Secretariat will again organise a HelpNet CLP workshop which will, inter alia, address typical industry questions on practical labelling challenges.	**Yes**	
Support the implementation and collection of results from the Forum's pilot project on CLP addressing internet sales of chemicals.	**Yes**	

1.3 Biocides

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Implement further measures to increase the efficiency of the active substance approval process and the Review Programme based on the outcome of the workshop with Member States that took place in 2015 and subsequent discussions in 2016.	**Yes**	
Support the Member States Competent Authorities for the preparation of BPC opinions on active substances.	**Yes**	
Start preparations for the (re)evaluation of the approvals of certain active substances vis-à-vis the new criteria for endocrine disruptors, once they are adopted.	**Yes**	
Support the preparation of the first BPC opinions on Union authorisation of biocidal products with a special emphasis on the efficiency of the opinion forming process and the coordination between Member States Competent Authorities dealing with related applications.	**Yes**	
Evaluate the new applications for inclusion in the Article 95 list.	**Yes**	
Further develop the Register for Biocidal Products (R4BP 3),) and the SPC editor, in order to progress towards the comprehensive implementation of the biocides legislation.	**Yes**	
Publish updates to the Guidance on the Biocidal Products Regulation: new guidance on Volumes I, II, III & IV, Part C, Evaluation.	**Yes**	Except for Volume I (foreseen in 2018).
Continue and finalise the European comparative assessment of biocidal products containing anticoagulant rodenticides active substances).	**Yes**	
Initiate the development of a new version of EUSES for biocides with the aim to cover new emission estimation models for all product types.	**No**	Development of a new version of EUSES has been postponed but updating the current version has started (procurement contract signed at the end of 2017).
Support the BPR enforcement by preparing the development of an IT tool for BPR inspectors and, if so desired by the Member States, by establishing and supporting a Forum subgroup to harmonise approaches to enforcing the BPR.	**No**	Postponed until 2019 due to constraints on resources.

1.4 PIC

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Process a continuously increasing number of notifications.	**Yes**	
Produce the three-year report on operation of the PIC Regulation, together with the routine annual report.	**Yes**	
Attend, in support of the Commission, the 8th Conference of the Parties to the Rotterdam Convention, provide scientific input and participate in the preparation of the Chemical Review Committee	**Yes**	

1.5 Data management and dissemination

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Consolidate different interfaces provided to the Authorities and Committees pursuing a secure single interface whereby different services (e.g. access to information on the progress of ECHA processes) are accessible. This will be supported by the Enterprise Data Model and into the Data Integration Platform.	**Yes**	
Implement the basis for recording information on substances and their related deficiencies and concerns across the different processes according to an Enterprise Data Model. Thus supporting the distribution of information to Authorities and reporting on actions and decisions taken across the regulatory processes on a substance or a dossier, supporting the sharing of information on the regulatory activities lifecycle and integrated views on multiple regulatory processes.	**Partially**	The project to record information on substances and their related deficiencies and concerns has been prepared both from a business and a technical point of view. The Enterprise Data Model has been redefined to cater for this need and a project plan has been approved by management to start the implementation work in 2018.
Enrich the dissemination of biocides information with the automated publication of data extracted from biocides dossiers such as Summary Product Characteristics and Product Assessment Reports.	**Partially**	Project has started but is still ongoing; planned delivery in 2018.
Upgrade the common Data Integration Platform in terms of technology – to replace obsolete components – and architecture – to further align with the enterprise data model	**No**	It has been rescheduled for 2018.
Upgrade the enterprise content management (ECM) platforms:		
(1) EMC Documentum - used to implement the ECHA solution for case management in the internal processes due to the end-of-life of the current version in use.	**Yes**	
(2) Microsoft Sharepoint – used to implement the ECHA solution for case, process and document management related to the non-regulatory processes due to end-of-life of the current version in use.	**No**	It has been rescheduled for 2018.
Prepare feasibility studies and implementation roadmaps for initiatives relevant to ECHA's stakeholders. For example, deliver data or access to data as a service to third parties when coherent with ECHA's mission; develop support for collection and dissemination of substances in articles data.	**Partially**	Feasibility study completed on data value discovery and presented to Management Board and other stakeholders. Dataset with results of studies on 15 000 chemicals made accessible to third parties.
Further develop tools and support to facilitate data provision by companies to national poison centres under Article 45 of the CLP Regulation.	**Yes**	
(1) Integrate latest legislative changes into the tools and formats developed by the Commission in 2016, i.e. XML, PC Editor, Product Category System and UFI generator. to.	**Partially**	UFI Generator and Product Category System (PCS) are completed. PCS publication scheduled for January 2018. XML and PC Editor have been postponed as an outcome of the feasibility study.

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
(2) Undertake, in collaboration with the Commission and Member States, a feasibility study into providing a 'one-stop notification' system that would enable participating Member States to receive notifications in the new format and facilitate companies notifications to multiple countries simultaneously.	**Yes**	
Continue to promote the data on chemicals to the general public, in collaboration with the media and accredited stakeholders.	**Yes**	

1.6.1 Nanomaterials Observatory

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Publish the first version of the observatory by June[30] 2017 based on readily available data and information sources.	**Yes**	
Start preparations for the second version to be published in 2018. The second version is planned to cover new information on sectoral legislation (e.g. food and cosmetics), further information on products and articles where nanomaterials are present, updated information on nanomaterials in EU market, and wider information on relevant research activities.	**Yes**	
Increase the focus on consumer oriented information.	**Yes**	
Complete the first step of an IT analysis to see what opportunities there are for creating e.g. search functionalities or interoperability between various data bases. Depending on the result initiate the development of them.	**Yes**	

30 Six months from the signature of the delegation agreement

1.6.2 EU Chemicals Legislation Finder

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Feasibility study	**Yes**	
Depending on the outcome of the feasibility study, start preparations for the definition and implementation of the project	**Partially**	More analysis is needed on the portal architecture and on the business model before a definitive go/no-go decision is made. This is planned for Q3 2018.

2.1.1 Committees

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Manage memberships of each Committee (renewals and new appointments/nominations), with specific focus on ensuring adequate capacity of RAC and SEAC. Review experiences gained with co-opted members.	**Yes**	
Implement efficiency improvements continuously in all Committees resulting from the completion and integration of IT tools.	**Yes**	
Prepare, run and follow-up the plenary meetings for the MSC (6), BPC (6), RAC (7) and SEAC (5).	**Yes**	

2.1.2 Forum

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Support via the Forum Secretariat, the harmonisation of national enforcement authorities' approaches to enforcement through three Forum plenary meetings, continued development through methodological tools, best practice and sharing of information.	**Yes**	
Continue preparing, executing and reporting from Forum coordinated enforcement projects. In addition, prepare the manual for the sixth Forum project (REF-6) and select the subject of seventh Forum project (REF-7).	**Yes**	
Continue establishing best practice in enforcement and testing enforcement approaches by running Forum pilot projects,	**Yes**	
Continue to examine enforcement proposals and deliver advice on enforceability of restrictions.	**Yes**	
Continue to promote intelligent use of information by maintaining institutional interlinks between ECHA and national enforcement authorities intended for enforcement of ECHA decisions by inspectors and provision of intelligence to the national authorities.	**Yes**	
Continue to support enforcement authorities by developing and delivering an annual training programme for inspectors to a group of national trainers.	**Yes**	
Continue to support enforcement by the national enforcement authorities via on-going improvement and modernisation of the IT-tools available to inspectors such as Portal Dashboard for national enforcement authorities	**Yes**	Not for BPR inspections

2.1.3 HelpNet and Security Officers Network

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Organise 1 HelpNet Steering Group meeting and 6 HelpNet workshops on BPR, CLP and REACH	**Yes**	
Continue preparing questions and answers sets (FAQs) on BPR, CLP and REACH	**Yes**	
Complete the review of the Security Model applied to remote access for MSCAs to take into account new technological possibilities and new working practices	**Yes**	
Keep the national REACH helpdesks informed on developments related to the 2018 registration deadline to allow them to provide advice and assistance to potential registrants, in particular to SMEs that may be struggling with the preparation of their dossiers	**Yes**	
Organize a training (update) for national helpdesk correspondents on dossier submission	**Yes**	

2.1.4 Board of Appeal

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Process and decide on incoming appeals which are expected to include an increased number of registration and data sharing related cases due to the manual completeness check and the reinforcement of the OSOR principle in the REACH-IT as well as a steady influx of cases in relation to substance evaluation and compliance check decisions.	**Yes**	
Adopt up to 25 final appeal decisions, closing an appeal.	**Yes**	
Adopt procedural decisions, as needed.	**Yes**	
Publish a robust body of high-quality decisions on-line, helping to build a set of consistent criteria for the Agency decision-making.	**Yes**	
Ensure effective (i.e. clear, accurate and timely) communication with the (potential) parties in relation to appeal proceedings.	**Yes**	

2.2 Management

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Coordinate and organize meetings and consultations with the Management Board, including its Working Groups	**Yes**	
Prepare and coordinate directors meetings including management decisions, delegations and policies	**Yes**	
Manage the Agency's reputation by: gathering feedback on the Agency's performance from stakeholders though surveys and by daily media and social media monitoring; and acting on the feedback received	**Yes**	
In recognition of both the need to communicate more effectively with consumers and workers, and the unsuitability of ECHA's website for these two target audiences, the Agency will build a separate website for them. This will retain ECHA branding and editorial content, but will have a different look and feel so as to make it more appealing to the general public. It will contain content on all aspects of chemicals in our life, including information on nanomaterials, as part of the remit of the EU Nanomaterials Observatory. The site will be developed in consultation with accredited stakeholders.	**No**	The preparation work started in 2017 but the go-live of the website has been postponed until March 2018.
Prepare suitable communication products and organise events to celebrate 10th anniversary of ECHA's establishment	**Yes**	
Contribute to the Commission's REACH review studies, communication and support documents, as well as to the implementation and follow-up of the exercise	**Yes**	
Perform audit activities in line with the annual audit plan.	**Yes**	
Optimise further the Integrated Quality Management and Internal Control Systems towards the 2017 surveillance audits	**Yes**	
Implement the Agency's environmental programme aiming at improving its environmental performance	**Yes**	
Implement the Archiving Strategy	**Yes**	
Respond to enquiries (ca. 500) from general public about ECHA and its activities.	**Yes**	
Support corporate planning and reporting on ECHA's activities	**Yes**	
Start implementing identified solution(s) to streamline planning and reporting activities	**Yes**	
Coordinate international cooperation activities as requested by the Commission, in line with an Exchange of Letters in 2014 between the Commission and ECHA establishing working arrangements for handling such activities, and carry out ECHA's third capacity building project for EU candidate countries and potential candidates under the IPA (Instrument for Pre-Accession) programme.	**Yes**	
Implement the corporate-wide efficiency development programme with new projects, competency development, communication and performance management	**Yes**	

2.3.1 Financial resources

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Prepare and manage the implementation of budget, including amendments and transfers, revenue collection and cash management, procurement and contracting, financial reporting including annual accounts.	**Yes**	
Continue regular exchange with Commission partner services on revenue estimates for the future, the needs to review the fee regulations and discuss ways of handling any shortfall or surplus during the calendar year	**Yes**	
Monitor and report on reimbursements to Member States and prepare eventual reviews of the Management Board rules on this matter	**Yes**	
Continue extending the IT support for ECHA financial processes, following the needs and gaps identified during the analysis performed in 2016.	**Yes**	
Continuously ensure correctness of the SME fee reductions claimed by registrants with focus on examining registrations from the 2013 deadline.	**Yes**	
Implement further efficiency measures, including automation and streamlining of financial processes as part of the corporate efficiency development programme.	**Yes**	

2.3.2 Human resources

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Conduct the annual objective setting, performance appraisal and reclassification exercises	**Yes**	
Provide all HR services with high quality to the staff	**Yes**	
Maintain good relations and dialogue with the staff committee and European School of Helsinki and other major stakeholders	**Yes**	
Conduct the Job Screening Exercise as part of a wider inter-Agency benchmarking exercise initiated by the European Commission.	**Yes**	
Provide relevant training activities to ensure continuous capacity-building of staff	**Yes**	
Ensure the integration of the general competencies in all HR processes	**Yes**	
Ensure availability of necessary interim workforce especially for the upcoming registration deadline	**Yes**	

2.3.3 Corporate services

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Implement an event management IT tool, according to the vision document prepared in 2016, to improve the efficiency of the process and better cope with the significantly increasing number of events per year	**Yes**	
Provide all corporate services at high quality to staff	**Yes**	
Maintain and enhance the use of the audio-visual equipment and facilities to reduce travel requirements of the members of ECHA bodies and its staff	**Yes**	
Prepare and submit to the European Parliament/Council a request for approval of the building project	**Yes**	
Final decision regarding the new long term lease in the same or a new building	**Yes**	
Maintain and further improve stakeholder relations via dedicated accredited stakeholder organisation communication activities, joint projects and events; interactions with Member States and EU partners in order to ensure efficient communication with a wide range of audiences throughout Europe.	**Yes**	
Maintain and improve all the internal and external communication vehicles of the Agency – website, newsletters, press materials, publications, audio-visual products, social media and intranet	**Yes**	
Continue to translate materials that are important for small companies and the general public into 23 languages	**Yes**	

2.3.4 ICT

Main actions and outputs specified in the Work Programme 2017	Achieved [Yes/No]	Additional information/explanation
Revise and strengthen the relevant IT services and the IT support for business continuity to be prepared for the 2018 deadline	**Yes**	
Complete the roll-out of the new IT facilities for the workplace initiated in 2016	**Yes**	
Establish new outsourcing framework contracts for ICT services and software and application management services;	**Yes**	
Support the new model of delivering ECHA Cloud Services to SMEs users	**Yes**	
Consolidate integration management after the achievement in 2016 of the target information systems architecture (as mostly defined in 2011)	**Yes**	
Define and pursue a new target architecture for the IT landscape post 2018 deadline; in this context analyse in particular:	**Yes**	
(1) the operational and administrative needs associated with delivering software as a service e.g. cloud services for SMEs	**Yes**	
(2) the needs for a mobile IT strategy to assess the opportunity of adapting some of the ECHA's IT tools (e.g. the Portal Dashboard for Enforcement field work) to mobile devices	**Yes**	
(3) the needs and opportunities which can be met by leveraging the data management capabilities, services and platforms established in the previous years	**Yes**	
(4) the identification of new candidates for common components and services in ECHA's IT landscape (e.g. mass mailing solution)	**Yes**	
Maintain the Technology roadmap and ensure an adequate technology update index to prevent risks of security, obsolescence, loss of efficiency	**Yes**	

Appendix 2:

Workload drivers and performance indicators

1.1.1 Registration dossier preparation

Performance Indicators	2017 estimate	2017 actual
Helpdesk questions received[31]	2800	2710
Inquiries concluded	1 700[32]	2171
Access to data older than 12 years	350	102
Data-sharing disputes	80	98
Decisions on data-sharing disputes	70	42
Appeals on data-sharing decisions	1	4

1.1.2 Registration and dossier submission

Performance Indicators	2017 estimate	2017 actual
Registration dossiers received (including updates)	13000	15885
Confidentiality requests processed	540	220
PPORD notifications received (including requests for extension)	300	269
Helpdesk questions received[33]	2000	2710
Decisions on completeness check (negative)	260	153
Decisions on confidentiality requests (negative)	65	53
Decisions on PPORD notifications	50	56
Appeals submitted[34]	2	1

31 Regulatory and non-regulatory questions related to dossier preparation only.
32 Since May 2017, it is no longer possible to submit late pre-registrations. If the current trend observed in the number of late pre-registrations received (12.000 late pre-registrations/year) continues, the number of inquiries is likely to increase dramatically.
33 Regulatory and non-regulatory questions related to dossier submission only.
34 Calculated as a percentage of negative decisions, where the percentage is based on the historical data of actual negative decisions appealed against in 2011-2015

1.1.3 Evaluation

Performance Indicators	2017 estimate	2017 actual
Draft decisions on testing proposals	70	58
Final decisions on testing proposals	150	58
Compliance checks concluded	220	222
Final decisions on compliance checks	180	139
Follow-up evaluations on dossier evaluation decisions concluded	330	327
Number of substances on the CoRAP list to be evaluated by the MSs[35]	24	22
Final decisions on substance evaluation	30	31
Appeals submitted	23	9
Helpdesk questions received[36]	750	349
Updates of the CoRAP for substances subject to substance evaluation	1	1

1.1.4 Communication of risk management advice through the supply chain

Performance Indicators	2017 estimate	2017 actual
Number of events organised with industry to improve the uptake of Roadmap products	5	5
Helpdesk questions received[37]	200	202

1.2.1 Identifying needs for regulatory risk management

Performance Indicators	2017 estimate	2017 actual
Upon request by the Commission, support provided for the development of RMO analyses and/or SVHC dossiers.	5	0
Number of expert and coordination meetings (incl RiME)	9	7

35 The declining trend in the number of substances under substance evaluation is mainly due to the refined interplay between substance evaluation and compliance check, i.e. more substances are first addressed under compliance check also for the endpoints relevant for the substance evaluation. This temporary trend is expected to turn in 2018.
36 Regulatory and non-regulatory questions related to evaluation only.
37 Regulatory and non-regulatory questions related to communication of risk management advice through the supply chain only.

1.2.2 Authorisation

Performance Indicators	2017 estimate	2017 actual
Number of proposals for identifying SVHCs[38]	15	11
Recommendation for inclusion of substances in the authorisation list	0[39]	0
Number of received Applications for authorisation	5	9
RAC & SEAC opinions[40] on applications for authorisation	40	58
Helpdesk questions received[41]	650	354

1.2.3 Restrictions

Performance Indicators	2017 estimate	2017 actual
Restriction proposals submitted by MS and ECHA (Annex XV)	6	3
Annex XV restriction dossiers (or preparatory reports) prepared on request by the Commission	5[42]	5
Restriction proposals or reports developed under Article 69(2)	1	0
RAC & SEAC opinions[1]) on restriction proposals	4	2
Helpdesk questions received[43]	600	323

1.2.4 Classification and labelling

Performance Indicators	2017 estimate	2017 actual
Proposals for harmonised classification and labelling	70	56
RAC opinions on proposals for harmonised classification and labelling	40	33
Alternative name requests	50	44
Helpdesk questions received[44]	250	310

38 The expected number of proposals for identification of SVHCs stems from the extrapolation of yearly consultation with the Member States Competent Authorities on their plans for developing such dossiers and adjusted by intelligence from the processes
39 Due to the 15-16 months planning cycle for the development of the Annex XIV recommendation the 8th recommendation will be sent to the Commission only in January 2018. Work to prepare this recommendation takes place during 2017 and has already started in 2016.
40 One opinion refers to a compiled version of the final opinions of RAC and SEAC for each use.
41 Regulatory and non-regulatory questions related to authorisation only.
42 Commission request to prepare an Annex XV restriction dossier on i) lead in shot in wetlands, ii) chemicals used in tattoo inks and in addition prepare preliminary reports on a) substances in recycled rubber granules, b) Bisphenol S in thermal paper and c) cadmium in recycled plastics (preparation for a review). More details in http://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions/current-activites-on-restrictions. Additional requests are possible for 2017.
43 Regulatory and non-regulatory questions related to restrictions only.
44 Regulatory and non-regulatory questions related to classification and labelling only.

1.3 Biocides

Performance Indicators	2017 estimate	2017 actual
Opinions on active substances approval (under the Review programme)	50	31
Biocides Inquiries received	50	60
Biocides Data sharing disputes	5	2
Applications for new active substance approval	8	11
Applications for renewal or review of active substances	2	3
Applications for Union authorisation for biocidal products	37	41
Applications for active substance suppliers (Article 95)	25	20
Assessment of technical equivalence	37	33
Submissions to Member States	3000	604
Appeals submitted	3	2
Helpdesk questions received[45]	3000	2018

1.4 PIC

Performance Indicators	2017 estimate	2017 actual
Export notifications	8900	9012
Helpdesk questions received[46]	650	263
Scientific and technical requests from the Commission, EU and non-EU DNAs	2200	2080
New TA posts to be filled for PIC	0	0

1.5 Data management and dissemination

Performance Indicators	2017 estimate	2017 actual
Number of dossiers to be disseminated	13000	12458
Number of external requests for data	60	69

45 Regulatory and non-regulatory questions related to Biocides only.
46 Regulatory and non-regulatory questions related to PIC only.

2.1.1 Committees

Performance Indicators	2017 estimate	2017 actual
MSC meetings	6	6
RAC meetings	7	7
SEAC meetings	5	4
BPC meetings	6	5

2.1.2 Forum

Performance Indicators	2017 estimate	2017 actual
Number of REF projects (at any stage of project life cycle)	4	4
Number of pilot projects (at any stage of project life cycle)	4	4
Forum meetings	3	3
Active working groups	12	23

2.1.3 HelpNet and Security Officers Network

Performance Indicators	2017 estimate	2017 actual
Number of HelpNet events	7	7
Number of SON events	1	1

2.1.4 Board of Appeal

Performance Indicators	2017 estimate REACH	2017 estimate BPR	2017 actual REACH	2017 actual BPR
Appeals submitted	24	3	14	2
Procedural decisions	15	2	31	3
Cases closed	22	3	14	1

2.2 Management

Performance Indicators	2017 estimate	2017 actual
Resolved general enquiries	600	1807
Management Board meetings	4	4

2.3.1 Financial resources

Performance Indicators	2017 estimate	2017 actual
SME status checks for REACH/CLP[47]	500	332

2.3.3 Corporate services

Performance Indicators	2017 estimate	2017 actual
Press enquiries and interviews	500	555

47 SME status checks for the BPR will be performed on demand, according to the rules of the BPR.

Work Programme 2017 Performance Indicators

1.1.1 Registration dossier preparation

Performance Indicators	2017 estimate	2017 result
Percentage of inquiries concluded within the target timeframe (20 working days)	80%	92%
Effective working time of ECHA staff used per inquiry concluded	1.8 – 2 person days	1.3 person days
Percentage of received data sharing disputes handled within relevant timeframes	100%	96%
Effective working time of ECHA staff used per data sharing decision	16 – 18 person days	11.4 person days
Percentage of ECHA Helpdesk questions related to dossier preparation, answered within established timeframe (15 working days)	90%	88%

1.1.2 Registration and dossier submission

Performance Indicators	2017 estimate	2017 result
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA	High	High
Unplanned IT system downtime preventing submission within service hours (average of related IT systems, per month)	2%	0.4%
Average time (working days) to manually perform the first completeness check of a registration dossier	15 days	4
Effective working time of ECHA staff used per processed registration dossier (incl. updates)	0.6 – 0.65 person days	0.48 person days
Percentage of ECHA Helpdesk questions related to dossier submission and substance identity, answered within established timeframe (15 working days).	90%	91%

1.1.3 Evaluation

Performance Indicators	2017 target	2017 result
Level of satisfaction of MSCAs with ECHA's coordination and support to substance evaluation.	High	High
Level of satisfaction of MSC members and stakeholder observers with the quality of the scientific, technical and regulatory support provided by the ECHA Secretariat	High	High
Percentage of unanimous MSC agreements on evaluation decisions	80%	97%
Percentage of concluded Compliance checks (draft decision sent or closed with no action) addressing the relevant higher tier hazard endpoint as portion of all concluded compliance checks in a year	>75%	83%
Effective working time of ECHA staff used per final dossier evaluation output	25 – 28 person days	27.8 person days
Percentage of Follow-up evaluations performed within 6 months from the deadline set in a Decision (TPE and CCH)	90%	73%
Percentage of substance evaluation decisions adopted within 60 days from the MSCA/MSC agreement	90%	97%
Percentage of ECHA Helpdesk questions related to evaluation, answered within established timeframe (15 working days)	90%	76%

1.1.4 Communication of risk management advice through the supply chain

Performance Indicators	2017 target	2017 result
Level of satisfaction of the interested parties with the quality of the support provided by the ECHA secretariat in the area of supply chain communication	High	High
Percentage of ECHA Helpdesk questions related to communication of risk management advice through the supply chain, answered within established timeframe (15 working days)	90%	91%

1.2.1 Identifying needs for regulatory risk management

Performance Indicators	2017 target	2017 result
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Effective working time of ECHA staff used per SVHC dossier	38 – 47 person days	44.8 person days

1.2.2 Authorisation

Performance Indicators	2017 target	2017 result
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Average time to deliver an opinion on an application for authorisation	13 months	10 months
Effective working time of ECHA staff used per authorisation opinion	38 – 46 person days	28.6 person days

1.2.3 Restrictions

Performance Indicators	2017 target	2017 result
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Average time to deliver an opinion on a Restriction proposal	15 months	15 months
Effective working time of ECHA staff used per restrictions opinion	200 – 255 person days	194 person days

1.2.4 Classification and labelling

Performance Indicators	2017 target	2017 result
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Average time to deliver an opinion on a CLH proposal	10 months	12 months
Effective working time of ECHA staff used per CLH opinion	45 – 55 person days	50
Percentage of ECHA Helpdesk question related to C&L, answered within the established timeframe (15 working days)	90%	94%

1.3 Biocides

Performance Indicators	2017 target	2017 result
Level of satisfaction of the members of the BPC (incl. its Working Groups), Coordination Group, the Commission, MSCAs and industry with the quality of the scientific, technical and regulatory support provided.	High	High
Unplanned IT system downtime preventing submission within service hours (average of related IT systems, per month)	2%	0.4%
Percentage of BPR inquiries concluded within the target timeframe (20 working days)	80%	100%
Percentage of received BPR data sharing disputes handled within 60 days	100%	100%
Average time to process an active substance dossier (from competent authority evaluation report to BPC opinion)	9 months	9 months
Effective working time of ECHA staff used per active substance opinion	27 – 33 person days	33 person days
Percentage of ECHA Helpdesk questions related to Biocides, answered within established timeframe (15 working days)	80%	81%

1.4 PIC

Performance Indicators	2017 target	2017 result
Percentage of export notifications processed within the legal timeframe	100%	99%
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission, Member State DNAs and industry	High	High
Average time to respond to a scientific and technical requests from stakeholders	<15 days	<5 days

1.5 Data management and dissemination

Performance Indicators	2017 target	2017 result
Level of Member States' and Commissions user satisfaction with data management services	High	High
Level of satisfaction of stakeholders with dissemination activities of ECHA	High	High
Maximum continuous downtime (% non-availability) of the website, Portal Dashboard, S-CIRCA and Dynamic Case	2%	0.4%
Percentage of registered dossiers published on the Dissemination Portal within 20 working days from completing the registration process	90%	95%

2.1.1 Committees

Performance Indicators	2017 target	2017 result
Level of satisfaction of ECHA Committees with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Percentage of members acting as rapporteurs in RAC and SEAC	>60%	75%

2.1.2 Forum

Performance Indicators	2017 target	2017 result
Level of satisfaction of the members and other participants with the functioning of the Forum Secretariat	High	High
Portion of Member States (EU or EEA) participating in REF projects	100%	94%

2.1.3 HelpNet and Security Officers Network

Performance Indicators	2017 target	2017 result
Level of satisfaction of HelpNet members with the HelpNet Secretariat support	High	High
Quality of the advice provided by SON as perceived by the Management Board members	High	High

2.1.4 Board of Appeal

Performance Indicators	2017 target	2017 result
Percentage of final Board of Appeal decisions made within 90 working days of the closure of the written or oral procedure	90%	60%
Average time to process an appeal	15 months	14 months
Effective working time of Board of Appeal and its Registry to conclude an appeal case against ECHA's decision	85 – 90 person days	87 person days

2.2 Management

Performance Indicators	2017 target	2017 result
Percentage of very important audit recommendations implemented within the deadline (IAS).	100%	N/A[48]
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	2% increase	8.1% increase
Level of satisfaction of MB Members with ECHA Secretariat's support to their governing role	High	High
Number of critical recommendations from any auditor	0	0
Proportion of work programme indicators for which the set targets were achieved	98%	91%

2.3.1 Financial resources

Performance Indicators	2017 target	2017 result
Commitment rate (of commitment appropriations at the end of the year).	95%	97%
Payment rate (of payment appropriations at the end of the year).	80%	86%
Carryover rate (% of committed funds carried over into the next year)	<20%	11%
Cancelled carryover payment appropriations.	<5%	3%
Percentage of payments made within the legal/contractual deadlines	>95%	99%

2.3.2 Human resources

Performance Indicators	2017 target	2017 result
Percentage of establishment plan posts filled	98%	98.3%
Turnover of TAs	< 5%	2.9%
Turnover of CAs (excluding short-term CAs)	< 10%	6.1%
Level of satisfaction of all staff with the HR services	High	High
Percentage improvement in the Job Screening Exercise	1%	3%
Percentage of days that staff are absent from work due to sickness	<5%	4%

48 There were no very important audit recommendations for implementation in 2017.

2.3.3 Corporate services

Performance Indicators	2017 target	2017 result
Level of satisfaction of the Committees, Forum and MB members with the functioning of the conference centre	High	High
Level of accredited stakeholder satisfaction with the information they receive and their engagement with ECHA.	High	High
Level of reader satisfaction with ECHA's written output, including language availability measured in terms of timeliness, content and usability	High	High
Level of satisfaction of the staff with the corporate services	High	High
Average time to resolve an internal, facility related request	<8h	<8h

2.3.4 ICT

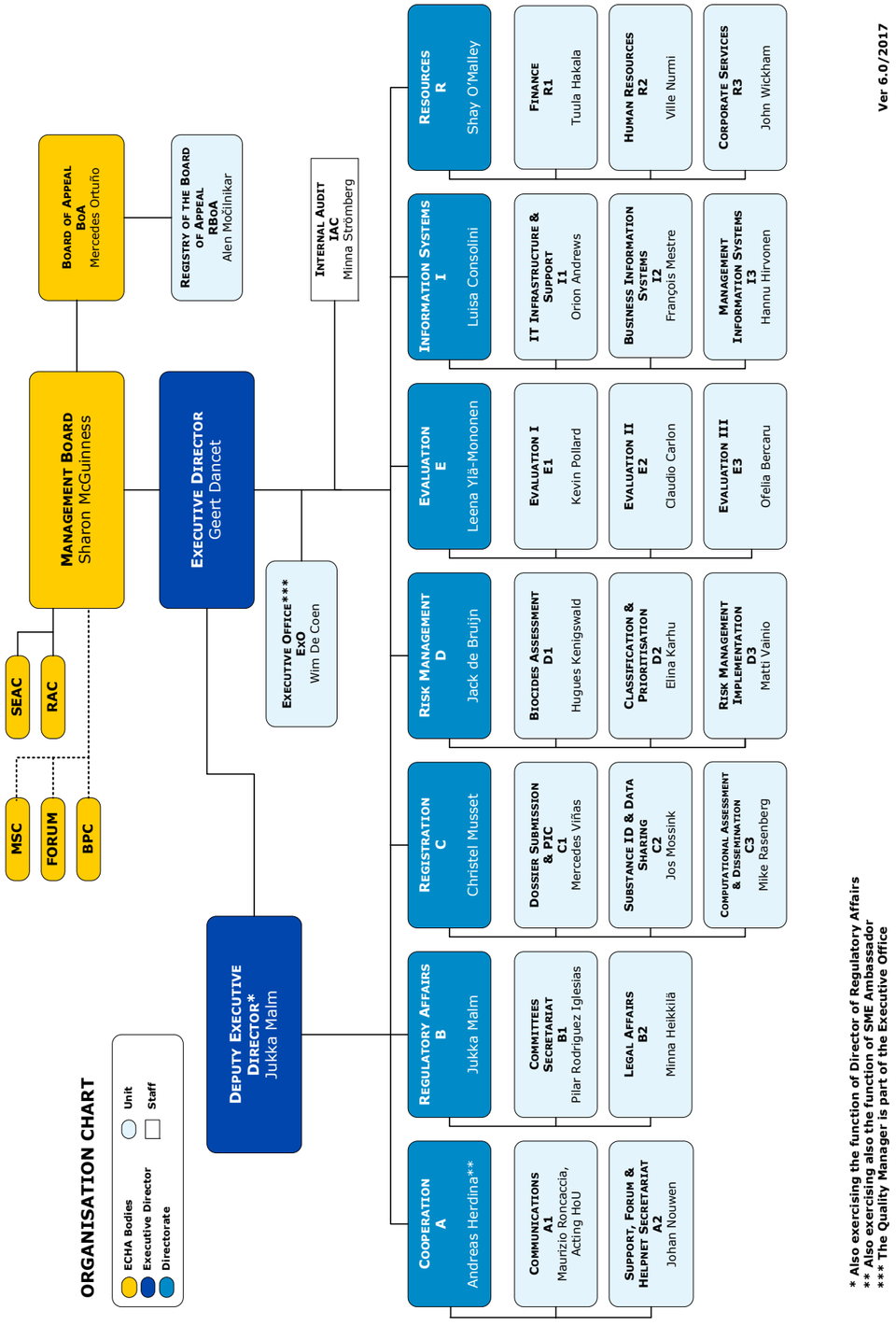
Performance Indicators	2017 target	2017 result
Availability of mission-critical systems for externally used IT systems (i.e. uptime during service hours).	99% (average 98%)	99.6%
Level of internal users satisfaction with the ICT services	High	High
Average time to resolve an internal, ICT service related request	<8h	<8h

Appendix 3: Resources 2017

WP 2017 Activity	Staff Resources 2017		Expenditure 2017 (C1 Payment appropriations + Delegated tasks)	
	"2017 planned FTEs (TA+CA)"	Actual FTEs*	Initial budget	Executed
1.1.1 Registration dossier preparation	49	47	12372401	12090824
1.1.2 Registration and dossier submission	42	43	9600553	9927670
1.1.3 Evaluation	106	105	17965774	17604318
1.1.4 Communication of risk management advice through the supply chain	16	18	3050560	3239853
1.2.1 Identifying needs for Regulatory Risk Management	16	18	3157139	3258276
1.2.2 Authorisation	31	35	5570956	5971200
1.2.3 Restrictions	16	17	3321483	3274592
1.2.4 Classification and Labelling	23	27	4465851	4797426
1.3 Biocides	59	58	10358000	11061644
1.4 PIC	7	8	1183000	1175999
1.5 Data management and dissemination	39	38	10137780	10403343
2.1.1 Committees	17	15	3372825	3007810
2.1.2 Forum	8	7	1558611	1380937
2.1.3 HelpNet and Security Officers Network	2	1	312952	167267
2.1.4 Board of Appeal	11	11	1706117	1663784
2.2 Management	42	38	7174695	6436219
2.3.1 Financial resources	26	22	3880882	3303244
2.3.2 Human resources	25	22	3688902	3265928
2.3.3 Corporate services	21	18	3098677	2672732
2.3.4 ICT	22	22	3246233	3262578
TOTAL	**578**	**570**	**109223390**	**108376452**
1.6 Delegated tasks	3	3	600000	410808

* 8 TA vacancies at 31.12.2017

Appendix 4: ECHA organisation 2017



* Also exercising the function of Director of Regulatory Affairs
** Also exercising also the function of SME Ambassador
*** The Quality Manager is part of the Executive Office

Members of the Management Board at 31 December 2017

Chair: MCGUINNESS Sharon (Ireland)

Deputy-Chair: LARSEN Henrik Søren (Denmark)

Representatives of the Member States	
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PELTOMÄKI Antti
SADAUSKAS Kestutis

Independent individuals appointed by the European Parliament
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VAN PUYVELDE Peter

Individuals appointed by the Commission to represent interested parties without voting rights
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SCHEUER Stefan
SMITH Peter

Observers nominated by EEA-EFTA and other countries	
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SÆMUNDSDÓTTIR Sigurbjörg	Iceland

Members of ECHA committees and Forum on 31 December 2017

Nominating state	MSC – Member State Committee Chair: Watze DE WOLF	RAC - Committee for Risk Assessment: Chair: Tim BOWMER	SEAC - Committee for Socio-economic Analysis Chair: Tomas ÖBERG	BPC – Biocidal Products Committee Chair: Erik VAN DE PLASSCHE	Forum for Exchange of Information on Enforcement Chair: Katja VOM HOFE BPRS[49]: Eugen ANWANDER
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Greece	Aglaia KOUTSODIMOU	Nikolaos SPETSERIS, Christina TSITSIMPIKOU	-	Nomination pending	Eleni FOUFA BPRS: Kornilia MITSOPOULOU
Hungary	Szilvia DEIM	Anna BIRO, Katalin GRUIZ	Endre SCHUCHTÁR	Emese SZÁNTÓ	Szilvia DEIM BPRS: Balázs NEMET
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Switzerland	-	-	-	Manuel RUSCONI	- BPRS: Heribert BUERGY
United Kingdom	Amanda COCKSHOTT	Stephen DUNGEY, Andrew SMITH	Gary DOUGHERTY, Stavros GEORGIOU	Michael COSTIGAN	Mike POTTS BPRS: Mike POTTS
n/a (Co-opted)		Elena-Ruxandra CHIURTU	Lars DRAKE		
n/a (Co-opted		Elzbieta JANKOWSKA	Robert CSERGO		
n/a (Co-opted)		Rudolf van der HAAR	Derrick JONES		
n/a (Co-opted		Susana VIEGAS			

49 BPRS: Biocidal Products Regulation Subgroup of the Forum for Exchange of Information on Enforcement ECHA organisation 2017

Appendix 5: Candidate List of substances of very high concern (SVHCs)

Substances added to the candidate list in 2017

Substance name	EC number	CAS number	Date of inclusion on candidate list	Reason for inclusion	Candidate list decision	Submitted by
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) covering any of its individual anti- and syn-isomers or any combination thereof	-	-	15/01/2018	vPvB (Article 57e)	ED/01/2018	United Kingdom
Benz[a]anthracene	200-280-6	56-55-3, 1718-53-2	15/01/2018	Carcinogenic (Article 57a) PBT (Article 57d) vPvB (Article 57e)	ED/01/2018	Germany
Cadmium carbonate	208-168-9	513-78-0	15/01/2018	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	ED/01/2018	Sweden
Cadmium hydroxide	244-168-5	21041-95-2	15/01/2018	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	ED/01/2018	Sweden
Cadmium nitrate	233-710-6	10022-68-1, 10325-94-7	15/01/2018	Carcinogenic (Article 57a) Mutagenic (Article 57b) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	ED/01/2018	Sweden
Chrysene	205-923-4	218-01-9, 1719-03-5	15/01/2018	Carcinogenic (Article 57a) PBT (Article 57d) vPvB (Article 57e)	ED/01/2018	Germany
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) with ≥0.1 % w/w 4-heptylphenol, branched and linear (4-HPbl)	-	-	15/01/2018	Endocrine disrupting properties (Article 57(f) - environment)	ED/01/2018	Austria
4,4'-isopropylidenediphenol Bisphenol A; BPA	201-245-8	80-05-7	12/01/2017	Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - environment) Endocrine disrupting properties (Article 57(f) - human health)	ED/30/2017[50] ED/01/2017 ED 01/2018[51]	Germany France
Perfluorohexane-1-sulphonic acid and its salts PFHxS	-	-	07/07/2017	vPvB (Article 57e)	ED/30/2017	Sweden

50 Update of existing entry in the candidate list (endocrine disrupting properties (Article 57(f) – human health, submitted by France).
51 Update of existing entry in the candidate list (endocrine disrupting properties (Article 57(f) – environment, submitted by Germany).

Appendix 6: Management Board Assessment of the Consolidated Annual Activity Report for 2017

MB/4/2018 FINAL
23/03/2018

ASSESSMENT OF THE CONSOLIDATED ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2017

In assessing the Consolidated Annual Activity Report 2017, the Management Board made the following observations:

1. The Report provides a detailed account of the activities carried out by ECHA in 2017, a comprehensive overview of activities, financial information, the risks related to organisational activities and the measures taken to address them.
2. In the view of the Management Board, the overall performance and quality of the outputs was high. The Management Board noted with satisfaction that ECHA's output in spite of staff reductions increased.
3. The Management Board welcomes the steps that ECHA has taken to implement the nine recommendations of last year's Management Board assessment, noting that some of these recommendations are of ongoing nature and still relevant.

The Management Board welcomes in particular the following achievements:

1. Out of the 79 performance targets set in the Work Programme 2017, ECHA achieved 43 performance targets, exceeded 27 and did not meet 9. Stakeholder satisfaction was high in all of the 14 areas measured.
2. The Agency adopted a significant number of opinions or agreements of which some were of a highly technically and scientifically complex nature. The Committee for Risk Assessment (RAC) adopted 99 opinions, the Committee for Socio-economic Analysis (SEAC) 60 opinions, the Member State Committee (MSC) adopted 2 opinions and reached 126 agreements and the Biocidal Products Committee (BPC) adopted 46 opinions.
3. In view of the preparations with regard to the 2018 REACH registration deadline, enhanced support was provided to small and medium sized enterprises (SME), including SME targeted guidance, more user-friendly and multilingual IT tools, as well as initiating direct contacts in view of providing tailor-made support. Furthermore, the development of a cloud service has been launched guiding SMEs through the dossier preparation steps.
4. The REACH authorization application process was further improved and streamlined with a result for ECHA to conclude on 58 opinions on applications for authorisation, sent to the European Commission.
5. Under REACH, substances were addressed in groups, rather than one-by-one, thus implementing the Agency's Integrated Regulatory Strategy for achieving the 2020 commitments made at the World Sustainable Development Summit 2002.
6. Together with the Member States, ECHA set up a common screening process to identify substances of potential concern and guide them to the appropriate REACH and CLP processes. The advances in the common screening approach, driven by the maturing Integrated Regulatory Strategy, allows ECHA and Member States to focus on potentially harmful substances to workers, consumers or the environment.
7. The further progress made in implementing tasks under other EU Regulations (BPR, PIC), including the adoption of two opinions on Union authorisation of biocidal products.
8. Achieving two important milestones in the area of nanomaterials (launching the European Union Observatory for Nanomaterials and updating four existing ECHA guidance documents for nanomaterials), performing a feasibility analysis on building an EU Chemicals Legislation Finder and providing opinions on two substances for the purpose of establishing Occupational Exposure Limits under the Occupational Safety and Health legislation.
9. The high degree of budget execution and low degree of vacancies, and notes the collection of higher than estimated volumes of fees and charges under the different regulations.
10. 10. That ECHA received approval by the Budgetary Authority for the lease contract of the future building of ECHA.
11. The adequate follow up of audit and ex-post evaluations recommendations.
12. The adequate management of risks, the progress made on transparency, prevention of conflict of interest, and in this context specifically welcomes the opinion making process in the case of glyphosate.
13. The data protection, security and business continuity, good compliance with ECHA integrated management standards and the efforts undertaken to improve economy and efficiency in all activities.

The Management Board recommends for 2018 to:

14. Continue to manage risks in relation to the 2018 REACH registration deadline including increase awareness raising of the Cloud Service for SME's, and continue to work on improvement of conformity and compliance of registrations, building on experiences from both formal and supplementary measures.
1. Provide adequate follow-up to relevant findings and recommendations of the European Commission's REACH Evaluation and involve ECHA's stakeholders transparently and inclusively in this process.
2. Prepare in a timely manner for new tasks arising from the Circular Economy package and other Commission initiatives.
3. Where necessary adapt the working methods and structures of the Agency to improve the support to Member States in execution of their tasks and to ensure under BPR, CLP and REACH the high quality and consistency of the opinions and the respect of legal deadlines set for the opinion process.

4. Analyse possible obstacles to the fulfilment of the targets of the biocides review programme and take necessary measures in collaboration with Member States and the Commission, as appropriate, to mitigate such obstacles including additional delays that may arise from the application of the scientific criteria for Endocrine Disruptors. In this context the technical guidance document of ECHA and EFSA on the implementation of the ED criteria should be finalised before 1 June 2018.
5. Audit the external communication of ECHA and take steps, as appropriate, to ensure that ECHA provides consistent and clear communication on risks and hazards, irrespective of the communication channels used.
6. Continue work on efficiencies and ensure in collaboration with the Commission and the Management Board that baseline targets are set and met as shown by an agreed set of indicators.
7. Continue to focus on meeting targets on budget execution and report on a 4-monthly basis to the Working Group on Planning and Reporting including on fees and charges income and the state of play of SME status verification.
8. To allow the Agency to carry over appropriations without breaching the budget annuality principle, the budget of the Agency shall contain differentiated appropriations where justified by operational needs (appropriations of multiannual nature). These appropriations shall consist of commitment appropriations and payment appropriations.
9. Build on experiences on grouping of substances and products in evaluation and other regulatory processes and further advance grouping approaches in REACH, BPR and CLP in order to achieve better consistency, efficiency and effectiveness and avoid regrettable substitution.
10. Continue integration of regulatory processes in the Agency's Integrated Regulatory Strategy and mapping the universe of chemicals in order to identify substances that need further regulatory intervention and expand work with Member States and the Commission to ensure that these are followed up.
11. Reassure that adequate structures and measures are in place to avoid conflicts of interests and if conflicts of interests arise, manage these in a transparent manner.
12. Prepare for the United Kingdom ´s withdrawal from the Union in order to manage and minimise disruption to ECHA's activities.

For the Management Board
The Chair
Sharon McGuinness

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