



ECHA Programming Document 2018 - 2020

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Foreword

The purpose of the EU's chemicals legislation is to ensure the safe use of chemicals throughout the supply chain, under the responsibility of industry, contributing to a high level of protection of human health and the environment, and to facilitate the free circulation of chemicals within the internal market. In addition, the aim is to enhance competitiveness and innovation, and to promote alternative methods to animal testing for assessing the hazards of chemicals. The EU regulatory system is based upon the principle that manufacturers, importers and downstream users (DUs) should make sure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment. The provisions are underpinned by the precautionary principle.

ECHA's mandate covers tasks under four regulations on chemicals: REACH, CLP, BPR and PIC. The successful implementation of these regulations requires a well-functioning Agency, capable of delivering independent, high-quality science-based and fit-for-purpose opinions and decisions within strict legal deadlines, as well as providing the necessary support to the concerned interested parties, including industry, in implementation of these regulations to ensure that the operational aspects of the legislation function properly.

However, the efficient operation of the regulations also depends upon ECHA's institutional partners, in particular the Member States of the EU and the European Commission (hereafter referred to as 'the Commission') on the one hand, and on industry to implement the regulations properly, on the other. In addition, contributions by distributors, retailers and consumers, as well as workers and their representatives, are needed. Through the implementation of the above legislation, ECHA also contributes towards achieving the targets of the EU's Seventh Environment Action Programme, the EU's industrial policy and the goals agreed at the Johannesburg World Summit on sustainable development (WSSD) in 2002.

ECHA's Single Programming Document 2018-2020 comprises the multiannual section (Multi-annual Programming 2018-20) and annual section (Work Programme 2018) and is prepared in connection with the draft budget. It fulfils also ECHA's commitments in line with the Common Approach on EU decentralised agencies on international activities. The final ECHA budget and the establishment plan for human resources (HR) will be adopted in December 2017 by its Management Board (MB), following the final adoption of the general budget of the European Union by the Budgetary Authority (European Council and Parliament). Should the total revenue or authorised staff figures differ significantly from the current estimates, the Work Programme 2018 will be adjusted accordingly.

The resource allocation for all activities under the BPR, PIC Regulations and the delegated task of Nano-observatory, as described under the relevant sections of the Work Programme 2018, is expressed as one single figure (both for human and financial resources), which also includes the relevant Governance and support activities. This enables a unified view of resources planned for the relevant Regulations. The Management and Resources activities for REACH and CLP Regulations are presented separately with their respective indicative resource allocation.

List of Acronyms

AD	Administrator
AST	Assistant
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
C & L	Classification and Labelling
CA	Contract Agent
CEOS	Conditions of Employment of Other Servants of the European Union
Chesar	Chemical Safety Assessment and Reporting tool
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
DNA	Designated National Authorities
DU	Downstream User
EC	European Commission
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
ED	Endocrine disruptor
EEA	European Economic Area
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENES	Exchange Network on Exposure Scenarios
ES	Exposure scenario
EU	European Union
EUSES	European Union System for Evaluation of Substances
FTE	Full Time Equivalent
Forum	Forum for Exchange of Information on Enforcement
HelpNet	Network of national BPR, CLP and REACH helpdesks
HR	Human Resources
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
ISO	International Organization for Standardization
ICT	Information Communications Technology
IR	Information Requirements
IT	Information Technology

IUCLID	International Uniform Chemical Information Database
MB	Management Board
MFF	Multiannual financial framework
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
NEA	National Enforcement Authority
NeRSAP	Network of REACH SEA and Analysis of Alternatives Practitioners
OECD	Organisation for Economic Cooperation and Development
Odyssey	ECHA's tool to support evaluation tasks
OSH	Occupational Safety and Health
PBT	Persistent, Bioaccumulative and Toxic
PIC	Rotterdam Convention on the Prior Informed Consent Procedure
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
PPPs	Plant Protection Products
(Q)SAR	(Quantitative) Structure-Activity Relationship
R4BP	Register for Biocidal Products
RAAF	Read-Across Assessment Framework
RAC	Risk Assessment Committee
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)
RMOA	Risk Management Option Analysis
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum
SDS	Safety Data Sheet
SME	Small and Medium-sized Enterprises
SON	Security Officers' Network
SPC	Summary of Product Characteristics
SVHC	Substance of Very High Concern
TA	Temporary Agent
vPvB	very persistent and very bioaccumulative
WP	Work Programme
WSSD	World Summit on Sustainable Development

Mission Statement

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 of implementation of the Regulation 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".

The recast 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. Certain tasks related to PIC were transferred from the Joint Research Centre of the European Commission to ECHA in 2014.

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

ECHA's Mission

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'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.

I GENERAL CONTEXT

1. The EU regulatory system for chemical safety

ECHA operates in a complex environment. Implementing the REACH, CLP, BPR and PIC regulations is a shared responsibility with many partners and these regulations are not the only pieces of legislation with effects on businesses in the EU. The range of companies impacted directly or indirectly by the four regulations managed by ECHA is vast and includes a high number of SMEs, which necessitates specific actions and focus by ECHA.

REACH and CLP

The purpose of the REACH and CLP Regulations is to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. REACH is also designed to promote the development of alternative methods for assessing the hazards of substances. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. At the same time, where needed, the European Union can take additional regulatory risk management measures on the most hazardous substances.

The core processes that ECHA was set up to manage are the following:

1. Registration

Companies are required to ensure that substances are used safely. All the necessary information on the substance they manufacture or import needs to be documented in a registration dossier and submitted to ECHA. This information is also the basis for communicating safe use up and down the supply chain. In order to promote the harmonised interpretations of data, and to reduce registration costs and testing on animals, registrants of the same substance have to share their data and submit their registration jointly. ECHA manages the registration process through its support to companies, facilitation of data-sharing and arbitration of data-sharing disputes. ECHA verifies the completeness of registration information before assigning a registration number, and at each update of the registration dossier. The aim is to ensure that each registration dossier contains all the required data elements. The information verified at the completeness check stage provides the basis for the subsequent regulatory processes under REACH, such as dissemination, evaluation and risk management.

2. Evaluation

ECHA and the Member States evaluate the information submitted by companies with a view to examine the compliance of the registration dossiers and the proposals for further testing and to clarify if a given substance constitutes a risk to human health or the environment. Evaluation under REACH focuses on three different areas:

- Examination of testing proposals submitted by registrants – ECHA examines the testing proposals and decides whether the tests are necessary or not.
- Compliance check of the dossiers submitted by registrants – ECHA verifies whether information requirements under the REACH Regulation are met.
- Substance evaluation - Member States evaluate substances to clarify whether their use poses a risk to human health or the environment. ECHA has a coordinating role in the substance evaluation process.

Once the evaluation is completed, registrants may be required to submit further information on the substance. This is done in a form of an ECHA decision, adoption of which always involves Member States. If Member States propose amendments to the draft decision, the case is referred to the Member State Committee to seek unanimous agreement.

3. Classification and Labelling

The CLP Regulation sets the rules for the classification and labelling of chemicals. It aims to determine whether a substance or mixture displays properties that lead to a classification as hazardous. The information on properties of substances that is part of the registration dossiers allows to check whether the criteria for classification under the CLP Regulation are met. Operators need to assess their substances in this regard. ECHA maintains a Classification and Labelling Inventory and manages the process with regard to harmonised classifications not only for industrial chemicals, but also for pesticides and biocides. Furthermore, it decides on alternative name requests where a company wishes to keep the precise name of a substance used in a mixture confidential.

4. Authorisation

The authorisation procedure aims to assure that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the functioning of the EU's internal market. After a two-step regulatory process managed by ECHA, SVHCs may be included in the Authorisation List and become subject to authorisation. These substances cannot be placed on the market for a use after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. Authorisation applications are submitted to ECHA. After the Committees for Socio-economic Analysis and Risk Assessment have issued their opinion, taking due account of the information provided during a public consultation, the European Commission together with the Member States, takes the decision to grant or refuse authorisation.

5. Restrictions

Restrictions are designed to manage unacceptable risks to humans or the environment in the EU. They limit or ban the manufacture, placing on the market or use of certain substances within the EU. A Member State, ECHA on request of the European Commission, or ECHA on its own initiative, can propose restrictions if they find that there are risks that need to be addressed on a Union-wide basis. After receiving the opinions of ECHA's Committees for Socio-economic Analysis and Risk Assessment, the European Commission, together with the Member States, takes the final decision.

In addition, ECHA is required to provide free and easy access to data on substances collected, including information on their properties (hazards), classification and labelling, authorised uses and risk management measures. The dissemination of information to the general public is balanced against the right of companies to protect their confidential business information.

BPR

The Biocidal Products Regulation (BPR) concerns the placing on the market and use of biocidal 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 contained in the biocidal product. ECHA 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 applications, establishment of technical equivalence, assessment of applications for alternative suppliers, resolution of data sharing disputes, dissemination, preparation of guidance, and communication.

PIC

The Prior Informed Consent procedure (PIC) Regulation implements the international Rotterdam Convention in the EU. It applies to banned or severely restricted chemicals within the EU and provides for information exchange mechanisms regarding the export outside and import inside the EU of those chemicals. ECHA manages the practical functioning of the PIC mechanisms and provides the Commission, upon request, with technical and scientific input and assistance.

COMBINING THE REACH AND CLP PROCESSES INTO AN INTEGRATED REGULATORY STRATEGY

Based on the first years of experience in implementing REACH and CLP regulatory processes, ECHA developed an integrated regulatory strategy which coherently brings all the processes together to achieve the aims of these Regulations, as well as contributing to meeting the 2020 goals of the World Summit on Sustainable Development¹.

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

Under the compliance check process, priority is given to full registrations of chemicals produced in volumes 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 concern is confirmed in the evaluation, a risk management option analysis (RMOA) process will usually follow 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.

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

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 by providing better use and exposure information. This level of coordination will also be instrumental in making sure that all relevant currently known SVHCs are on the Candidate List by 2020 with the best risk management options identified as provided by the SVHC Roadmap.

In summary, the integrated strategy ultimately aims to achieve the following impact:

- 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;
- efficiently select substances that raise potential concern, generating the necessary information for assessing their safety through a compliance check or other means so that any remaining concerns can subsequently be addressed through the most suitable regulatory risk management instrument;
- 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.

¹ Outcome of the World Summit on Sustainable Development, Johannesburg 2002:
http://www.unesco.org/education/tlsf/mods/theme_a/img/02_WSSDOutcomes.pdf

2. Working with others

The successful implementation of the REACH, CLP, BPR and PIC Regulations requires the collaboration of many players. It depends on companies, ECHA's institutional partners at EU level, the Member States, and key stakeholders playing their parts.

EU Partners (EU institutions, other EU agencies) and Member States

The EU chemicals legislation assigns shared responsibility for its implementation. The Member States (in the form of competent authorities and enforcement authorities – which may or may not be the same) and the European Commission are ECHA's primary regulatory partners.

At EU level, ECHA has exchanges with a number of related Agencies and European Commission services. These include EFSA and EMA – with whom a close cooperation exists on science-based opinion making in order to ensure consistent decision-making.

Member States play pivotal roles in decision-making and also carry the primary responsibility for the enforcement of the law. The resources made available for REACH, CLP, BPR and PIC responsibilities in Member States have a direct impact on the progress that can be made at EU level on each of the regulations and therefore on their ultimate success. Effective, proportionate enforcement and dissuasive sanctions for non-compliance will need to provide the ultimate back-stop for the implementation of the EU chemicals safety regime and of ECHA's regulatory decisions.

Duty holders

Chemicals legislation places many duties on companies. Risk assessment, the safe use of substances, classification and labelling and communication down the supply chain are the responsibility of individual companies. ECHA's support to the industry aims to ensure that companies understand how to comply with the legislation.

Accredited stakeholder organisations (ASOs) and scientific communities

ECHA also collaborates with many stakeholder organisations, in particular with organisations representing industry, NGOs, civil society and trade unions. Their involvement in ECHA's work provides transparency, engagement, mutual understanding and valuable input into the regulatory decision-making – for example through their participation as observers in ECHA's Committees. In addition, ECHA is closely following the recent developments in science and technology and maintains an active interface for the scientific community and academia. Technological developments like nanotechnology for example have raced ahead, and regulatory science has to respond to ensure that the potential risks of substances with nanoforms can be adequately assessed. ECHA in turn takes account of these scientific developments in making judgments about the adequacy of the information provided in dossiers.

By the same token, developments in assessing the properties of substances by using alternative test methods to animal testing and prediction techniques such as read-across and computational methods also have a significant impact on the scientific justifications provided by companies and ECHA's examination of these. Furthermore, within these scientific communities, ECHA provides training for young professionals seeking to work in regulatory science.

The worldwide scene

ECHA shares experience with an increasing number of countries, including both authorities and industry, adopting chemicals safety legislation akin to REACH. The Agency will also encourage data owners to share data across different regulatory areas.

ECHA continues to work with international organisations, in particular with the OECD, on activities of mutual interest. It is greatly to the advantage of both regulators and companies in terms of competition and innovation that the legislative regimes in place throughout the world have common building blocks. ECHA also continues to work with regulatory authorities of countries with whom it has cooperation agreements – Australia, Canada, Japan, and the USA – to share best practice, exchange information and to learn. The Agency continues to support EU policies in its dealings with the outside world, such as with EU candidate or neighbourhood policy countries, as well as to support the European Commission in representing the EU in multilateral arena on chemical safety,

in particular the UN Globally Harmonised System of classification and labelling and the Rotterdam Convention, as well as SAICM².

3. ECHA's drivers

The programming period 2018-20 will, for some part, fall beyond the scope of the current Multi-annual strategic plan 2014-18. A new strategic plan for years 2019-23 is under preparation and will be further developed during 2017, along with identification of ECHA's new strategic objectives.

At the same time, the REACH regulation and the bundle of other EU legislation on chemicals is undergoing an evaluation as part of the Regulatory Fitness and Performance (REFIT) programme, followed by the Commission's review of the REACH legislation and a parallel assessment of the performance of ECHA. The resulting actions and recommendations will affect the work expected during the planning horizon in 2019 and 2020.

Within the programming period 2018-20, ECHA will further contribute to the "World Summit of Sustainable Development (WSSD) 2020 goals" in order to honour the commitment of the EU and Member States in achieving a "toxic-free" environment. REACH and CLP Regulations are the main tools in the EU for implementing the goal of sound management of chemicals throughout their lifecycle so that, by 2020, chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment.

The success in achieving the WSSD 2020 goals will mean that by 2020:

1. Robust data is available on all chemicals in Europe
 - a) Registration dossiers are up to date and contain appropriate and complete data covering the hazards and uses of substances. This allows them to be adequately classified, labelled and used safely. Companies can use the information for substituting hazardous substances, and by that spur innovation.
 - b) Hazard data is generated using non-animal testing methods and new approaches wherever possible.
 - c) ECHA has concluded, preferably in co-operation with the relevant stakeholders, which high-volume substances (above 100 tonnes per year):
 - i. Are of concern;
 - ii. Are currently not of concern; or
 - iii. Need more data for a judgement to be made.
 - d) All chemicals critical for the supply chain in Europe are registered without unnecessary market disruption.
 - e) A plan describes how ECHA will identify candidates for further evaluation and/or risk reduction amongst the lower volume substances (1-100 tonnes per year).
 - f) Divergence in industry self-classification has decreased significantly.
2. Effective regulatory risk management of the most hazardous chemicals takes place
 - a) Substances of concern are identified, either individually or in groups. The most appropriate regulatory risk management measure to protect health or the environment, either under REACH and CLP or other legislation has been initiated.
 - b) The processes for authorisation, restrictions, and harmonised classification and labelling are fully optimised and operate based on fit-for-purpose dossiers. They allow efficient opinion-forming in the committees and swift decision-making by the Commission.
3. Effective communication takes place about the safe use of chemicals up and down the supply chain
 - a) Information about substances flows effectively up and down the supply chain. Companies that use chemicals inform their suppliers about what they do with them, and in return, manufacturers and importers provide information on how to use them safely.

² Adopted by the International Conference on Chemicals Management (ICCM) on 6 February 2006 in Dubai, United Arab Emirates, the Strategic Approach to International Chemicals Management (SAICM) is a policy framework to foster the sound management of chemicals.

- b) Importers and EU producers of articles have improved their knowledge on the substances present in their articles to provide adequate safe use advice to their customers and promote substitution.
4. A step-change for citizens, businesses and the regulators takes place
- a) Information on chemicals is reliable, understandable, freely available, and easy to use. This allows citizens, stakeholders, businesses and regulators to make informed choices on using and substituting hazardous substances, and to increase their confidence in the safety of chemicals – not just in Europe, but around the world.
 - b) The experience of REACH and CLP, the information, methods and tools developed are increasingly recognised and used worldwide.
 - c) Companies experience firm, and fair enforcement, focusing on ensuring the safe use of hazardous chemicals and fostering a level playing field.

In the years to come ECHA will also be taking on new regulatory tasks. The Agency will for instance provide tools and support to notifiers of information relating to emergency health response to be used by national Poison Centres, that face a first deadline in 2020. Furthermore, it is expected that the Commission will, in the near future, request ECHA to support the implementation of the Regulation on Persistent Organic Pollutants (POPs).

ECHA is also expected to contribute with its scientific expertise in hazard, exposure and risk assessment to the establishment of Occupational Exposure Limits (OELs) for the implementation of the EU Occupational Safety and Health (OSH) legislation, namely the Carcinogens and Mutagens Directive 2004/37/EC (CMD) and the Chemical Agents Directive 98/24/EC (CAD). ECHA will be prepared for regular work on OSH in the future, should the Commission decide to allocate this work systematically to ECHA.

Looking ahead and beyond 2020, and keeping in mind the developments and goals established under the 2030 Agenda for Sustainable Development³, ECHA will further investigate how to best establish a framework for ensuring that the data collected under REACH is broadly used to the benefit of human health and environment, e.g. through extension of the dissemination activities or data delivery, through providing further support to companies in substituting hazardous substances with safer alternatives and providing a comprehensive view on how a chemical is regulated across various legislations in Europe.

The driving force behind this framework will undoubtedly be the further optimisation of efforts and investments made by all stakeholders in demonstrating the safe use of chemicals. Further integrating the wealth of information on chemicals and their uses, towards other legislative domains in the EU will definitely strengthen and optimise the chemicals regulatory landscape. These initiatives need also to be seen in the context of the Juncker Commission's Agenda for Jobs, Growth, Fairness and Democratic Change where a strong emphasis is put on the right regulatory environment. Chemicals also play an important role in the action plan for circular economy, especially concerning substances in articles. ECHA will contribute where relevant to ensure that the ambitious targets of this package can be realised. Within the same context, ECHA will pay high attention to REACH's aims to increase innovation and competitiveness within the EU's chemical sector and to ensure a level playing field in the EU and EEA.

³ Adopted by the General Assembly of the United Nations on 25 September 2015 describing 17 Global Goals. The specific targets for chemicals management foresee by 2030

- to substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination;
- to improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally;
- to achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.

II MULTI-ANNUAL PROGRAMMING 2018 - 2020

1. Multi-annual objectives

ECHA will pursue the following four strategic objectives as described below. Progress in achieving each of these objectives is monitored via indicators and targets.

Strategic objective	Indicator	Target
Maximising the availability of high quality information to enable the safe manufacture and use of chemicals	Measurable increase in the availability and quality of information on safe manufacture and use of chemicals	Continuous positive trend
Mobilising authorities to use information intelligently to identify and address chemicals of concern	Chemicals of concern are successfully identified and addressed proficiently through adequate regulatory risk management measures with an increased number of Member States authorities involved	Continuous positive trend
Addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors	Progress made on scientific and technical aspects of regulatory challenges in collaboration with partners and stakeholders	Tangible and significant outcome generated in a form of scientific capacity, key-events, reports, guidance and advice by 2020
Embracing current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints	Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	Steady increase at a minimum level of 2% year to year

2. Strategic areas of operation

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

REACH shifted the responsibility for establishing the safe use of chemicals to companies manufacturing and importing them. The information they provide needs to be of high quality, in other words, scientifically sound, understandable and reliable. Currently, the quality of the information provided by the companies shows serious shortcomings and thus clear opportunities for improvement. The deficiencies relate to their compliance with the legal requirements and/or how the hazard, exposure and use information is converted into adequate and reliable safety instructions. To this end, IT tools were reviewed ahead of the 2018 registration deadline for better supporting registrants in providing appropriate information in their dossiers. For SMEs especially, the provision of cloud services, by providing simpler access and integrated verification tools, is expected to have a positive impact on quality. The promotion of the cloud services will be done as targeted communication for all SME pre-registrants, around 25 000 SMEs outside the regular ECHA target audience, and consultants. In addition, they will be promoted through the normal ECHA

channels where, for example, the audience for ECHA's weekly e-news is around 14 000 stakeholders and up to 1 million accounts can be reached through social media.

Also under the BPR, good quality data is a success factor as it facilitates the evaluation carried out by authorities, thus promoting the safe use and reliability of publicly disseminated data. Achieving good quality data on the intrinsic properties of chemicals and their use is an important contribution for the EU as a whole in achieving the WSSD 2020 goals. For this purpose, relevant hazard and use data are key elements in managing chemicals in an appropriate way.

ECHA plays a central role in increasing the reliability of its public database on chemicals and has a mandate to issue legally binding decisions on chemical companies to provide information to redress deficiencies in registration dossiers. The challenge for ECHA during the coming period is to keep inducing improvements in the quality of this information so that it effectively enables the safe manufacture and use of chemicals. ECHA will inform Member States of any concerns about companies in their territory and will continue to support the coordination of enforcement across the EU/EEA through the work of the Forum.

The focus of ECHA's action concentrates also on measures to help registrants and downstream users to improve the communication of risk management advice throughout the supply chain – all the way down to the articles produced for workers and consumers. It includes dialogue between ECHA and sector organisations and further actions to stimulate a demand for robust information on safe use in the market.

The Agency provides advice and assistance to duty holders via guidance, helpdesk and dedicated events. Emphasis for these support activities, often sector wide, is given to SMEs and less experienced actors. ECHA's website as well as its social media campaigns are the core vehicles to inform a variety of relevant audiences with specific support to fulfil their legal obligations. Within the multi-annual timeframe, ECHA's communications will increasingly address the relevant audiences including downstream to end users, the general public and consumers. ECHA will further facilitate and stimulate the communication on safe use of chemicals as well as the more detailed information via ECHA's Info Cards and other relevant dissemination tools.

As part of anticipating future strategic actions under this objective, ECHA will explore how the current wealth of information on chemical hazards, properties and uses can be best employed to support other regulatory applications. Exploratory work as well as feasibility studies are anticipated in order to explore and assess the benefits, added-value and opportunities of ECHA's unique databases for dedicated areas related to chemicals management.

Overall this strategic objective will be achieved via the following action areas and milestones specified below:

Strategic action area 1 - Improving quality of information in dossiers			
Priority area	2018	2019	2020
Preparation of dossiers	Delivery of Cloud services to SMEs.	<p>QSAR Toolbox enhanced version published, extending its applicability to other types of substances (e.g. inorganics and nanomaterials) and higher-tier endpoints.</p> <p>ECHA Cloud Services undergoes an ex-post evaluation and a roadmap for the service and the IUCLID tool is defined</p>	<p>Programmes in place in relevant sectors for continuous improvement of dossiers</p> <p>New Vision on ECHA Cloud services and IUCLID implemented</p>
Submission of dossiers	Successful management of the 2018 registration deadline: companies are adequately informed/helped	Priority setting methods adapted to information available for substances registered in low tonnages, especially 1-10 tonnes	<p>Assessment of the confidentiality requests in 2018 registration dossiers completed</p> <p>Retrospective completeness check of registration dossiers for substances registered over 100 tpa, to ensure</p>

Strategic action area 1 - Improving quality of information in dossiers			
Priority area	2018	2019	2020
			<p>availability of key human health and environment data as well as level playing field among registrants</p> <p>Guidance and regulatory advice as well as HelpNet activities revised to identify post-2018 customer needs</p> <p>REACH-IT is optimised as the communication platform between ECHA and industry</p> <p>REACH-IT is the single submission point for REACH and CLP, including other submission types as needed</p>
Evaluation of dossiers	<p>At least 100 priority substances of concern addressed under complementary measures or compliance check, in accordance with the refined priorities set in 2017.</p> <p>More than 10% of the priority substances (over 100 tn) checked for compliance for the key human health and environment endpoints⁴.</p>	<p>Plan for compliance checks 2019-2020 established</p> <p>At least 100 priority substances of concern addressed under complementary measures or compliance check, in accordance with the priorities set in the plan for 2019-2020.</p>	<p>Report on Evaluation of high volume substances</p> <p>Testing proposals from 2018 registration deadline concluded</p> <p>At least 100 priority substances of concern addressed under complementary measures or compliance check, in accordance with the priorities set in the plan 2019-2020.</p>
Strategic action area 2 - Maximising the impact of communication of risk management advice in the supply chain			
Priority area	2018	2019	2020
Exposure scenarios and safety data sheets	Improved understanding of what the gaps are in supply chain communication and how to address these in the years to come	Industry has started to make improvements and ECHA with the Commission and the Member States have encouraged this through voluntary and regulatory action.	Joint evaluation of the activities and recommendations for next five years established.
Substances in articles	Forum pilot project focusing on substances of concern in articles	Based on the learnings of the pilot project, ECHA and its stakeholders raise a targeted awareness campaign for importers and EU producers of articles	Report on the state of play and conclusions on next steps
Strategic action area 3 – Improving the dissemination information			
Priority area	2018	2019	2020
Dissemination of substance information	<p>Dossiers from 2018 registration deadline published for maximising public availability of information on chemicals</p> <p>Dissemination portal is extended to cover additional information on authorisation of biocidal products</p>	Pending the outcome of the feasibility study, first phase of development of the "EU chemicals legislation finder"	<p>Lessons learned for the next phase of data dissemination</p> <p>Report on the evolution in the differences in self-classification of hazardous substances</p>

⁴ Reflects the aim to conclude, by the end of 2018, at least 420 CCH on the priority endpoints of the ca. 4200 substances with standard registration requirements in >100 tpa tonnage bands

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

Under REACH and CLP, the individual Member States and the Commission have the right to initiate regulatory risk management. Jointly, authorities need to use REACH and CLP information to target regulatory action as early as possible on priority substances and uses that cause the highest potential risks. Those concerns need to be addressed by well-informed decisions on regulatory measures that are effective in reducing the risk. Achieving a common view amongst authorities on how to select the best regulatory instrument and to use this in an effective manner is a prerequisite to reach this objective.

By focusing on identifying new substances for risk management and including such substances on the Candidate and Authorisation lists or potential candidates for restriction, ECHA will contribute significantly to the promotion of the substitution of the most dangerous substances in the EU. Via the common screening approach, ECHA will work together with Member States to identify the substances of potential concern that deserve dossier or substance evaluation to clarify the concern, ensure that the necessary information is generated and initiate relevant regulatory action after a risk management option analysis.

The BPR is based on the principle that active substances are approved at EU level and biocidal products are authorised either at EU or national level. It contains provisions aimed at focusing attention on substances, products and uses of the highest concern especially through the application of exclusion criteria and the identification of candidates for substitution while the simplified authorisation procedure aims to facilitate the authorisation of products containing substances of lowest concern. In addition, the opportunities for cross fertilisation between REACH, CLP and the BPR will be taken to ensure that resources and scrutiny are targeted on the substances that represent the highest potential risks.

ECHA's strategic outlook will strive to anticipate any relevant future initiative it deems necessary to facilitate the work under this objective. Special focus will be given to future approaches and opportunities in using chemical use information more intelligently in close collaboration with Member States. In addition, ECHA will explore how its four pieces of chemical regulation can most optimally add value for other EU regulations linked to chemical safety.

The overall implementation approach is divided into three action areas and relevant milestones as specified below:

Strategic action area 1 – Mobilising authorities and aligning their views			
Priority area	2018	2019	2020
Mobilising authorities and aligning views	Progress review on the SVHC roadmap and reaching the WSSD 2020 goals Enforcement Projects (implement REF-6 and prepare REF-7)	Review workshop(s) on the SVHC roadmap and reaching the WSSD 2020 goals Enforcement Projects (implement REF-7 and prepare REF-8)	Enforcement Projects (implement REF-8 and prepare REF-9)
Strategic action area 2 - Identification of substances for regulatory risk management			
Priority area	2018	2019	2020
Screening	Further strengthen the grouping of substances for further information generation and regulatory action.	Systematic screening of 1-10 tn and 10-100 tn dossiers initiated to support priority setting for evaluation	For substances registered above 100 tonnes it has been concluded whether they are of (potential) concern or whether they are currently of low priority for further regulatory work ('mapping the universe of chemicals')

Criteria, approaches and tools	Annual report on 2020 SVHC roadmap implementation	Annual report on 2020 SVHC roadmap implementation	Final report on SVHC roadmap
Filling information gaps			Plan for prioritisation of the low volume substances
Strategic action area 3 - Addressing identified concerns through REACH, CLP and other legislation			
Priority area	2018	2019	2020
Through REACH & CLP	Have identified the needs for capacity building for companies and Member States to carry out alternative assessments and consequent substitution		All relevant currently known SVHCs included in the candidate list
Other legislation	Workshop on the practical use of REACH/CLP information to support compliance with other legal obligations at company level	Follow-up workshop on topics identified in 2018	Report on how REACH information has been used by other EU legislation

2.3 Addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of member states, European institutions and other actors

ECHA's activities are rooted in a strong regulatory science foundation. Hence, its technical and scientific expertise needs constant updating especially since new scientific findings continuously emerge within the various disciplines supporting chemicals management. Furthermore new paradigms gradually push the boundaries of traditional hazard assessments (e.g. systems biology, bioinformatics, (eco)toxicogenomics) offering for example opportunities for reduction in traditional animal testing. This is also true for aspects of exposure assessment of chemicals as well as in the field of socio-economic assessment (e.g. evaluating benefits of risk reduction measures).

ECHA will keep on developing its scientific and regulatory capacity and expertise, in partnership and dialogue with the science community, and encompass scientific developments and emerging regulatory needs. It will also take into account the scientific capacity of its own Committees, of Member State authorities, including other agencies, international partners and relevant actors. In addition, ECHA will actively interact with the professional and academic scientific community.

These two inter-related and synergistic aspects of ECHA's scientific capacity, i.e. institutional knowledge and interaction and influence in the science community, contribute to the ultimate third strategic objective of ECHA to be a hub for regulatory science by providing leadership and catalysing improvements and developments in chemical safety, not only within EU but also internationally. This requires consistent and regular interaction with Member States, EU institutions, the OECD and other relevant actors. The third strategic objective is not isolated from the three other objectives: without up-to-date scientific and technical capacity, which is under regular review and constant development, the other strategic objectives cannot be successfully implemented.

The overall implementation approach is divided into three areas of operation and relevant milestones as specified below:

Strategic action area 1 – Expertise and capacity building			
Priority area	2018	2019	2020

Expertise and capacity building	Improvement actions completed to enhance ECHA's staff capacity to assess alternative methods and approaches.	Action plan prepared to ensure adequate scientific and regulatory capacity for ECHA post-2020, including for potential new tasks (covering e.g. data management, circular economy, new approach methods for hazard assessment).	Start implementation of the action plan for post-2020 capacity.
Strategic action area 2 – A hub for excellence in regulatory science			
Priority area	2018	2019	2020
Hub for excellence in regulatory science	Implement learnings and actions from ECHA report on the regulatory applicability of alternative methods, and the 2017 117.3 report, including the provision of input to relevant stakeholders for development needs. Carry out a scoping of activities to further improve exposure assessment tools.	Regulatory science cooperation with international partners reviewed. Action plan for international collaboration on the use of new approach methods and other data in prioritisation and risk assessment defined	4 th Report on use of alternatives under Art 117.3 published
Socio-economic analysis	A well-functioning platform established among EU and OECD countries to exchange experiences and cases on risk management, in particular from the point of view of socio-economic analysis and to foster common methodologies.		Results of the research on values available to support impact assessment published and disseminated
Strategic action area 3 – ECHA's Regulatory Science Strategy			
Priority area	2018	2019	2020
ECHA's Regulatory Science Strategy	Updated communication from ECHA towards research community on R&D needs serving ECHA's priorities.	ECHA contribution to priorities for the next framework programme for research (after Horizon 2020)	ECHA's Regulatory Science Strategy reviewed and updated.

2.4 Embracing current and new legislative tasks efficiently and effectively (while adapting to upcoming resource constraints)

ECHA is facing a growing number of tasks while its resources are under pressure. Without achieving higher efficiency and maximising the synergies between the Agency's tasks, ECHA will not be able to achieve the ambitions set out in this multi-annual plan and by the WSSD 2020 goals on chemicals. At the same time, higher levels of efficiency must not mean lower levels of effectiveness. The continuous improvement of its more mature operations should aim at both higher efficiency and increased effectiveness.

Based on the Commission review of REACH and on the external review of the Agency, ECHA will implement the relevant recommendations to improve its work and the relevant operations.

With the experience and expertise gained since its foundation in 2007, the Agency will further strengthen its capabilities and expertise in the area of chemicals management and will further elaborate towards synergies and possibilities to integrate its current operations towards other legislative areas in service of the European Commission and the Member States. This includes some new activities such as supporting the implementation of the new provisions of the CLP Regulation related to emergency health response to be used by European Poison Centres, maintaining the EU Nanomaterials Observatory, potentially developing an EU Chemicals Legislation Finder, assessment of the endocrine disruption properties in biocidal active substances, or supporting the Commission in the circular economy package. Under this strategic objective ECHA anticipates to address such emerging opportunities for example via Management Board workshops and feasibility studies.

The overall implementation approach is divided into three areas of operation and relevant milestones as specified below:

Strategic action area 1 – Maximising the effectiveness and efficiency of existing and new work processes			
Priority area	2018	2019	2020
Process re-engineering	First round of efficiency improvements through re-engineering of REACH and CLP processes completed	Start the adaptation of REACH processes to the post-deadlines phase	
Biocides		Five year report on the implementation of the BPR and its contribution to the WSSD goals Review the Union Authorisation process on the basis of experience gained with first years of implementation, focusing on the internal peer review process including on-going evaluations of biocidal products and the interaction between ECHA, competent authorities and the Commission. Review of the active substance approval process performed	
PIC		Assist COM in preparing the listing of additional chemicals in the PIC Regulation and the notification of chemicals to the Convention Secretariat	
Nano-Observatory	Second version of the observatory launched	Third version of the observatory launched	
Poison Centres	Development of the notification portal with the resources allocated in 2017 to ECHA's 2017/18 budget for this purpose. Notification format and editor, unique formula identifier (UFI) generator and product categorisation system are in place for companies to prepare for notifications; maintenance of those tools. Completion of guidance and support material for the notification to the poison centres by end 2018. Capacity built to perform the operations to run the notification portal.	Formats, tools, guidance, helpdesks and support material are in place to enable companies to prepare submissions and to enable poison centres to receive submissions around one year ahead of the deadline of 1 January 2020. If agreed that ECHA will develop the one-stop notification portal further and subject to resources are available, roll-out the second version and develop the enhanced version.	Maintenance of formats, tools, guidance and support material for notifications to the poison centres If agreed that ECHA will develop a one-stop notification portal further and resources are available, develop the third version, ultimately achieving the full scope identified by the feasibility study in 2017.
Strategic action area 2 - Delivering integrated and re-usable IT systems and services			
Priority area	2018	2019	2020
Deliver IT support for regulatory processes	Current target IT architecture pursued with particular focus on the provision of Cloud Services for SMEs and data managements services Further implement the roadmap for improving IT support for collaboration with MSCAs and Committees members (ECHAInteracts)	Design new IT architecture for post 2018-DL taking into account the evaluation of the SME Cloud services	Target IT architecture post-2020 pursued Consolidation of IT support for collaboration with MSCAs and Committees members (ECHAInteracts)
Deliver IT support for administrative processes	Consolidation of the Management Information Systems solutions Upgrade of the internal document management system	Reassessment of the IT architecture for the Management Information Systems after the REACH deadlines phase (post 2020 architecture)	Target architecture post-2020 pursued

Ensure adequacy of ICT infrastructure	Transition to new outsourcing channels Workplace IT facilities upgrade started in conjunction with the implementation of the ECHA building project	Infrastructure Services upgraded Workplace IT facilities upgrade continued in conjunction with the implementation of the ECHA building project	
Strategic action area 3 - HR policies and initiatives			
Priority area	2018	2019	2020
HR Policies and Initiatives	Review of competency mapping framework	Future building project completed	

2.5 Workload drivers of ECHA's regulatory activities

The magnitude of ECHA's regulatory activities, tasks and outputs in a given year depend, to a large extent, on a number of external and regulatory drivers as identified and presented in the table below. The forecasted values indicate the Agency's assumptions about the future workload or available capacity, based on the original Commission estimates updated with any new information ECHA has gained.

Baseline figures for 2018-2020

ECHA's main activity drivers	2018	2019	2020
Registration dossiers (including updates)	60 000	19 500	18 900
Testing proposals	240	70	50
Confidentiality requests	3 290	450	400
Access to data older than 12 years	390	320	300
PPORD notifications (incl. requests for prolongation)	300	300	300
Inquiries concluded ⁵	1 900	2 000	2 000
Data sharing disputes	170	20	20
Restriction proposals submitted by MS and ECHA (REACH Annex XV)	8	8	8
Restriction proposals (or reports) developed by ECHA on behalf of the Commission	5	4	4
Restrictions proposals (or reports) developed under Article 69(2).	1	1	1
Proposals for harmonised classification and labelling (CLP Annex VI)	75	85	85

⁵ The late pre-registration ends June 2017, which will potentially result in an increase in the number of inquiries.

ECHA's main activity drivers	2018	2019	2020
Proposals for identification as SVHC (REACH Annex XV) ⁶	20	25	25
Authorisation applications received	15	15	15
Alternative name requests	50	50	50
Substances on the CoRAP to be evaluated by MSs	40	50	50
Notifications of information for Poison Centres ⁷	0	15-24 million	15-24 million
Evaluation decisions			
- Testing proposal	105	165	165
- Compliance Check	180	180	180
- Substance evaluation	30	22	30
Decisions on data sharing	140	15	15
Decisions on PPORD	50	50	50
Decisions on completeness check (negative) ⁸	1 200	400	380
Decisions on confidentiality requests (negative) ⁹	340	150	50
Appeals			
Appeals submitted	37	30	30
Cases closed	25	25	25
Others			
Updates of the CoRAP for substances subject to substance evaluation	1	1	1
Recommendations to the European Commission for the Authorisation List	1	1	1

⁶ The actual number of SVHC dossiers arriving will depend on the outcome of the RMO analyses.

⁷ The number of expected notifications to Poison centres is calculated on the basis of the estimates provided in the cost and benefits study published in 2015 by the Commission together with assumptions of 80% of notifications to be submitted via the centralised portal and a 20-30% of reformulation rate. These numbers may increase for 2019 due to the ongoing discussions on interpretation of mixtures intended for industrial use.

⁸ Calculated as a percentage of number of dossiers received, where the percentage is based on the historical data of actual negative decisions in 2011-2015 (i.e. 1%), increased with an estimated 1% for the enhanced and retrospective completeness checks starting mid-2016.

⁹ Calculated as a percentage of number of confidentiality requests received, where the percentage is based on the historical data of actual negative decisions in 2011-2015

ECHA's main activity drivers	2018	2019	2020
Received helpdesk questions on REACH and CLP	12 000 – 24 000 ¹⁰	8 000	6 000
Resolved general enquiries	1 200	600	600
Press enquiries and interviews	600	400	400
SME checks	400	400	400
Management Board meetings	4	4	4
MSC meetings	5	5	5
RAC meetings	4	4	4
SEAC meetings	4	4	4
Forum meetings	3	3	3
Biocides			
Received helpdesk questions on Biocides	3 000	3 000	3 000
Biocides data sharing disputes	5	5	5
Applications for new active substance approval	28	8	8
Applications for renewal or review of active substances	11	5	11
Opinions on active substances in the Review Programme	50	50	50
Applications for Union authorisation	30	40	50
Opinions on Union authorisation	10	15	15
Assessment of technical equivalence	45	45	45
BPC meetings	6	6	6
PIC			
Notifications	10 700	12 900	15 500

¹⁰ In the year of REACH Registration deadline ECHA expects a surge in the number of REACH/CLP helpdesk questions based on the analysis of historical trends and the assumption from an updated Commission Staff Model that 60 000 new dossiers will be submitted in 2018, mostly by smaller and less experienced companies that rely primarily on ECHA's support and advice

ECHA's main activity drivers	2018	2019	2020
Received helpdesk questions and other requests received on PIC ¹¹	2500	2900	3300

¹¹ Number of PIC questions for 2017 includes only questions coming from industry via the ECHA Helpdesk. In order to better reflect ECHA's workload, the numbers for 2018-2020 include requests from all stakeholders.

3. Human and financial resource outlook for 2018-2020

3.1 Overview of the past and current situation

Staff population overview

Detailed data is provided in Table 1 of Annex II.

While ECHA's workload will remain high, and increase in certain activities (for example, to ensure the effective management of the 2018 registration deadline), the Agency will continue to adapt to an overall reduction in financial and staff resources during the period of 2018-2020, in line with the Commission Communication on the resourcing of EU Agencies (COM(2013)519). It should be noted that a number of potential new tasks for ECHA are presently being discussed with partner DG and, in addition, ECHA is actively working on its Strategic Plan for the period 2019-2023. The new tasks that may be entrusted to the Agency, as described in the dedicated section below, will require additional financial and human resources, subject to final agreement. Equally, ECHA clearly recognises the present economic and budgetary circumstances and their impact on its operating environment and, therefore, steps will continue to be taken to further improve efficiency in operational and administrative processes.

Staff-related expenditure in 2018

Detailed data provided in Table 1 of Annex II.

3.2 Resource programming for the years 2018-2020

3.2.1 Financial Resources

Detailed data is provided in Tables 1-3 of Annex II. It is to be noted that the assessment provided below, including ECHA's actual financial resources allocation for the period 2018-2020, is subject to ongoing deliberations of the Commission and budgetary authority, within the EU budgetary process, that should conclude in November 2017. As a result, the information provided below is subject to change.

3.2.1.1 REVENUES

REACH /CLP

ECHA's REACH/CLP income is comprised of fees and charges and the EU subsidy. The forecasted fee income and, consequently, the required subsidy, vary substantially over the years covered by the planning period. This is due to the fact that the final registration deadline under the REACH regulation falls in 2018, resulting in a significant peak in the fee income in that year. In 2018, the fees and charges are currently estimated to total c. € 71 million and the required balancing EU subsidy is c. € 31 million.

The annual subsidy needs for the planning period have been based on the current MFF ceilings. As mentioned, there is, however, a high degree of uncertainty related to the fee income estimates for 2018, as they are based on the estimated volume of incoming dossiers¹². In the event that the income does not materialise to the extent presently forecasted, ECHA may require a subsidy higher than currently requested or, alternatively, would be forced to reduce its expenditure with the associated potential negative impact on the achievement of the 2018 objectives.

BPR

ECHA's BPR activities are funded by fee income and the EU subsidy. The high uncertainty continues with respect to the budgeted revenue from fees and charges, which is based on estimated dossier

¹² There is currently reluctance from industry to provide their registration intentions to the authorities

application volumes. In 2018, the fees and charges are presently estimated at c. € 9.6 million and the requested balancing EU subsidy was c. € 2.5 million. The requested subsidy exceeded the amount foreseen in the MFF by c. € 320 000 and was not included in the Commission Draft Budget for 2018, although it was in line with the amount recommended in the Ecorys study undertaken on behalf of DG SANTE. DG SANTE has, however, confirmed that additional CAs could be recruited by ECHA if the revenues from fees are higher than planned in 2018. Therefore, the corresponding reduction in the expenditure for 2018 has to be implemented. ECHA will now carefully assess which activities to deprioritise while aiming to minimise disruption to planned activities. In addition, the manner of implementation of the adopted criteria on endocrine disrupting properties will require additional resources (see below).

The EU subsidy foreseen for the years 2019 and 2020 (c. 5.8 million and c. 7.0 million, respectively) is not in line with the EC Communication of July 2013 and needs to be accepted by the Commission services. The additional subsidy needs stem from the predicted increase in the number of incoming applications and the consequent need for additional staff to handle these. In addition, if ECHA would implement from 1 January 2019 the payment in instalments of fees for active substance and Union authorisation applications, significantly higher subsidy amounts would be needed in 2019 and 2020 in order to compensate for income that would be delayed to subsequent years.

PIC

ECHA's PIC activities continue to be funded by the EU subsidy over the planning period. As indicated in the programming document 2017-2019, ECHA has examined whether the faster-than-anticipated increase in the number of substances in Annex I and the corresponding increase in activities (support, IT maintenance, etc.) would require a higher subsidy for the years 2018-2020. Based on the review and, given that ECHA will receive an additional post in 2018, the EU subsidy requested for each year was € 100 000 higher than foreseen in the MFF. The additional request exceeding the MFF was not included in the Commission's Draft Budget 2018 and, additionally, a penalty of € 46 000 was applied to the 2018 subsidy as ECHA did not meet the budget execution targets in 2016. ECHA will now carefully assess which activities to deprioritise in the areas of IT development and stakeholder support, while aiming to minimise disruption to planned activities.

3.2.1.2 EXPENDITURE

Title 1

REACH/CLP

For 2018, the needs for staff-related expenditure (Title 1) will increase to c. € 66 million. The increase stems mainly from the indexation of salaries and from the employer's contribution to the pension scheme, which is paid based on the proportion of the revenues without the EU subsidy, and the total revenues. As the estimated fee income in 2018 is significantly higher than in 2017, due to the final registration deadline, the employer's pension contribution also increases.

It is to be noted that salaries represent 93% of the total Title 1 budget, while other staff-related expenditure accounts for 7% of the total.

BPR

The total amount for staff-related expenditure under BPR in 2018 is estimated at c. € 8 million, representing an increase of 14% in comparison with 2017. This increase stems mainly from the additional posts allocated for 2018. Direct salary costs affected by indexation represent 90% of the total staff-related expenditure at € 7.0 million, while other staff costs constitutes 10% at € 0.8 million. As noted above, there are ongoing discussions with DG SANTE with respect to the additional financial and human resource requirements of ECHA's proposed BPR endocrine disruptor activities, which would have an impact on the present planning figures.

PIC

Total amount for staff-related expenditure under PIC is estimated at c. € 0.6 million. This represents an increase of 3% compared to 2017, stemming from the additional post to be received in 2018 and indexation of salaries. The increase is rather low due to the fact that ECHA will not be in a position to fill the additional post from the beginning of the year, due to the limited financial

resources. The direct salaries represent c. € 0.63 million (82%) and other staff costs c. € 0.135 million (18%).

Title 2

The overall Title 2 (infrastructure and operating expenditure) for 2018 amounts to c. € 17 million, which is 13% higher than in 2017.

Chapters 20 (Rental of buildings and associated costs) and 22 (Movable property and associated costs) increase compared to 2017 as a result of the need to incorporate preparations for the new office building. As planned, the Agency has submitted its proposal to the Budgetary Authority in Q4 2017 and a final decision is expected before the end of 2017.

Chapter 21 (Information and communication technology) includes the hosting services for which a transition from the first generation outsourced hosting services and managed services is foreseen in 2018, resulting in increased expenditure.

It is to be noted that ECHA's current lease contract on its building expires in 2019. Should the tendering process for the future building result in recommending a purchase option, ECHA would need to insert the required own financing as an additional subsidy request for 2019, as discussed with DG BUDG.

Operational Titles

Title 3 (REACH / CLP)

Due to the salary increases, ECHA has reduced its expenditure in the operational title below what would normally be required for its activities.

The year 2018 marks the last registration deadline for the phase-in substances, resulting in a significant peak-in-workload and a requirement to increase the workforce, with an associated cost increase¹³. Therefore, the expenditure for registration foreseen for 2018 is significantly higher than in the other years of the planning period. In addition, the need for legal support and litigation costs are expected to increase due to the deadline, resulting in a significant increase in the expenditure for the Management Board and management of the Agency. Furthermore, a notification portal for the notifications related to emergency health response to be used by the Poison Centres will be developed in 2018. This development will cater for millions of notifications across Europe, MS access and related support to stakeholders requiring significant resources in terms of operations including IT development.

In 2017, ECHA performed a feasibility study, and in 2018, ECHA will develop the portal with the resources allocated in 2017 to ECHA's 2017/18 budget for this purpose.

The demand for communication activities to reach out to new registrants, particularly to SMEs, with more support and, where possible, simplified and shorter information, will not reduce. Moreover, continued support will be needed post 2018 for companies who update their dossiers.

Substance evaluation is expected to start increasing again in 2018, with ca. 40 substances to be evaluated, and further increase in 2019. The evaluation work is undertaken by Member States Competent Authorities and, in line with the Fee Regulation, a proportion of funds is transferred to them to compensate for part of the work carried out.

The IT costs in Title 3 are intended to cover all the costs for developing and maintaining IT tools such as REACH-IT, IUCLID, Cloud Services for SMEs, CHESAR, BIDI, Dynamic Case, Portal Dashboard, ODYSSEY and other ECM Programme tools, quality assurance services for these applications and other services. Title 3 also includes critical software development services for which a transition of framework contract is foreseen in 2018 (e.g. software development services for the REACH dossier preparation and dossier submission tools), resulting in a special absorption of resources in that year. The ECM Programme will support ECHA to complete the objectives on

¹³ An extraordinary high number of interims is going to be needed to support the statutory staff to handle the workload stemming from processing the incoming registration dossiers and providing support to the registrants

archiving. Funds are reserved for the implementation of the new ECHA Interact roadmap, aimed at establishing a single interface for Competent Authorities and Committees with easy access to all case and substance information, and standardised interactions with ECHA Processes. Costs related to the Data Management and Dissemination of REACH/CLP data fall under Title 3, as well.

Title 4 (BPR)

The main expenditure item in 2018 for BPR is related to the development of IT tools. In 2018 ECHA will complement the dissemination of information according to the BPR requirements, focusing in particular on biocidal product authorisations. Initially, it was intended to keep the expenditure foreseen for R4BP above the level of the financial fiche in 2018 to support development activities. However, as the requested subsidy for BPR activities was reduced, it might be necessary to scale down further development although the application is expected to go into maintenance mode by end-2018.

Another significant expenditure item relates to the Biocidal Products Committee and the Forum BPR Sub-Group. Through the Committee, ECHA continues delivering opinions for the European Commission to support decision-making on biocidal active substances and products. In fact, ECHA is not only coordinating the evaluation of active substances and the Union-wide authorisation of biocidal products; it is also the central hub for all applications, establishment of technical equivalence, assessment of applications for alternative suppliers, resolution of data sharing disputes, dissemination, preparation of guidance, and communication.

As mentioned above, there may be increased budget needs stemming from the implementation of the criteria on endocrine disrupting properties, subject to their adoption.

Title 5 (PIC)

The largest portion of the PIC budget for 2018 is allocated to the maintenance of the IT tools related to the support of the export notifications and the import consents as well as related reporting. Additional budget was requested, in particular, to ensure the progressive maintenance of the IT system and the timely processing of export notifications and the continuation of stakeholder support in view of the ongoing workload increase. Other main elements are allocated to communications activities, particularly translating materials into 22 languages. As the subsidy currently foreseen for 2018 is lower than requested, and taking account of the imposition of the financial penalty, ECHA will carefully re-assess its priorities, while aiming to minimise the disruption of the activities mentioned above.

Detailed information on budget outturn and cancellation of appropriations is provided in Table 3 of Annex II.

3.2.2 Human resources

Resource outlook over the years 2018 to 2020 (detailed data provided in Table 1 and 2 in Annex III)

As stated above, ECHA is aligned with the Commission Communication COM(2013)519 with respect to the number of TA posts for REACH/CLP, BPR and PIC. ECHA intends to continue maintaining its low vacancy rate for all regulations and implementing proactive human resource management practices to ensure low staff turnover.

A key factor in ECHA's workload during this period will be ECHA's responsibilities in the largest REACH registration deadline in 2018, resulting in ECHA's registration activity undergoing significant growth until end-2018 and requiring potentially significant internal redeployment of staff. ECHA will strive to ensure delivery of its ambitious work programme (including the registration deadline) over this period through the use of the additional six FTEs (CAs) to handle invoicing tasks, internal redeployment, competency development and efficiency measures.

ECHA will also continue to carefully monitor its Establishment Plan and ensure good forward planning with respect to recruitment, mobility and promotions. This will include consideration of changes in the recruitment grades of profiles to maintain, and build, scientific capability, enhance

overall organisational performance and optimise the utilisation of ECHA's allocated human resources within the overall establishment plan. If ECHA cannot maintain its full REACH/CLP Establishment Plan, it will examine the use of additional flexibility measures to ensure that it has the necessary human resources in place to implement the programme of work over the 2018-2020 period. Such flexibility measures will include modification of ECHA's Establishment Plan, in accordance with Article 32(1) and 32(2) of ECHA's Financial Regulation.

ECHA will also continue to work closely with the Network of EU Agencies, the Network of Fee Receiving Agencies (EFRAN) and the Commission services, as appropriate, to develop a viable model for authorising additional human resources in the event of increased workload in 2019-2020.

New tasks:

Since 2015, ECHA has been undertaking a strategic analysis of its future direction and potential tasks with its Management Board and key stakeholders. At present, there are a number of new tasks that have been agreed, or are under discussion, with the Commission services, which will require additional financial and human resources in the period 2018-2020, subject to final agreement. An overview of the main tasks under discussion is provided hereunder.

Poison Centres

The recently published Commission Regulation (EU) 2017/542 adding a new Annex VIII to the CLP Regulation gives ECHA a number of tasks related to the provision of harmonised formats for the obligation to notify hazardous mixtures placed on the market. For 2017, ECHA has absorbed the new tasks regarding formats and technical support for submission of information with its current resources. However, several Member States and stakeholders have expressed their support for ECHA to develop a central notification platform to receive, and make available to the national appointed bodies industry notifications on emergency health responses of all hazardous mixtures placed on the market in the European Economic Area. The Commission has asked ECHA to explore different options, including the provision of database services for those Member States that wish to use these services.

In 2017, ECHA performed a feasibility study, and in 2018, ECHA will develop the portal enabling notifications from companies, dispatching of notifications to the relevant Appointed Bodies/Poison Centres, and central storage of the notifications for auditing purposes and possible retrieval by submitters with the resources allocated in 2017 to ECHA's 2017/18 budget for this purpose. Moreover, ECHA will be ready develop an option for Member States who wish so to get a searchable access to the notification database. This would be dependent on the longer term financing and clarifications on other aspects of the activity which are still under discussion between the Agency and the Commission services.

Endocrine Disruptors (BPR activities)

In the area of BPR activities, a new task for ECHA that would commence in 2018 - following the planned adoption of the criteria for endocrine disruptors by the Commission - is the categorisation of the approved active substances regarding potential endocrine disrupting properties. This represents a significant scientific workload due to the high number of dossiers to be considered for the 150 approved active substances. It is foreseen to use both internal resources and outsourced activities to limit the need for additional expert scientific internal resources. It is expected that, following agreement on the endocrine disruptors criteria, a Commission Communication would be developed, including the related resource implications for both ECHA and EFSA covering the period 2018-2020. This work is still in progress.

Further tasks regarding Occupational Exposure Limits (OELs)

Based on a communication¹⁴ to the Council and Parliament of 10 January 2017 the Commission said to request scientific advice from either the Committee for Risk Assessment (RAC) or the

¹⁴ COM (2017) 12 final.

Scientific Committee on Occupational Exposure (SCOEL) in relation to chemical exposure in the workplace. Consequently, in March 2017, ECHA received a first request from the Commission for RAC to assess the scientific relevance of Occupational Exposure Limits for five carcinogenic chemical substances. Two such opinions were submitted in 2017 and at least three are foreseen for 2018. While this present *ad hoc* request will be handled with a re-allocation of ECHA's current resources, further requests in this area are still in the pipeline for work in 2018, or later, and will require additional resources¹⁵. Depending on the number of cases the scientific staff requirements range from two to four FTEs per year and some additional financial resources are necessary. The Commission is invited to prepare a Communication on the resourcing of such work, especially in the event that a structural decision is taken to allocate this work systematically to ECHA.

Persistent Organic Pollutants

In the context of a recast of Regulation (EC) No 850/2004 on Persistent Organic Pollutants, the Commission is expected to request ECHA to undertake tasks related to providing assistance and technical guidance to the Commission and Member States. A specific financial statement has been developed by the Commission for this purpose, incorporating 2 FTEs and a budget of approximately €0.5 million per year. As the new legislative proposal has not yet been adopted, it is currently expected that this activity will only start in 2019. Therefore, these staff and budget proposals will not be introduced at this stage in the current programming document.

Circular Economy/Non-toxic Environment

The Commission is conducting a targeted stakeholder consultation with respect to the interface between chemicals, products and waste legislation, in support of its commitment under the Circular Economy Action Plan to analyse this interface and deliver a recommendation on policy options by the end of 2017. This work is closely linked to ECHA's (limited) activities in the area of substances in articles, for which it is currently developing a longer-term strategy. While the outcome of the Commission recommendation may indicate the need for future involvement of the Agency in implementing the policy options, the Commission should urgently indicate if ECHA will be required to support the Commission. These activities would require additional resources which are presently estimated to amount to 4 FTEs.

¹⁵ These five cases are estimated to require about 2.5 FTE and about €120000 in total. The staff and financial resources have been re-allocated on an *ad hoc* basis from ECHA's current risk management and evaluation activities and will in the future need to be compensated from other sources than REACH (OSH budget line).

In summary, the table below shows ECHA's indicative estimated human resources needs (in FTEs) for the proposed new tasks:

	2018	2019	2020
Poison Centres	8 ¹⁶	8	8
Endocrine disruptors (BPR)	3	3	3
Occupational Exposure Limits (OELs)	3	3	3
Persistent Organic Pollutants (POPs)	0	2	2
Circular Economy/Non-toxic Environment	1	2	3
TOTAL	15	18	19

Delegated tasks

EU Observatory for Nanomaterials

Hosting the EU Observatory for Nanomaterials is a new task based on a delegation agreement between the European Commission and ECHA, signed in 2016. The Observatory will analyse, evaluate and disseminate information on nanomaterials present on the EU market. While its implementation commenced in 2017, the period when this new task becomes fully operational, involving three additional Contract Agent positions for ECHA, are the years 2018-2020.

EU Chemicals Legislation Finder

A feasibility study on the proposed EU Chemicals Legislation Finder has been concluded in 2017 identifying 55 EU legislations in the desired scope of the tool as first priority. Based on the identification of ECHA as most suitable body, it has been decided to proceed with the task in form of a delegation.¹⁷ At the same time further analysis on architectural and business related aspects of the tool is needed. This analysis will be carried out in 2018. The delegation could be still implemented in Q4 2017 with the project implementation starting in Q1 2019. The funding (from the COSME funds) to be allocated for the first version of a portal is currently set at €1.3 million with a first phase amounting up to €300,000 to develop detailed conceptual and architectural models, and the development phase for a first version of the portal, conditional to a go/no-go decision mid-2018, amounting up to €1.0 million. The total time frame of the project is 2017-2020. The additional staff and budget requirements for running costs are within the scope of the feasibility study.

Growth of existing tasks:

Resource outlook for REACH/CLP-related tasks

This section provides a detailed overview of the anticipated workload associated with ECHA's existing REACH/CLP tasks, the growth of these tasks and the anticipated human resource implications.

As outlined earlier, ECHA's **registration activity** will undergo significant growth until end-2018 as a result of the largest REACH registration deadline in 2018. Successful management of the 2018 deadline is critical to the continued success of REACH and will be a major step in 'closing the information gap' on chemicals. The average number of dossiers to be processed by ECHA in 2018

¹⁶ Only partially absorbed by existing posts, 5 new posts are needed.

¹⁷ Delegation in accordance with Article 8 of the ECHA Financial Regulation.

is anticipated to be ca. 60.000 although there is a considerable uncertainty on the predicted number. This number represents a 20-fold increase in the volume of initial submissions to be handled in a regular year. The 2018 peak registrations will generate additional work, mainly to process the incoming dossiers within the legal deadlines and to offer helpdesk support, particularly to SMEs, handle the data-sharing disputes, assess the confidentiality requests in the dossiers and publish the registration information on ECHA's website. In addition, ECHA will continue the manual verification of certain data requirements (e.g. related to substance identity), as part of the submission process, to ensure that the registrations contain meaningful information. This includes a retrospective verification of existing registrations as well as a check that the registrants register jointly for the same substance. ECHA also expects to receive an increased number of appeals due to these developments.

Although ECHA proposes to engage interim support to handle the peak in workload stemming from the 2018 registration deadline, the tasks related to guidance and regulatory advice, as well as the invoicing process must be handled by statutory staff. Our current estimations indicate that this requires additional workforce, in addition to the interim staff, of six FTEs (temporary Contract Agents), for invoicing, in 2018. The level of industry activity, combined with survey work that is undertaken in 2017, will give ECHA a clearer picture of the level of workload to expect as we approach 2018. In this respect, we may need to revise the current estimations and assess whether internal redeployment is necessary, which may lead to an impact on the delivery of the work programme 2018 as currently planned.

A more robust overview of the currently foreseen scenarios of the 2018 Registration deadline workload volumes and related fee income is presented in Annex XII.

After the registration deadline, the workload related to performing completeness checks and assessing confidentiality requests and, later, to SME verification, will continue to be high until end-2019. From 2019, it is expected that ECHA will continue receiving high number of dossiers per year (approximately 20 000), covering the continuous submission of registrations of high-volume substances as well as dossier updates. This means that the related support and maintenance of the registration-related tools needs to continue and that the number of required staff on registration-related activities shall remain at a high level.

ECHA is also anticipating a steady increase related to handling **data sharing disputes** and providing adequate support to the **substance information exchange forums (SIEFs)**, with a potential significant increase in inquiries as means to get in contact with other registrants due to the closure of the pre-registration option in May 2017. This, in conjunction with enforcing joint submission on legacy cases, will have an important impact on the human resource requirements until end-2018.

ECHA's activity related to **data analysis and demands from EU Authorities**, or other stakeholders, is expected to grow steadily until May 2018 and, then, increase due to the volume of information that will be stored in ECHA's databases. ECHA will enhance screening and prioritisation for subsequent evaluation and risk management work. It will also build capacity for ensuring that this information can serve as a basis for other regulatory work on chemicals. This will require a solid IT platform and IT-related support to provide added-value solutions and services.

In 2017, ECHA is launching new IT **Cloud Services for SMEs** that will require additional resourcing (1 CA in 2018). In 2019, such new services will undergo an evaluation to assess the achievement of the benefits for SMEs and agree on the next steps. In the event of a continuation of this project, the resourcing of the services will be confirmed.

While ECHA's **evaluation activity** is expected to remain relatively stable in this period, certain existing tasks are expected to grow. Following the Commission decisions on over 200 dossier evaluation decisions related to reproduction toxicity, ECHA aims to examine the re-submitted testing proposals by end-2018, and finalise the decision-making on these cases by end-2019. Furthermore, ECHA will start examining all the testing proposals from the 2018 registration deadline, with the aim of concluding these by end-2020. ECHA's Regulatory Strategy foresees a comprehensive evaluation of high-volume priority substances and endpoints until end-2020, which, due to the complexity of the cases, requires at least sustaining, or increasing, resources. The follow-up of decisions will, in many cases, become more complex. ECHA will need to continue intensifying its role in assessing that the vertebrate animal testing is used only as a last resort, which will also

increase the workload. Following the clarification of REACH information requirements for nanomaterials, ECHA expects an increase in the compliance checks for dossiers including substances in nanoform. Although not high in numbers, this is a demanding area due to the scientific and technical complexity.

Existing tasks in the areas of **screening substances** for evaluation, SVHC identification, development of the Annex XIV recommendation, restrictions and harmonised Classification and Labelling are likely to remain stable or grow slightly. This is due to:

- further implementation of the actions foreseen under the Integrated Regulatory Strategy and the SVHC Roadmap
- the fact that the fraction of complicated dossiers will increase (for example, Article 57(f) SVHC cases and CLH dossiers for PPPs/biocides), and more support from ECHA is requested by Member States for coordination work (for example, screening/RMOA) and during preparation of risk management proposals (for example, restrictions).

Whilst there is a decrease foreseen in the number of applications for authorisation for 2017 and the first half of 2018, this temporary drop in activity is compensated by a substantial increase in requests by the Commission to ECHA to develop **proposals for restrictions**.

A substantial increase is foreseen in the number of **CLH dossiers for pesticides**, in particular due to the review programme for pesticides and the policy agreement to review their classification in parallel. The number of CLH dossiers for industrial chemicals will likely increase as well due to the fact that proceeding with REACH authorisation and restrictions and with actions under other EU legislation requires or strongly benefits from the harmonised classification.

For the **substances in articles and in recycling materials**, the current resources are minimal. Should ECHA work towards a situation where the risks resulting from substances in articles are addressed at a level similar to the risk related to the use of substances on their own or in mixtures, it will require an increase in resources. Similarly, this applies if ECHA is requested to support further activities to ensure that chemicals are not hindering the Circular Economy. Further work will, in particular, be needed to support supply-chain communication tools and mechanisms (from the production of materials outside the EU to articles entering the recycling), and improved exposure assessment tools and approaches.

Finally, from 2017, ECHA will reorient its activity to assist industry to improve the **supply chain communication**. ECHA intends to create a programme for Safe Use of Substances in Europe where it will collaborate with industry stakeholders to support channelling appropriate, 'fit-for-purpose', information to the end users of substances, and their use of this information in a meaningful way. At the same time, the end-users need to communicate their uses to the manufacturers and importers of substances so that the information flow constantly improves.

In summary, due to the above-mentioned increased activity in the peak year 2018, as the Commission has decided to strictly follow the MFF staff planning, it is foreseen to compensate the loss in part-time working arrangements by additional AD posts (4 in total), in line with the relevant provision in the Staff Regulations.

Resource outlook for BPR regulation

It is estimated that ECHA's work related to the BPR is perceived as a growing activity in which the workload will increase in the period 2018–2020, and beyond, requiring additional resources. It is in the interest of both the Commission services and ECHA to ensure that ECHA has the necessary resources to successfully manage these important tasks, which may require deviation from the MFF planning (which dates from 2013).

The rationale for ECHA's 2018 budget request for an increase in human resource requirements was twofold. Firstly, in 2016, ECHA received a much higher than planned number of applications for both Union authorisations and approval of active substances that generates scientific work in 2018 and requires additional resources (four FTEs). Secondly, in line with the information presented above, following the adoption by the Commission of criteria for endocrine-disrupting properties under the BPR, ECHA needs to re-evaluate a number of approved active substances vis-à-vis these new criteria, with a consequent increase in resources.

An increase in Union authorisation applications is foreseen, potentially rising to 50 in 2018. The peer review work for the 2015 Union authorisation applications will occur mostly in 2018, while the peer review work for 2016 Union authorisation applications will occur between Q4 2018 and 2019. 2019 should also see some of the peer review work for the 2017 applications while, in 2020, there will be work related to 2017 applications and, to a lesser degree, 2018 applications.

In addition, a significant peak of applications for the approval of active substances has been received in relation to the legal deadline of 1 September 2016 for Articles 93 and 94 of the BPR. This will translate into increased workload for the corresponding peer review activities in 2018, 2019 and, possibly, the following years as some of the evaluations might be delayed because of the need for additional data. Another peak of active substance applications is foreseen in 2018, linked to the two-year period for applying, following the acceptance of the 2016 notifications. The major part of the resulting workload should take place in 2020 and 2021.

Resource outlook for PIC regulation

For the PIC Regulation, relating to the export and import of hazardous chemicals, it is proposed to follow the legislative financial statement and the Commission Communication COM(2013)519 with respect to the number of TA posts for PIC tasks, which includes one additional post in 2018. However, it is to be noted that the number of notifications is increasing every year by a higher number than initially estimated and, by end-2016, will have already exceeded the volume estimated for 2017, requiring additional interim support for handling the peak of notifications in Q4 of each year.

Efficiency gains and negative priorities

In 2014, ECHA initiated a process – ‘ECHA 2020’ – to take the existing and future resource and policy challenges as an opportunity to start reshaping ECHA's resourcing priorities. A number of activities were identified as potentially decreasing in resource requirements over the planning period, with the general aim to refocus resources to leaner and more impactful regulatory work. At the same time, ECHA has been taking on new tasks and integrating them within its operations.

The Efficiency Programme is expected to continue in its current form until at least 2018, having supported the optimisation of key existing processes by then. ECHA's management system, which is ISO9001-2015 certified, according to internationally recognised good practice, will continue to drive improvement in work practices. The overall resource savings created through the efficiency programme will lead to increased allocation of resources to processes that create operational output.

The objectives of efficiency work in 2019-2020 will be scoped on the basis of the multi-annual strategic objectives 2019-2023, which should also reflect the conclusions and recommendations of the REACH review and the REFIT exercise undertaken by the Commission on the EU chemicals legislation in 2017. ECHA's drivers, presented in Section 3, such as raising the quality of information on chemicals and addressing chemicals of concern, are expected to remain priorities for further efficiency improvement, as well as the integration of new legislation and the more impactful use of the wealth of data collected under the various regulations.

In addition, ECHA will continue to report on its efficiency gains in the context of the Commission's annual Job Screening Exercise.

Opportunities for redeployment

ECHA will maintain its proactive approach to human resources management and will continue to actively promote redeployment, leveraging internal skills and increasing overall flexibility. As an example, ECHA will implement an internal flexible redeployment programme to support the 2018 registration deadline. In addition, in relation to substance evaluation, the number of evaluations in

2017 is expected to temporarily reduce the workload in ECHA in 2018-2019, allowing re-allocation of resources to dossier evaluation and other tasks related to regulatory strategy implementation.

Conclusion on evolution of resources compared to the Commission Communication 2014-2020

Since the publication of the Commission Communication - COM(2013)519 – ECHA has complied fully with the REACH/CLP and PIC imposed Temporary Agent posts reductions, while its BPR activity was under-resourced in comparison with this Communication. For 2018, ECHA is in line with COM(2013)519 with respect to REACH/CLP, BPR and PIC Temporary Agent post allocations. With respect to the longer term, as stated earlier, ECHA has been engaged in a strategic analysis of its future direction, and potential new tasks, with its Management Board and key stakeholders and there are presently a number of new tasks that have been agreed, or are under discussion, with the Commission services, which will require additional human resource requirements, subject to final agreement.

It is considered that the retention of performing staff is central to ECHA's continued success. Key issues to be addressed during the period of this Plan include effective performance management; competency development; people development strategies and allocation of posts to priority areas. The appropriateness of ECHA's organisation will also be reviewed, as needed. Finally, it is recognised that it will be a significant management challenge to proactively motivate staff in the achievement of our priorities in a context of increasing workload and decreasing resources.

III WORK PROGRAMME 2018

Executive summary

The fifth and last year of implementing ECHA's five-year strategy, described in the Multi-Annual Work Programme (MAWP) 2014-2018, involves further pursuit of the four strategic objectives. These four objectives are – as before – complemented with specific support to SMEs, embedded in ECHA's activities, since a growing proportion of these companies have imminent obligations under the four regulations managed by ECHA.

2018 is the year of the last REACH registration deadline for companies manufacturing or importing substances on the market in the EU in volumes of 1 to 100 tonnes per year. ECHA has estimated the likely number of registrations for this deadline. Any major deviation from this assumption may affect the implementation of the Work Programme either through reduced fee income or through an increased workload to support the registration process.

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

The year 2018 is a year of the third and last registration deadline for phase-in substances affecting maybe the largest group of registrants - the small and medium-sized enterprises (SMEs). SMEs will have access to centrally hosted cloud services to support them in meeting their registration obligations. By the end of the year, ECHA expects to process an increasing number of dossiers including in some cases manual tasks, before assigning a registration number. All related processes will be enhanced to cater for this increased number of submissions, including support to SIEF members, by solving late data sharing disputes and ensuring that all registrants can get access to the joint submission.

Finally, ECHA will use its chairmanship of the Directors' Contact Group (DCG) to identify any risks of unexpected withdrawal of low volume substances that are critical for the supply chains.

Based on the updated CSR/ES Roadmap, and especially under the Downstream User Communications Strategy, ECHA will further improve its downstream user tools and provide them to all users, not least SMEs, in user and reader-friendly formats.

In order to improve the safety information on substances that matter, ECHA conducts compliance checks or takes complementary measures such as sector approaches to address the highest priority substances, focusing on higher tier human health and environment endpoints in lead and individual dossiers. Together with other actions, this allows ECHA to progress on the mapping of the substances on EU market (i.e. the 'chemical universe'), as part of its integrated regulatory strategy.

After the release of new dissemination platform in early 2016 and improvements made in 2017 to increase its performance in view of the voluminous 2018 deadline, ECHA will continue publishing information on substances, with a focus on the BPR data (especially Summary of Product Characteristics and Product Assessment Report) and the information stemming from the 2018 deadline; it will also make further improvements to the dissemination web section. ECHA will also further develop its communications targeted at non-expert audiences, such as retailers and consumers.

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

The integrated screening activities will continue to identify substances of potential concern, which should either be addressed under compliance check or placed on the Community Rolling Action Plan (CoRAP) for substance evaluation. Based on experience gained in 2017, this work will focus more on addressing groups of substances rather than single substances. ECHA anticipates that the number of substance evaluations initiated in 2018 will be higher than in the previous year and will continue contributing to the regulatory risk management processes.

Should the concern be ascertained already at the screening stage, the appropriate risk management measure shall be identified through risk management option analysis (RMOA) or, if the measure is decided upon directly, via a proposal for that specific measure (i.e. restriction, authorisation, harmonised classification). Thanks to the new hazard information coming from previous evaluation decisions it is expected that the number of substances put forward for the Candidate List or number of proposals for harmonised classification and of restrictions will increase.

The recommendations from the review of the SVHC roadmap implementation plan will be used to adapt the work towards 2018-2020 and where needed introduce changes to the co-operation and co-ordination structures with all authorities to ensure optimal impact of the work on substances that matter the most. It is also expected that a larger number of Member States will participate in these efforts thus contributing to the implementation of the integrated regulatory strategy.

More focus will be given to the implementation of a strategy that aims at increasing the capacity of Member States and industry to carry out analysis of alternatives and consequent successful substitution of hazardous substances. Also substances in articles will be addressed at the national enforcement level through a dedicated Forum pilot project.

Finally, further screening and monitoring of substances that are inquired, newly registered, or notified for PPORD might provide indications whether less hazardous substances are entering the market, also as a result of substitution. Additionally, information regarding renewable, recovered or recycled materials will become available, thus supporting policy goals for the circular economy and the non-toxic environment.

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

ECHA will continue building up a systematic approach for further developing the scientific capacity in accordance with its science strategy defined in 2014, which outlined the areas that are most important from the regulatory decision-making perspective.

ECHA will also prepare a plan to update all relevant guidance to the latest developments in regulatory science. Special emphasis is put to guidance that can be used by industry and regulators to improve the quality of registration data through evaluation decision-making and spontaneous updates of registration dossiers. ECHA will use its expert group on endocrine disruptors to apply the criteria to identify such substances under REACH and BPR, as described in the guidance to be published in 2017, and this way will gather experiences in implementing the criteria adopted by the Commission.

After the Commission's review of the REACH annexes relevant for nanomaterials, ECHA will review its guidance for nanomaterials to be adopted after the registration deadline. This guidance would eliminate any remaining uncertainty on how the safety of nanomaterials should be addressed as part of REACH registration. ECHA will also focus on improving its capacity to assess the alternative methods to animal testing in the context of regulatory assessment of chemicals, leveraging its scientific expertise and data management capabilities, and building on its report on applicability of the alternative methods to be published in 2017.

Furthermore, ECHA will continue providing scientific advice to the Commission on how the REACH data can be used in support of other legislation.

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

To achieve the ambitious targets of the Work Programme, ECHA will continue to improve its efficiency and effectiveness. Regarding implementation of the Biocidal Products Regulation (BPR), ECHA will start reviewing the Union Authorisation process on the basis of experience gained in the first years of implementation. The increase in application related workload for the Secretariat and the Biocidal Product Committee will require monitoring and further efficiency measures.

In 2017 a pilot is being performed to validate a vision that ECHA, Authorities & Committees become a seamless virtual team on applicable regulatory tasks by sharing the same tools enhanced for collaboration. Taking stock of the pilot's results, in 2018, the Agency will further pursue the improvement of IT support for collaboration with Member States authorities and Committee members.

ECHA will launch the second version of the European observatory for nanomaterials with enhanced content for various audiences, and launch the preparations for the third phase which will complete the set up phase of the observatory in 2019.

Following the clarification of the legal basis by the Commission concerning Poison Centres, start the development of a one-stop notification portal for the notifications by companies of emergency health response information to the national authorities, in time for the first deadline (01.01.2020). For this, ECHA will build on its expertise, in developing and operating submission systems, e.g. security, assistance through helpdesk, technical checks, etc.

Based on the measurements developed in 2014 and refined in 2017, ECHA will report on the progress made in achieving its strategic objectives in the view of closing the 5 year multi-annual planning period 2014-2018. It will also continue to monitor the evolution of its annual performance indicators introduced for the first time in 2017.

Finally, ECHA will also adopt its new strategic plan 2019-2023, which should reflect also the conclusions and recommendations of the REACH review and of the REFIT exercises undertaken by the Commission on the EU chemicals legislation in 2017.

1. Operational activities

1.1 REACH and CLP dossier management and assessment

ECHA provides assistance and tools to companies in the elaboration and submission of their registration dossiers via its regulatory advice, 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 the substance identity, hazard, use and exposure information as well as testing proposals submitted by companies to verify compliance and hereby improve the safety information and thereby risk management of chemicals, and to support identification of candidates for regulatory risk management measures. The Member States evaluate substances in order to clarify whether a given substance may pose a risk to human health or the environment.

Enforcement of the REACH Regulation is the responsibility of the Member States. However, the Forum for Exchange of Information on Enforcement as a body of ECHA constitutes a network involving Member State enforcement authorities for the purpose of harmonising their approach to enforcement of REACH provisions.

1.1.1 Registration dossier preparation

Overview

It is more cost effective to support companies while they are preparing their dossiers rather than asking for updating the dossier after the initial submission. Therefore, ECHA provides structured IT tools as well as extensive advice and assistance to industry to support them in fulfilling their legal obligations. The level of provided support includes not only reactive to received requests, but also proactive via webinars, participation in training events, etc.

To support companies in fulfilling their information requirements, the Agency provides guidance and contributes actively to the further development of test methods, including alternative test methods to animal testing, and the use of weight of evidence. ECHA also co-manages the development of the Organisation for Economic Cooperation and Development (OECD) Quantitative Structure-Activity Relationship (QSAR) Toolbox with the view of helping companies in providing robust scientific justifications for the use of alternative methods and grouping of chemicals.

The Agency provides IT systems for dossier preparation: IUCLID and ECHA Cloud Services for SMEs for preparing the registration dossier and Chesar, for carrying out the chemical safety assessment and preparing the chemical safety report and the exposure scenarios in the extended safety data sheets (SDS). Under international cooperation activities requested by the Commission, the submission formats and software, especially IUCLID, are developed in cooperation with the OECD to promote international harmonisation that may help companies to re-use their data under other regulatory regimes.

To facilitate the joint registration, which is a legal obligation, the Agency provides scientific advice to registrants on the identification of their substance and facilitates data-sharing by putting registrants in contact via the inquiry process. ECHA also decides on submitted data-sharing disputes and gives access to data when appropriate. In addition, continued sector approach allows for both, specific advice and better reach-out to relevant (SME) companies.

ECHA informs key audiences in non-EU countries, in order to heighten their understanding of the EU chemicals safety regime and the information needs of EU duty holders.

The ECHA Secretariat supports the Forum to further strengthen and harmonise the effective enforcement of the data-sharing decisions in the EU/ European Economic Area (EEA) Member States.

ECHA's data-sharing decisions are appealable to the Board of Appeal and ECHA's legal defence is provided by the Secretariat.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Helpdesk questions received ¹⁸	3 298	2 800	5 000 – 10 000
Inquiries concluded	1 235	1 700 ¹⁹	1 900
Access to data older than 12 years	167	350	390
Data-sharing disputes	23	80	170
Decisions on data-sharing disputes	7	70	140
Appeals on data-sharing decisions	0	1	8

Key objective

Registrants, especially SMEs, have access to data, tools and guidance for preparing complete and compliant dossiers.

Main actions and outputs of 2018

- Carry out the final phase of ECHA's REACH 2018 roadmap for the last registration deadline of phase-in substances, and specifically:
 - Continue 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 remind chemical companies of their REACH obligations and orient late comers towards the relevant support.
 - Publish the last phase of the Roadmap ('Keep your registration dossier up-to-date').
- Support companies in fulfilling their registration obligations for the 2018 registration deadline, and specifically:
 - Support national helpdesks with *ad hoc* training and information sharing so that they can support registrants in their own language, as well as participation in national events to provide training to companies on registration.
 - Reply to an increasing number of regulatory questions from registrants in relation to the registration deadline. The topics will be on registration obligations (tonnage band calculation, possible exemptions); data and cost sharing, and joint submission obligations. In the final months before the deadline ECHA may contact the registrants by phone, as done in 2010 and 2013.
 - Tackle unexpected generic issues of broad impact in a coordinated manner by means of the Directors' Contact Group (DCG).

¹⁸ Regulatory and non-regulatory questions related to dossier preparation only. A surge foreseen in 2018 is related to the REACH Registration deadline; estimation is based on the analysis of historical trends and the assumption from an updated Commission Staff Model that 60 000 new dossiers will be submitted in 2018, mostly by smaller and less experienced companies that rely primarily on ECHA's support and advice

¹⁹ After 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.

- Continue the progressive maintenance of IUCLID 6 and CHESAR, the IT tools necessary for the 2018 registrants, including support and training to users.
- Provide cloud services to SMEs to enable them to manage their data and prepare their IUCLID dossiers directly online on an ECHA hosted and supported platform so that they can focus their resources on data requirements matters rather than IT tools management.
- Promote the implementation of the CSR/ES Roadmap products, particularly the uptake of use maps as an input to the new registration dossiers and updates, and make them available to their users in user and reader-friendly formats, as part of ECHA's Downstream User Communications Strategy.
- Cooperate with industry sectors on continuous improvement of registration dossiers.
- SIEF management
 - Manage the expected high number of data-sharing disputes arising from the reinforcement of the One Substance One Registration (OSOR) principle in REACH-IT to ensure that SIEF members can get access to the joint submission, and provide support and advice in this context.
 - As the obligation to inquire continues also after the registration deadline, process the expected high number of inquiries, and thus provide swift access to the market for companies.
- Continue promoting appropriate use of alternative methods to animal testing by:
 - Promote the QSAR Assessment Framework (QAF) and Read-Across Assessment Framework (RAAF).
 - Continue to promote QSAR Toolbox and support the users by organising training and providing additional materials.
 - Communicate on the outcome of the report on alternatives to animal testing and recommendations to registrants.
- Carry out a review of ECHA's guidance for nanomaterials to adapt it to the revised REACH annexes
- Prepare a vision how to deliver services and tools to companies after the last registration deadline

Performance indicators²⁰	2016 actual	2017 estimate	2018 target
Percentage of inquiries concluded within the target timeframe (20 working days)	95%	80%	80%
(NEW) Effective working time of ECHA staff used per inquiry concluded	NA	1.8 – 2 person days	1.8 – 2 person days

²⁰ For new proposed indicators the values for 2015 and 2016 are not available (NA);

(NEW) Percentage of received data sharing disputes handled within relevant timeframes ²¹	NA	100%	80%
(NEW) Effective working time of ECHA staff used per data sharing decision	NA	16 – 18 person days	16 – 18 person days
(NEW) Percentage of ECHA Helpdesk questions related to dossier preparation, answered within 15 working days	NA	90%	90%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	13 443 371	12 330 283	12 503 085
Human resources (FTE)	45	49	50

1.1.2 Registration and dossier submission

Overview

The Agency processes registration dossiers, requests for temporary exemption of registration obligations (Product and Process Oriented Research and Development PPORD), notifications by producers and importers of substances of very high concern contained in articles and reports submitted by downstream users.

Before assigning the registration number, the Agency verifies the completeness of the information and the payment of the registration fee in order to ensure that all the elements required are included in the dossier and are meaningful. This may include a manual verification of the submitted information. The Agency also performs retrospective completeness checks on existing registrations to ensure level playing field with new or updated submissions. Once the registration decision has been adopted, the Agency verifies whether confidentiality requests introduced by the registrants in their dossiers are justified. It also checks the correctness of reductions granted to SMEs and of the level of fees paid to ECHA, and in case of abuse, may revoke the registration decision.

The Agency assesses the PPORD notifications and may set conditions where it matters for safe use, after consultation with the member states competent authorities.

ECHA's registration decisions can be appealed and ECHA's legal defence is submitted to the Board of Appeal by the Secretariat.

To support the submission and processing of the dossiers, the Agency develops and maintains the REACH-IT system which also provides a secure communication channel between all involved parties. Furthermore, high quality of identifiers for substances used in the ECHA databases is important to ensure consistency on regulatory decisions across all legislations managed by ECHA. This is increasing in importance with the possible development of the central notification portal for Poison Centres and the European Legislation Finder.

ECHA Secretariat supports the Forum to further strengthen and harmonise the effective enforcement of ECHA's regulatory decisions.

²¹ Disputes for non-phase-in substances have a legal deadline of 1 month while disputes for phase-in substance do not have a legal deadline (only internal deadline of 40 working days)

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Registration dossiers received (including updates)	11 357	13 000	60 000
Confidentiality requests processed	187	540	3 290
PPORD notifications received (including requests for extension)	212	300	300
Helpdesk questions received ²²	2 292	2 000	5 000 – 10 000
Decisions on completeness check (negative)	89	260	1 200
Decisions on confidentiality requests (negative)	24	65	340
Decisions on PPORD notifications	44	50	50
Appeals submitted ²³	2	2	10

Key objective

ECHA processes registrations in an efficient manner to ensure that companies get swift access to the market, while ensuring that their registration dossiers are complete (“no data, no market”).

Main actions and outputs of 2018

- Manage successfully the registration deadline of 31 May 2018:
 - Monitor, in cooperation with the stakeholders, the overall progress of REACH 2018 registrations.
 - Process efficiently a high number of registrations within the legal timeframes.
 - Perform completeness checks of the dossiers received, including a manual check where necessary, and provide advice as needed on how to complete the dossier.
 - Support registrants who need specific support with their registration dossier submission including proactive contacts as necessary and feasible.
 - Deploy resources as needed - including flexible redeployment and on-boarding of new interim staff- in order to react promptly to any potential issues that might endanger the registration.
 - Initiate significant number of confidentiality assessments with the purpose of concluding on all confidentiality requests present in 2018 registrations during 2020.
- As part of implementation of ECHA's regulatory strategy, and depending on the resources needed to handle the peak of registrations:

²² Regulatory and non-regulatory questions related to dossier submission only. A surge foreseen in 2018 is related to the REACH Registration deadline; estimation is based on the analysis of historical trends and the assumption from an updated Commission Staff Model that 60 000 new dossiers will be submitted in 2018, mostly by smaller and less experienced companies that rely primarily on ECHA's support and advice

²³ 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

- Continue to carry out retrospective completeness checks of registration dossiers submitted prior to the entry into force of the enhanced completeness check in June 2016, to ensure a level playing field among registrants and to ensure the availability of key information in the registration database as input for subsequent regulatory processes and dissemination.
- 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, verification of the intermediate status of substances of very high concern, and other measures so that the quality of registration information is further enhanced.
- Prepare and decide on the initiation of Forum pilot projects on enforcement of registration obligations.
- Further develop capacity to enhance the quality of substance identifiers used in the database e.g. to identify and remove duplicates for registrations submitted using different substance identifiers for the same substance, while promoting the consistency of substance sameness within joint registrations in general.
- Analyse inquiries, new registrations and PPORDs with the aim to track substitution, renewables and recycled or recovered materials with a view to provide information relevant to policies on circular economy and the non-toxic environment.

Performance indicators ^{24 25}	2016 actual	2017 estimate	2018 target
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA	High	High	High
(NEW) Percentage of dossiers where the first completeness check is performed within 15 days (working days) (time between starting and finishing the check) ²⁶	NA	100%	90%
(NEW) Effective working time of ECHA staff used per processed registration dossier (incl. updates)	NA	0.6 – 0.65 person days	0.55 – 0.6 person days
(NEW) Percentage of ECHA Helpdesk questions related to dossier submission and substance identity, answered within 15 working days.	NA	90%	90%

²⁴ To measure ECHA's performance as perceived by its internal and external stakeholders and to assess their satisfaction with ECHA's services the Agency conducts a survey at the end of each year. The stakeholder survey is sent out in several parts addressing different groups of customers and different types of ECHA's activities. The average of the results for all satisfaction questions (e.g. How satisfied are you with...?) for a given activity constitute the annual satisfaction rate per activity which then constitutes the result of each performance indicator related to satisfaction level. A high satisfaction rate is reached when satisfaction is 75% or higher, a medium satisfaction rate is reached when it is 50% or higher and a low rate is given when the result is below 50%. This methodology applies to all performance indicators measuring satisfaction throughout the Work Programme 2017

²⁵ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

²⁶ The REACH Regulation provides 15 working days as deadline to perform the first completeness check of a dossier since its submission date. An extended deadline is granted in Article 20(2) for dossiers submitted up to two months before the registration deadline (i.e. a first completeness check must be performed within three months after the registration deadline). In order to preserve the efficiency of the process, ECHA aims to remain within 15 working days from the starting until the finalisation of the first completeness check for all dossiers regardless of their submission date. This means that while the completeness check of a dossier submitted between 1 April and 31 May may be opened at any point in the three-month period after the deadline, ECHA aims to resolve 90% of cases in a period no longer than three weeks throughout 2018.

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	9 856 308	9 564 452	11 454 871
Human resources (FTE)	39	42	45

1.1.3 Evaluation

Overview

Once the substances are registered ECHA conducts compliance checks on a proportion of registration dossiers to examine whether they are in compliance with the information requirements of the REACH Regulation. In doing so ECHA focuses on filling potential information gaps for higher tier endpoints of substances that matter, in line with the integrated regulatory strategy. Moreover, testing proposals included in the registration dossiers are examined to make sure that the generation of information on a given substance is tailored to real information needs and that unnecessary animal testing is avoided. After the final decision, follow-up evaluation continues to assess the adequacy of the submitted information in response to ECHA dossier evaluation decisions and to flag substances for further action, including relevant regulatory risk management measures.

ECHA coordinates and supports the substance evaluation which is performed by the Member State competent authorities (MSCAs) to clarify potential concerns, and involves an assessment of all available information. It may also lead to requests for further information from registrants, if appropriate. The starting point for substance evaluation is the annually updated Community rolling action plan (CoRAP) for substances subject to substance evaluation.

ECHA Member State Committee (MSC) participates in the evaluation decision-making on cases where MSCAs or, in case of substance evaluation, the ECHA Secretariat have proposed amendments to draft decisions prepared either by the ECHA Secretariat or a MSCA. The ECHA Secretariat supports the MSC to ensure high efficiency and quality of outputs. The ECHA Secretariat supports the Forum to further strengthen and harmonise the effective enforcement of the evaluation decisions in the EU/EEA Member States.

ECHA's dossier evaluation and substance evaluation decisions can be appealed and ECHA's legal defence is submitted to the Board of Appeal by the Secretariat.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Substances assessed for priority for regulatory actions	tbc	tbc	tbc
Draft decisions on testing proposals	133	70	145
Final decisions on testing proposals	116	150	105
Compliance checks concluded	176	220	200
Final decisions on compliance checks	132	180	180
Follow-up evaluations on dossier evaluation decisions concluded	355	330	330
Number of substances on the CoRAP list to be evaluated by the MSs	39	25	40

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Final decisions on substance evaluation	27	30	30
Appeals submitted	8	23	18
Helpdesk questions received ²⁷	801	750	500

Key objective

ECHA identifies and addresses, in an efficient manner, non-compliant registrations for substances where it matters most for risk management. ECHA identifies and addresses, in an efficient manner, substances where additional information may be needed to clarify concerns of importance for risk management.

Main actions and outputs of 2018

- Perform a preliminary assessment on a broad number of substances to define which should be shortlisted for regulatory actions and which are of lower priority, thus 'mapping the universe of chemicals'
- As part of implementing ECHA's regulatory strategy and in coordination with other activities, continue compliance checks addressing relevant higher tier hazard endpoints for substances of potential concern over 1000 tn dossiers and 100-1000 tn dossiers. 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.
- With the aim to accelerate closing data gaps on priority substances and endpoints, and building on the experience gained in 2017, continue addressing selected groups of priority substances using read-across or grouping approaches also through other means than compliance check, including informal interaction with registrants or sector groups and working in collaboration with Member States competent authorities.
- Establish a plan for compliance checks for years 2019-2020 in view of the WSSD 2020 target to understand for which (high volume) substances more hazard data are still needed to clarify their potential concern.
- Continue providing improved visibility to content and outcome of compliance checks through the dissemination platform and the annual Evaluation Report with recommendations to registrants.
- 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.
- Plan the examination of testing proposals included in the registration dossiers from the 2018 deadline.
- 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 the information obtained and any conclusions made are fed back into screening and

²⁷ Regulatory and non-regulatory questions related to evaluation only.

regulatory risk management processes.

- Ensure, together with Member States, that substance evaluation contributes in an effective and efficient manner to the implementation of the integrated regulatory strategy and supports the regulatory risk management processes. 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.
- Provide useful regulatory advice to registrants and other interested parties on information requirements, and dossier and substance evaluation processes.

Performance indicators²⁸	2016 actual	2017 estimate	2018 target
Level of satisfaction of MSCAs with ECHA's coordination and support to substance evaluation.	High	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	High
Percentage of unanimous MSC agreements on evaluation decisions	99%	80%	80%
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	94%	≥75%	≥75%
(NEW)Effective working time of ECHA staff used per main, final dossier evaluation output (compliance checks concluded with no draft decision, decisions on testing proposals and compliance checks)	NA	25 – 28 person days	25 – 28 person days
(NEW)Percentage of Follow-up evaluations performed within 6 months from the deadline set in a Decision (testing proposals and compliance checks)	NA	90%	80%
(NEW)Percentage of substance evaluation decisions adopted within 45 days from the MSCA/MS agreement	NA	90%	90%
(NEW)Percentage of ECHA Helpdesk questions related to evaluation, answered within established timeframe (15 working days)	NA	90%	90%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	18 503 168	17 874 662	19 095 180
Human resources (FTE)	106	106	106

²⁸ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

1.1.4 Communication of risk management advice through the supply chain

Overview

ECHA supports registrants and downstream users in the development (and application) of tools and communication processes to ensure that meaningful information on uses and conditions of safe use is communicated up and down the supply chain. Support is provided through regulatory advice, HelpNet, communications and guidance activities as well as the Exchange Network on Exposure Scenarios (ENES). This activity corresponds to the commitments of ECHA under the Chemical safety report / Exposure scenarios Roadmap (CSR/ES Roadmap²⁹). It also links with ECHA's actions related to Registration dossier preparation (Activity 1.1.1) as the communication up the supply chain has a direct impact on the fulfilment of the information requirements.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Number of events organised with industry to improve the uptake of Roadmap products	5	5	5
Helpdesk questions received ³⁰	173	200	250

Key objective

ECHA facilitates the generation and communication of information on uses, exposure and risk management up and down the supply chain so that an effective cycle of information to manage risks from chemicals is created.

Main actions and outputs of 2018

- Improved knowledge on what kind of information and in what format downstream users at the end of the supply chain would need from suppliers, taking into account different national requirements.
- Have further developed tools and templates to support formulators to process exposure scenarios into meaningful information for their customers, including SMEs.
- Operators have increasingly meaningful information from the exposure scenarios (and thus extended SDS) so that they can generate site specific information (e.g. work place instruction cards) to ensure health of their workers.
- Through collaboration with the US Occupational Safety and Health Administration (OSHA), have the "Healthy Work Place campaign 2018-19" on hazardous substances contributing to the improved chemicals management in the EU and creating synergies between the implementation of OSH requirements and REACH requirements.
- Provide useful regulatory advice to stakeholders in relation to communication in the supply chain, downstream users, safety data sheets and exposure scenario, amongst other.
- Make the products emanating from the work of the ENES in accordance with the CSR/ES Roadmap publicly available to their users, in particular to small and medium-sized companies, in user and reader-friendly formats, in line with ECHA's Downstream User Communications Strategy.

²⁹ [CSR/ES Roadmap](#) link

³⁰ Regulatory and non-regulatory questions related to communication of risk management advice through the supply chain.

- Report from the Forum's fifth coordinated enforcement project on extended safety data sheets (REF-5).

Performance indicators ³¹	2016 actual	2017 estimate	2018 target
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	High
(NEW)Percentage of ECHA Helpdesk questions related to communication of risk management advice through the supply chain, answered within established timeframe (15 working days)	NA	90%	90%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	3 098 187	3 036 807	2 911 108
Human resources (FTE)	15	16	16

1.2 Risk management

ECHA supports the implementation of the restrictions and authorisation titles under REACH. The authorisation procedure aims to assure that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring 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. ECHA provides, through its Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC), opinions for the European Commission on authorisation applications and on proposals for restrictions.

Based on the Commission's request ECHA will prepare the basis and issue opinions to underpin the Commission's possible proposals for Occupational Exposure Limit (OEL) values. Two such opinions were submitted in 2017 and at least three are foreseen for 2018³².

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

ECHA keeps duty holders and national helpdesks updated on developments via its communications, regulatory advice, HelpNet and guidance activities.

ECHA will continue its contacts with peer agencies in Australia, Canada, Japan and the United States of America to exchange knowledge and experience particularly on risk identification and risk

³¹ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

³² These five cases are estimated to require about 2.5 FTE and about €120000 in total. The staff and financial resources have been re-allocated on an *ad hoc* basis from ECHA's current risk management and evaluation activities.

management topics.

1.2.1 Identifying needs for Regulatory Risk Management

Overview

ECHA's strategic objective 2 calls for intelligent use of REACH and 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. These processes should eventually as well enable the identification of substances that have no or low priority for further regulatory action.

The Risk Management Option Analysis (RMOA) framework supports selection of the most appropriate regulatory risk management instrument(s) to address the identified concerns. In line with the intentions of the SVHC roadmap to 2020 the common screening approaches and RMOA together aim to ensure an efficient and integrated use of the REACH and CLP processes for clarifying, by further data generation where needed, and addressing the identified concerns.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Upon request by the Commission, support provided for the development of RMO analyses and/or SVHC dossiers	0	5	5
Number of expert and coordination meetings (PBT and ED Expert groups and Risk Management Expert Meetings - RiME)	8	9	9

Key objective

Early identification and improved prioritisation of substances with highest concerns of importance for risk management, is provided, and the preferred REACH or CLP or other regulatory process to confirm and address the identified concerns is indicated.

Main actions and outputs of 2018

- Adapt the common screening to allow the newly registered substances to be directed to the relevant REACH and CLP processes. The new registration data will be used to complete the picture of the chemicals universe. Grouping of substances at the screening phase will be used to allow more holistic and effective assessment and processing of substances that matter throughout the regulatory steps.
- The identification of the needs for the regulatory risk management will make full use of the further information generated by CCH and SEv. This is enhanced by further aligning the screening, RMOA and evaluation processes. Integration of the risk management thinking to screening and evaluation processes will help optimise the number and sequence of the regulatory steps. Early RMOA is also used to increase transparency of foreseen regulatory actions as well as conclusions to not take further action.
- Continue coordinating and providing support to Member States in preparing RMOAs and develop them upon request by the Commission.
- The endocrine disruptor (ED) identification guidance developed in 2017 to support the use of the ED criteria is foreseen to accelerate the informal assessment process. Therefore, the ED Expert Group will need to increase its capacity to support this phase. ECHA will also continue to address more detailed guidance needs identified during the work done in 2017.
- PBT assessment work is stable and supported by the guidance updated in 2017 and the new

insights on how to use a wide range of (eco)toxicological information.

- REACH data and compliance with REACH obligations can significantly contribute to the implementation of circular economy. To this end, and depending on availability of additional resources, ECHA will continue to develop article service-life exposure assessment approaches and to support industry in improving service-life parts of their CSA/ESs. Furthermore, together with the Commission, ECHA will explore how to improve interfaces between REACH and other legislation to support the circular economy and non-toxic environment objectives.
- The fourth SVHC roadmap progress report (March 2018) will include a review of the implementation. The outcome of the review will be used to adapt the work during 2018-2020, where necessary, as well as to initiate discussion on the concrete follow up after 2020.
- Based on the review carried out in 2017, the necessary changes to the co-ordination and co-operation structure will be implemented. Maintain high level of efforts for co-operation and co-ordination with all authorities of the work on SVHC roadmap implementation and beyond.
- Continue to have up to date information on ECHA's website on screening and assessments providing industry better predictability on which substances will be under authorities' attention and consequently more time to plan for substitution and improving safety.

Performance indicators ³³	2016 actual	2017 estimate	2018 target
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	High
(NEW) Effective working time of ECHA staff used per SVHC dossier	NA	38 – 47 person days	38 – 47 person days

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	2 926 922	3 143 386	3 163 176
Human resources (FTE)	18	16	17

1.2.2 Authorisation

Overview

ECHA regularly updates the Candidate List of substances of very high concern (SVHCs) based on the proposals for identifying SVHCs provided by Member States or by ECHA, based on requests by the Commission. Where necessary, the identification of SVHCs includes agreement seeking in MSC.

Using an agreed prioritisation approach, ECHA assesses annually the priority scores for all the substances included on the Candidate List to decide which ones should be recommended for inclusion in the Authorisation List as a priority, taking into account the opinion of the MSC.

³³ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

The ECHA Secretariat supports RAC and SEAC, and in particular their rapporteurs, to develop high quality opinions on applications for authorisation in a transparent and efficient manner that can effectively support the Commission's decision-making on granting or refusing an authorisation.

ECHA actively promotes the participation of third parties in the consultation process for each application for authorisation to make sure that appropriate information on alternative substances or techniques, if available, will be fed into the opinion-making process.

ECHA provides support particularly to potential applicants by providing regulatory advice and by engaging the national REACH helpdesks as well as its communications.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Number of proposals for identifying SVHCs ³⁴	10	15	20
Recommendation for inclusion of substances in the authorisation list.	1	0 ³⁵	1
Number of received Applications for authorisation (number of uses)	112	5	15
RAC & SEAC opinions ¹⁾ on applications for authorisation	63	40	11
Helpdesk questions received ³⁶	843	650	500

¹⁾ One opinion refers to a compiled version of the final opinions of RAC and SEAC for each use

Key objective

ECHA efficiently produces updates of the Candidate List, recommendations for inclusion of substances in the Authorisation List and opinions on authorisation applications of high scientific, technical and regulatory quality.

Main actions and outputs of 2018

- Process a potentially increasing number of SVHC dossiers that more often relate to PBTs, EDs or other substances of equivalent concern and hence require specific effort and involvement from the respective expert groups and from the MSC.
- Provide a well-founded Annex XIV recommendation, which takes into account the effectiveness of the whole authorisation process.
- Available approaches to identify and address concerns related to the presence of substances in articles are not as developed as those related to substances on their own and in mixtures. Furthermore, the implementation of the circular economy and toxic-free environment targets require better information, enhanced communication and further regulatory measures on substances in articles. To bridge these gaps in the knowledge and methods ECHA continues, together with the Commission, Member States and stakeholders i) to

³⁴ 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

³⁵ 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.

³⁶ Regulatory and non-regulatory questions related to authorisation only.

develop the exposure assessment methods of substances in articles during their service-life and waste stage, ii) to explore effective ways to identify the relevant substances, in particular, in the imported articles, iii) to investigate how to support the development and wider implementation of communication tools and, iv) where needed, to trigger relevant regulatory actions.

- Continue to raise awareness on the obligation for industry to communicate in the supply chains on the presence of SVHCs in articles and the need to notify information to ECHA
- RAC and SEAC will evaluate and issue opinions on the first Review Reports. This experience will allow ECHA to establish whether the “bottom-up” communication between downstream users and authorisation holders about the authorised use of SVHCs has been useful. Based on this experience, ECHA will take corrective action, as necessary.
- Continue to provide timely support to applicants and authorisation holders through pre-submission information sessions, possible new versions of the Practical Guide, updated application formats, “reference” DNELs and dose-response relationships of substances.
- Support the rapporteurs and the committees in the preparation of opinions of “fit-for-purpose” sufficient quality and consistency to meet the expectations of the Commission, Member States and stakeholders.
- Continue to support the Commission during the decision making of authorisations, to support and learn from the national enforcement authorities in the enforcement of the granted authorisations.
- Continue to improve and adapt the communication through its web to facilitate the preparation and processing of “fit-for-purpose” applications for authorisation, especially for the preparation of initial authorisations.
- Implementation of ECHA's strategy on how to increase the capacity of Member States and industry to carry out analyses of the available information on alternatives and consequent successful substitution of hazardous substances. This is likely to comprise of the establishment of a network among Member States on analysis of alternatives and substitution.
- Develop further the analysis of alternatives activities under the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) and hold one or two meetings to improve the knowledge and skills of European applied economists, providing analysis in industry on applications for authorisation or regulatory settings for restrictions.
- Continue to provide timely support to ECHA's Scientific Committee through notes on methodological questions, including socio-economic issues.
- Prepare a report from the Forum pilot project on substances in articles

Performance indicators ³⁷	2016 actual	2017 estimate	2018 target
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	High
(NEW) Average time to process an application for authorisation	NA	13 months	13 months

³⁷ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

(NEW) Effective working time of ECHA staff used per authorisation opinion	NA	38 – 46 person days	38 – 46 person days
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Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	5 715 551	5 544 310	4 657 389
Human resources (FTE)	35	31	26

1.2.3 Restrictions

Overview

Following the European Commission's requests, ECHA prepares Annex XV restriction dossiers, reviews existing Annex XVII entries and investigates the need to prepare a restriction proposal.

The ECHA Secretariat provides scientific, technical and administrative support to RAC and SEAC and their rapporteurs for the development of opinions on the restriction proposals by Member States or ECHA. In parallel, the Forum provides advice on the enforceability of these proposed restrictions.

Article 69(2) of REACH requires ECHA to prepare restriction dossiers for articles that include substances that are on the Authorisation List and pose a risk that is not adequately controlled.

ECHA supports Member State enforcement authorities and helpdesks, and continues to improve the accessibility and readability of the table on its website containing the list of restrictions in Annex XVII. In addition, ECHA answers questions relating to interpretation and enforcement of the restrictions.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Restriction proposals submitted by MS and ECHA (Annex XV)	4	6	8
Annex XV restriction dossiers (or preparatory reports) prepared on request by the Commission	1	5	5
Restriction proposals or reports developed under Article 69(2)	2	1	1
RAC & SEAC opinions ¹⁾ on restriction proposals	2	4	6
Helpdesk questions received ³⁸	847	600	500

¹⁾ One opinion includes both the opinion of RAC and SEAC

Key objective

ECHA produces high quality Annex XV restriction proposals or reports and efficiently produces opinions of high scientific, technical and regulatory quality on restriction proposals.

Main actions and outputs of 2018

³⁸ Regulatory and non-regulatory questions related to restrictions only.

- Provide support to the Member States during their preparation of restriction dossiers, e.g. in Pre-Restriction Information Meetings, restriction workshop with Member States and other mechanisms.
- Support further development of methodologies for risk to impact assessment work (including estimations related to human via environment) and work on improved guidance for MS and Committees on analysis of alternatives.
- Further develop and implement a capacity building programme for Member States and members of the RAC/SEAC on regulatory impact assessment, in particular on methods used in socio-economic analysis.
- Continue improving the efficiency and effectiveness of the restriction process through implementation of the Restriction Efficiency Task Force recommendations, monitoring of efficiency and identification of potential new recommendations.
- Support the Commission, stakeholders and enforcement authorities to clarify the existing restriction entries by developing Q&As.
- Further develop methodologies related to socio-economic analysis, in particular in the context of the OECD. This comprises both the valuation of health and environmental endpoints and learning lessons from regulatory risk management cases in different OECD member countries.
- Review any lessons learnt from the Forum's fourth coordinated enforcement project on restrictions (REF-4) and integrate any resulting advice in the relevant guidance (e.g. Annex XV reporting format).

Performance indicators ³⁹	2016 actual	2017 estimate	2018 target
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	High
(NEW) Average time to deliver an opinion on a Restriction proposal	NA	15 months	15 months
(NEW) Effective working time of ECHA staff used per restrictions opinion	NA	200 – 255 person days	200 – 255 person days

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	3 306 157	3 454 427	4 251 330
Human resources (FTE)	17	17	24

1.2.4 Classification and Labelling

Overview

³⁹ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

The classification of carcinogenic, mutagenic and reprotoxic (CMR) substances, as well as for respiratory sensitisers, is normally harmonised at EU level. ECHA supports this process and develops opinions of its Committee for Risk Assessment (RAC) on the proposals submitted by the Member States.

ECHA maintains a database of all notifications of substances in the C&L Inventory.

In certain cases, manufacturers, importers and downstream users can request the use of an alternative chemical name to keep the precise name of certain ingredients in their mixtures confidential.

ECHA provides support to duty holders and national helpdesks via its support activities, including a CLP HelpNet workshop and the provision of tools and support to the notification of emergency health response to national bodies.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Proposals for harmonised classification and labelling	40	70	75
RAC opinions on proposals for harmonised classification and labelling	35	40	80
Alternative name requests	33	50	50
Helpdesk questions received ⁴⁰	261	250	500

Key objective

ECHA efficiently produces opinions of high scientific, technical and regulatory quality on proposals for harmonised classification and promotes the harmonisation of self-classifications included in the CLP inventory.

Main actions and outputs of 2018

- Process an increasing number of incoming CLH dossiers resulting from the joint Commission, EFSA and ECHA efforts to encourage timely submission of dossiers for pesticides. Furthermore, the increased integration of CLH to REACH work, in particular common screening and evaluation processes, will result in more proposals on industrial chemicals.
- Continue working together with the Commission and EFSA to reduce the overlapping work for PPP/BP/CLH processes in MSCAs, committees and agencies. This will include support to the use of integrated assessment templates to reduce the workload of dossier submitters, increase efficiency of the processes as well as clarity of the outcome.
- Update the CLP guidance, as necessary, to reflect changes in information requirement as well as guidance updates for other purposes. Guidance and templates developed to apply weight of evidence, including read across, will be in use for CLH to improve the quality of the CLH dossiers.
- Continue monitoring the convergence of self-classifications; where appropriate take focussed actions encouraging industry to agree on classifications and update notifications accordingly. 2018 registrations will be used to reduce the obsolete notifications related to those substances.

⁴⁰ Regulatory and non-regulatory questions related to classification and labelling only.

- 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).
- Provide useful regulatory advice on self and harmonised classification, labelling and packaging, including the request for alternative names and interaction with safety data sheets obligations, including the work of selected GHS working groups, notably the working group on the use of non-animal testing methods for classification
- Organise regular workshops on CLP for HelpNet correspondents and observers, keeping them up to date on regulatory developments and agreeing on common understanding on issues raised by notifiers and other stakeholders.
- Further develop tools and support to facilitate data provision by companies to be used by national Poison Centres under Art 45 of the CLP Regulation:
 - Finalise, maintain and host the poison centres' notification format and editor, the unique formula identifier (UFI) generator and the product categorisation system in response to feedback from stakeholders.
 - Start the development of the notification portal, to enable participating Member States to receive notifications from industry in the new format and facilitate company notifications to multiple countries simultaneously.
 - Provide advice and support to companies to enable them to prepare for the submission deadline of 1 January 2020.
- Carry out the Forum project on CLP (REF-6)
- Prepare a report from the Forum pilot project on CLP internet sales

Performance indicators ⁴¹	2016 actual	2017 estimate	2018 target
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	High
(NEW) Average time to deliver an opinion on a CLH proposal	NA	10 months	10 months
(NEW) Effective working time of ECHA staff used per CLH opinion	NA	45 – 55 person days	45 – 55 person days

(NEW) Percentage of ECHA Helpdesk questions related to C&L, answered within the established timeframe (15 working days)	NA	90%	90%
Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	4 272 487	4 446 081	4 762 036
Human resources (FTE)	24	23	27

⁴¹ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

1.3 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 contained in the biocidal product. ECHA delivers, via its Biocidal Products Committee (BPC), opinions for the European Commission to support decision-making on biocidal active substances and products. ECHA 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 establishment of technical equivalence, assessment of applications for alternative suppliers, resolution of data sharing disputes, dissemination, preparation of guidance, and communication. ECHA keeps duty holders and national authorities abreast with developments via its communications, Helpdesk and HelpNet activities.

Overview

ECHA provides support to the preparation of BPC opinions on active substances, Union authorisations of biocidal product as well as on scientific or technical matters concerning mutual recognition or at the request of the Commission or of Member States' competent authorities.

In addition, support is provided to the Biocidal Products Committee and its eight permanent and ad hoc working groups for the harmonisation of risk assessment approaches and preparation of emission scenario documents and guidance.

ECHA processes the applications for data sharing (inquiries and data sharing disputes) and assesses the applications for technical equivalence and for inclusion in the Article 95 list.

Advice is provided to duty holders as well as information and training for national BPR helpdesks via HelpNet.

ECHA supports the evaluations of the active substances and Union authorisation applications and performs the public consultations defined in the biocides legislation and manages the participation to the Review Programme and the Article 95 list.

In close collaboration with Member States and stakeholders ECHA works on the further development of the IT tools (in particular the Register for Biocidal Products (R4BP) 3 and the Summary of Product Characteristics (SPC) editor) in order to progress towards a more efficient and comprehensive implementation of the biocides legislation.

Some of ECHA's decisions are appealable to the Board of Appeal and ECHA's legal defence is provided by the Secretariat. Some decisions can only be challenged in the General Court where ECHA's legal defence is also provided by the Secretariat.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Opinions on active substances approval (under the Review programme)	41	50	50
Biocides Inquiries received	56	50	50
Biocides Data sharing disputes	2	5	5
Applications for new active substance approval	39	8	28
Applications for renewal or review of active substances	0	2	11
Applications for Union authorisation for biocidal products	24	37	30

Applications for active substance suppliers (Article 95)	54	25	25
Assessment of technical equivalence	23	37	45
Submissions to Member States	1 368	3 000	3 000
Appeals submitted	4	3	1
Helpdesk questions received ⁴²	2 790	3 000	3 000

Key objective

ECHA produces decisions/opinions of high scientific, technical and regulatory quality on the use of biocidal active substances and products.

Main actions and outputs of 2018

- Support the Member States Competent Authorities for the preparation of BPC opinions on active substances.
- Support the Member States Competent Authorities for the preparation of 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.
- Start the identification of potential endocrine disruptors among the approved biocidal active substances, ensuring coordination with EFSA for substances that are also approved for use in plant protection products.
- Organise a workshop with competent authorities to evaluate the impact of the measures put in place in 2016 to increase the efficiency of the active substance approval process and the Review Programme and consider further measures.
- Further develop the Register for Biocidal Products (R4BP 3) and the SPC editor.
- Publish updates to the Guidance on the Biocidal Products Regulation.
- Based on a vision for EUSES developed in 2017, ECHA will further work on the technical requirements with the aim to initiate IT development in 2019.
- Support exchange of information and coordination between the BPR enforcement authorities through the activities of the Forum BPR sub-group. In particular execute a BPR-related module of Forum's coordinated enforcement project on CLP (REF-6) and prepare the next enforcement project on BPR.
- Further develop the dissemination of information in relation to the BPR, in particular on the authorisation of biocidal products.
- Organise one workshop on BPR for HelpNet correspondents and observers, keeping them up to date on regulatory developments and agreeing on common understanding on issues

⁴² Regulatory and non-regulatory questions related to Biocides only.

raised by registrants, notifiers and other stakeholders.

Performance indicators ⁴³	2016 actual	2017 estimate	2018 target
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	High
(NEW) Percentage of BPR inquiries concluded within the target timeframe (20 working days)	NA	80%	90%
(NEW) Percentage of received BPR data sharing disputes handled within 60 days	NA	100%	100%
(NEW) Average time to process an active substance dossier (from competent authority evaluation report to BPC opinion)	NA	9 months	9 months
(NEW) Effective working time of ECHA staff used per active substance opinion	NA	27 – 33 person days	27 – 33 person days
(NEW) Percentage of ECHA Helpdesk questions related to Biocides, answered within established timeframe (15 working days)	NA	80%	80%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	8 207 359	10 358 000	11 899 055
Human resources (FTE)	50	59	64

1.4 PIC

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.

Overview

ECHA is responsible for administrative and technical tasks. It develops and maintains the IT system for receiving and administering the notifications. The Agency provides technical and scientific guidance to industry, the designated national authorities (DNAs) both from the EU and from third countries. Each year, the Agency publishes the summary report on actual volumes of exports and imports at the Union level that have occurred in the previous year for substances listed in Annex I of the PIC Regulation.

The Agency provides scientific and technical support to the Commission, as needed, in support of their management of the legislation and related activities at the Rotterdam convention, and with the agreement of the Commission, to the Designated National Authorities (DNAs) both from the EU and from third countries. Finally, ECHA also provides the secretariat for the Forum and supports it to further strengthen and harmonise the effective enforcement of the PIC regulation in the EU Member States.

⁴³ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA).

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Export notifications	7967	8 900	10 700
Helpdesk questions received	227	300	375
(NEW) Scientific and technical requests from the Commission, EU and non-EU DNAs	NA	2 200 ⁴⁴	2 800

Key objective

ECHA ensures effective management of the export and import notifications of hazardous chemicals listed in PIC Regulation so that European companies can trade these chemicals while respecting the shared responsibility for their safe use.

Main actions and outputs of 2018

- Process a continuously increasing number of notifications (25% vs. 12% estimated increase on a yearly basis) and related tasks.
- Produce and publish the annual report on PIC exports and imports.
- Support the Commission in establishing which chemicals to propose for inclusion in the PIC Regulation and which to notify to the Rotterdam Convention Secretariat.

Performance indicators⁴⁵	2016 actual	2017 estimate	2018 target
Percentage of export notifications processed within the legal timeframe	100%	100%	100%
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission, Member State DNAs and industry	High	High	High
(NEW) Average time to respond to a scientific and technical requests from stakeholders	NA	<15 days	<15 days

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	1 082 842	1 183 000	1 096 320
Human resources (FTE)	7	7	8

1.5 Data management and dissemination

Tasks covered in this area include for the four legislations: data governance, data harmonisation, data architecture, data security, data warehousing and business intelligence, computational

⁴⁴ This number is based on the actual number of requests for regulatory/technical support received by the ECHA from authorities in EU and non-EU countries. The 1800 technical requests in 2016 were estimated to increase in 2017 and subsequent years as a result of an increase in notifications.

⁴⁵ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA).

methods for data mining as well as data dissemination to stakeholders and public at large.

The Dissemination Portal provides, since early 2016, the world's largest public data base on the properties of industrial chemicals in a tiered format – with InfoCards for lay persons and more detailed information for experts drawn from a multitude of ECHA's data bases – and is expected to be attracting ever-increasing attention from interested readers.

Overview

Data management and dissemination is a distributed function in ECHA that comprises:

- Providing IT systems and support services to Member States Competent Authorities (so called Portal Dashboard for Competent Authorities, MSCAs IUCLID central database for REACH&CLP, MSCAs IUCLID central database for Biocides), to Enforcement Authorities (so called Portal Dashboard for Enforcement Authorities), and to the European Commission to facilitate their access to ECHA's databases on chemicals.
- Integration of data across different sources and processes according to an Enterprise Data Model and into a common Data Integration Platform used to support Dissemination, the Portals for Authorities, reporting as well as the regulatory processes performed in ECHA. This activity includes the adaptation of the existing information systems to improve the reporting on deficiencies and concerns and the mapping of the chemical universe.
- Data mining for dossiers and substance screening purposes in order to focus the evaluation and risk management processes.
- Analysis of data quality parameters on high volume registered dossiers and notifications.
- Performing specific data analysis upon request for ECHA's institutional partners.
- Developing ways to make data suitable for use in other applications such as OECD QSAR Toolbox, scientific software such as the QSAR modelling, or SDS generation software used by data holders.
- Developing ways to make data available to actors in support of increased safe use of chemicals and/or reduction in animal tests needed.
- Providing case management tools to support the processing of regulatory or administrative files in the application of the legislations or the internal administrative practices.
- Publishing of information on properties and uses of chemicals on the ECHA website, complemented by information on whether the substance is under evaluation or subject to risk management action.
- Exploring the opportunities to link data that ECHA is holding to external, product based websites, thereby bringing data on chemicals more directly to the attention – and thereby use – of citizens.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Number of dossiers to be disseminated	5 494	13 000	56 000
Number of external requests for data	143	60	50

Key objective

Data submitted on chemicals, data generated by regulatory processes and external data sources is securely accessible to support the regulatory tasks for REACH, CLP, Biocides and PIC, and non-confidential data is freely accessible to the public and professional users in a user-friendly format.

Main actions and outputs of 2018

- Dissemination activities
 - Extend the dissemination portal to cover additional information on authorisation of biocidal products.
 - Publish registration information from the 2018 deadline for maximising public availability of information on chemicals.
 - Further integration of ECHA's regulatory activities in the disseminated information, including the display of the life-cycle of evaluation decisions.
- Start the implementation of a major upgrade of the Business Intelligence Data Integration (BIDI) platform to address in particular: change of end-of-life technology; improvement of master data management of the Regulatory Master List of Substances.
- Progress in the development of a reporting system in support of the integrated regulatory strategy, in particular for mapping the chemical universe and informing which substances are of potential concern and for which a regulatory action is ongoing or planned or, alternatively, which substances can be considered as low priority for further work.
- Provide useful regulatory advice to registrants, academia, public institutions and other interested parties on what and how data is disseminated by ECHA, including its use and validity.
- Complete the piloting phase of ECHA Interact with RAC and SEAC members, and gradually deliver new collaboration features and ways of working with ECHA stakeholders.

Performance indicators⁴⁶	2016 actual	2017 estimate	2018 target
Level of Member States' and Commissions user satisfaction with data management services	High	High	High
Level of satisfaction of stakeholders with dissemination activities of ECHA.	High	High	High
(NEW) Maximum continuous downtime (% non-availability) of the website, Portal Dashboard, S-CIRCA and Dynamic Case	NA	2%	2%
(NEW) Percentage of registered dossiers published on the Dissemination Portal within 20 working days from	NA	90%	70%

⁴⁶ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

completing the registration process			
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Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	11 163 016	10 104 257	10 441 117
Human resources (FTE)	38	39	40

1.6 Delegated tasks

A Delegation Agreement is used by the European Commission to entrust the Agency budget implementation tasks that are outside of its core mandate. The purpose of the Agreement is to define the entrusted tasks, to lay down the rules applicable to their implementation and to define the rights and obligations of the Parties in their implementation. According to ECHA Financial Regulation⁴⁷ the tasks entrusted should be referred to in the annual work programme of the Agency for information purposes only, and the Executive Director shall consult the Management Board before signing the delegation agreement.

1.6.1 EU Observatory for Nanomaterials

Based on a delegation agreement between the European Commission and ECHA the Agency is hosting the Observatory for Nanomaterials. The objective of the Observatory is to provide better access to information on nanomaterials on the EU market, their uses and safety aspects, and related research activities. The Observatory integrates available information, and communicates it to decision-makers, authorities and the general public in a balanced, user-friendly and easily understandable way. The observatory is a response to the concerns expressed by policy makers and stakeholders on the lack of information about nanomaterials in the EU market, in articles sold to consumers and in workplaces.

Overview

The EU Observatory for Nanomaterials 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 maintain 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. The observatory does not create any legal obligations for companies to report. ECHA establishes the observatory in three phases where the second and third phase are planned to be released in 2018 and 2019.

Key objective

⁴⁷ MB/WP/03/2014, Article 8

Objective information on nanomaterials in the EU market allows both professional and general audiences review and increase their understanding of how nanomaterials are used in the EU, what safety information is available on them, and what safety research is ongoing.

Main actions and outputs of 2018

- Publish the second phase of the observatory website with enhanced content (updated information on nanomaterials on the EU market, further information on products and articles where nanomaterials are present, and wider information on relevant research activities).
- Complete first IT analysis on available databases, and based on its outcome initiate relevant development project(s).
- Start preparations for the third phase to be published in 2019.

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	800 000	600 000	600 000
Human resources (FTE)	NA	3	3

1.6.2 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.

Overview

The Commission entrusted ECHA at the end of 2016 to undertake a feasibility study with a view to creating an 'EU Chemicals Legislation Finder' to improve the business environment for EU companies, and SMEs in particular, with regard to access to information on regulation applicable to a given chemical substance. The study concluded that it is feasible to build such a tool, identified 55 EU legislations in the scope of the tool as a first priority, and identified ECHA as the most suitable body to host the tool. However, it was also acknowledged that a more detailed business and architectural analysis is required before there is a sufficient basis for ECHA to decide whether it can start developing the tool. Hence the implementation of the EU chemicals Legislation Finder is divided into two phases, with the first phase, and the subsequent ECHA decision on starting the development of the EU chemicals Legislation Finder, carried out in 2018.

Key objective

Improve the business environment for EU companies and SMEs in particular with regard to access to information on legislation applicable to a given chemical substance. This will also contribute to building confidence in the public at large, as they will be able to understand how chemical substances are regulated at EU level more easily. In a longer-term perspective, help identifying opportunities for streamlining legislations or addressing overlaps as well as gaps in the legislative landscape.

Main actions and outputs of 2018

- Based on the 2017 feasibility study and the delegation agreement, start the first phase of setting up the EU Chemicals Legislation Finder aiming at providing a comprehensive view on how a chemical substance is regulated across various legislations in Europe.

2. Governance and support activities

2.1 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 aim of harmonising their approach to enforcement.

ECHA and the national BPR, CLP and REACH helpdesks operate a network of helpdesks (HelpNet) with the objective to exchange information, to cooperate, particularly with a view to provide consistent and harmonised advice. HelpNet is governed by the HelpNet Steering Group composed of ECHA, the national BPR, CLP and REACH helpdesks, the Commission and observers from the European Enterprise Network, candidate countries/other third countries, and/or Accredited Stakeholder Organisations.

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 provide interested parties with the possibility of administrative legal review of certain ECHA's decisions.

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

2.1.1 Committees

Overview

The ECHA Secretariat organises the meetings of the Committees, including their working groups and preparatory meetings, manages the written consultations, manages the membership, including the implementation of conflict of interest policy, the accredited stakeholder observers' participation in the Committees, and provides the Chairmen and the secretariat to the Committees. The Secretariat also manages the work planning of the Committees and implements their Rules of Procedure. The opinion forming activity is covered under the Operations section.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
MSC meetings	7	6	5
RAC meetings	8	7	4
SEAC meetings	6	5	4
BPC meetings	5	6	6

Key objective

The ECHA Secretariat supports and facilitates the work of the Committees by providing the necessary infrastructure and support for running the decision-making processes efficiently and effectively.

Main actions and outputs of 2018

- Manage membership (renewals and new appointments/nominations) of each Committee with specific focus on ensuring adequate capacity of RAC, SEAC and BPC, including co-opted members in RAC and SEAC.
- Continue implementing efficiency improvements in all Committees, including the on-going development of IT support tools and their regular integration.
- Prepare and adopt scientific opinions in support of proposals for Occupational Exposure Limit values, requested by the ED under Art 77(3)c of REACH
- Cooperation activities with other EU bodies such as EFSA's Panels and Scientific Committee, and the Commission's Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health, Environment and Emerging Risks (SCHEER) and the Scientific Committee on Occupational Exposure Limits (SCOEL).

Performance indicators ⁴⁸	2016 actual	2017 estimate	2018 target
Level of satisfaction of ECHA Committees with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High	High
(NEW)Percentage of members acting as rapporteurs in RAC and SEAC	NA	>60%	>60%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	3 581 580	3 358 212	3 043 994
Human resources (FTE)	17	17	16

2.1.2 Forum

Overview

The ECHA Secretariat organises the meetings, manages the membership and provides the secretariat to the Forum and its Chair. The Forum will hold three plenary meetings per year, including an open session to liaise with accredited stakeholder organisations. The Forum will also discuss and find harmonised solutions to practical challenges faced by inspectors which will be recorded in its manual of conclusions. Specific projects and specific support of the Forum to ECHA's operations is covered above under Section 1, "Operations", of this Work Programme.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Number of REF projects (at any stage of project life cycle)	3	4	4
Number of pilot projects (at any stage of project life cycle)	5	4	4
Forum meetings	3	3	3
Active working groups	18	12	11

⁴⁸ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

Key objective

The ECHA Secretariat will support and facilitate the work of the Forum so that it will be able to promote harmonised enforcement of REACH, CLP, PIC and BPR regulations efficiently and effectively.

Main actions and outputs of 2018

- Prepare the REF-7 project, and prioritise the subject for REF-8 project
- Review the Interlinks Guide, considering experience gained since its introduction in 2016
- Continue expanding the Manual of Conclusions recording the Forum agreements on enforcement practices
- Continue work on tightening cooperation of the Forum with customs authorities
- Prepare and organise the annual training for enforcement trainers
- Prepare the next Forum activity plan for the years 2019-2021

Performance indicators ⁴⁹	2016 actual	2017 estimate	2018 target
Level of satisfaction of the members and other participants with the functioning of the Forum Secretariat	High	High	High
(NEW) Number of REF project phases completed within the planned timeline:	NA	4	4

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	1 646 407	1 551 735	1 795 489
Human resources (FTE) ⁵⁰	8	8	8

2.1.3 HelpNet and Security Officers Network

Overview

ECHA provides the HelpNet Secretariat which supports the administration and organisation of the network, coordinates the work of HelpNet with that of other ECHA services and the Commission, manages ECHA's input to questions from the national helpdesks and manages the preparation of FAQs. ECHA also provides training and supports the exchange of information and best practice between national helpdesks through HelpNet Steering Group meeting(s) and HelpNet workshops on BPR, CLP and REACH. In the immediate run-up to the REACH 2018 registration deadline, the HelpNet will be crucial in keeping national REACH helpdesks informed on developments to allow them to provide advice and assistance to potential registrants, in particular to SMEs.

The SON provides advice to ECHA on security issues related to the secure exchange of information pertaining to the REACH and CLP Regulations, between ECHA, MSCAs, Mandated National

⁴⁹ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

⁵⁰ Biocides resources are not included in this estimate but under the Biocide Activity in section 1.3 of the Work Programme

Institutions and the European Commission. ECHA provides its secretariat and coordinates the network.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Number of HelpNet events	7	7	7
Number of SON events	1	1	1

Key objective

ECHA Secretariat supports and facilitates the work of the networks by providing the necessary infrastructure and assistance for their efficient and effective functioning.

Main actions and outputs of 2018

- Organise one HelpNet Steering Committee meeting in the second half of the year, back to back with three workshops: BPR, REACH and CLP.
- Keep National Helpdesks up to date with the latest developments and advice through the regular publication of the HelpNet update, and possibly by organising an *ad hoc* Webex conference before the REACH registration deadline, if a clear need is identified.
- Keep the published FAQs up to date regarding their content by prioritising registration-related ones, and regarding their form by using clear, simple language.
- Analyse an extension of the current security model for granting access to ECHA IT systems to national authorities. The extended model would contemplate secure access for individuals acting in their capacity of experts in the ECHA Committees

Performance indicators ⁵¹	2016 actual	2017 estimate	2018 target
Level of satisfaction of HelpNet members with the HelpNet Secretariat support	High	High	High
(NEW) Quality of the advice provided by SON as perceived by the Management Board members	NA	High	High
Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	295 458	311 233	334 708
Human resources (FTE)	2	2	2

2.1.4 Board of Appeal

Overview

Board of Appeal decides on appeals against certain decisions of the Agency (see Article 91 of the REACH Regulation and Article 77 of the BPR). The Board is supported by a Registry, which, as the

⁵¹ For new proposed indicators the values for 2015 and 2016 are not available (NA)

Board itself, acts entirely independent from the ECHA Secretariat when it supports the Board in the exercise of the latter's duties.

Workload driver estimates	2016 actual		2017 estimate		2018 estimate	
	REACH	BPR	REACH	BPR	REACH	BPR
Appeals submitted	10	4	24	3	36	1
Procedural decisions	12	2	15	2	23	1
Cases closed	22	2	22	3	24	1

Key objective

High-quality decisions are adopted by the Board of Appeal without undue delay.

Main actions and outputs of 2018

- Process and decide on incoming appeals which are estimated 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.
- Adopt procedural decisions, as needed.
- Publish a robust body of high-quality decisions on-line, helping to build a set of consistent criteria for the Agency decision-making.
- Ensure effective (i.e. clear, accurate and timely) communication with the (potential) parties in relation to appeal proceedings.

Performance indicators ⁵²	2016 actual	2017 estimate	2018 target
Percentage of final Board of Appeal decisions made within 90 working days of the closure of the written or oral procedure	79%	90%	80%
(NEW)Average time to process an appeal	NA	15 months	15 months
(NEW)Effective working time of Board of Appeal and its Registry to conclude an appeal case against ECHA's decision	NA	85 – 90 person days	85-90 person days

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	1 622 936	1 696 662	1 805 558
Human resources (FTE)	11	11	11

⁵² New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

2.2 Management

ECHA is governed by a 36-member Management Board. The Board appoints the Executive Director who is in charge of the day-to-day management and administration of the Agency. 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.

Overview

The Agency's secretariat strives towards an efficient and lean governance of its organisational structure and processes, according to the highest EU and international standards including engagement of its stakeholders.

ECHA works closely with its accredited stakeholders and involves them in its work. The Agency works towards having stakeholders satisfied that their views are heard and taken into account. This engagement takes place throughout the year at events, network meetings and through the annual strategic workshop to discuss priorities for the future.

ECHA uses an activity and process-based integrated management system, which is ISO 9001:2015 and ISO 14001:2015 certified. The environmental management aims at efficient and effective use of resources in support of sustainable development. The management of information is balanced between openness and security principles, while in the longer term the Agency strives to become paperless by applying a digital archiving strategy.

The core functions of the Management Board include the adoption of the budget, work programme, and annual report, as well as the adoption and review of internal Agency rules and the appointment of key functions, such as the Executive Director and the members of the Board of Appeal. In addition, the Management Board closely monitors the performance of the Agency and the implementation of its strategic objectives. To this end, the Board receives regular reports on the progress with work programme implementation, and specific topic-related reports from the Secretariat. The Secretariat supports the work of the Management Board and its working groups in its role as the governing body of the Agency.

ECHA cooperates closely with other EU agencies and institutional partners. Under international cooperation activities requested by the Commission, ECHA pursues mutually beneficial cooperation with the regulatory agencies in non-EU countries with which ECHA has concluded cooperation agreements, in line with the bilaterally established Rolling Work Plans.

Solid defence is given to ECHA in legal proceedings e.g. on human resources issues, procurement, and access to documents. Complaints are effectively analysed from the legal perspective.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Number of corporate management meetings ⁵³	77	75	75
Number of audits and evaluations to take place in a year ⁵⁴	14	17	15

Key objective

The Agency is governed through efficient and effective management and IT governance, which ensures the proper planning of activities, allocation of resources, assessment and management of risks, communication and stakeholder engagement, safety of staff, environmental protection and security of assets and information, and provides an assurance of the conformity and quality of

⁵³ Includes: Directors Coordination Meeting, Business Programme Board, IT Directors Programme Board, Management Board and its Working Groups meetings, MSCA Directors meeting

⁵⁴ This includes the internal audits and their follow-up performed by the European Commission's Internal Audit Service (IAS) and ECHA's Internal Audit Capability (IAC) as well as ECHA's Integrated Quality Management System audits and financial Evaluations

outputs. At the same time, the Agency secretariat pro-actively works on further improving its key policies related to Transparency and Prevention of Conflict of Interest. Furthermore the Agency ensures that its regulatory science strategy is kept up to date and well communicated towards the relevant scientific communities.

Main actions and outputs of 2018

Corporate governance and support activities will continue following the planning, monitoring and reporting cycles, ensuring continuity, effectiveness and efficiency of the Agency's work, as well as timely action towards risks and opportunities. Specific activities in 2018 include:

- Support that relations are established between the newly appointed Executive Director and the institutional partners, in particular the European Parliament, the Commission, Member States and other EU agencies, with a view to further increasing cooperation and supporting the implementation of ECHA's mandate.
- Support the Commission in the implementation and monitoring of the actions resulting from the 2nd REACH review in 2017.
- Finalise ECHA's strategic plan for 2019-2023 (including public consultation on the plan and related review of ECHA's corporate identity, Vision, Mission and Values) and cascade the strategic plan into annual work programmes and relevant internal monitoring systems.
- Support the Management Board in discharging its statutory responsibilities, through the organisation and preparation of plenary meetings, Working Groups and efficient administration of other Board proceedings.
- Support the internal coordination of ECHA's executive management, through the preparation and coordination on internal management meetings, and by facilitating the preparation of management strategies, decisions, delegations and policies.
- Manage the Agency's reputation by: gathering feedback on the Agency's performance from stakeholders through surveys and by daily media and social media monitoring; and acting on the feedback received.
- Maintain sound managerial overview of the various implemented regulations and delegated tasks, to achieve maximum integration, synergy of shared services and transparency of performance.
- Continue optimising ECHA's Integrated Management and Internal Control systems to support ECHA operations, while successfully maintaining relevant ISO standards.
- Review and update the corporate-wide efficiency development programme, its scoping and role, in line with the updated strategic direction 2019-23.
- Perform Audits and Evaluations in line with the annual audit plan.
- Continue implementing the digitalisation of ECHA's Archives.
- Respond to general requests for information on the ECHA website, the Agency's activities, and questions outside its remit.
- Coordinate ECHA's contribution to inter-agency activities via dedicated (network) meetings and joined initiatives.
- 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.

- Prepare measures which ECHA will need to put into place to accommodate the withdrawal of the United Kingdom from the European Union

Performance indicators ⁵⁵	2016 actual	2017 estimate	2018 target
Percentage of very important audit recommendations implemented within the deadline (IAS, IAC, CoA) ⁵⁶ .	100%	100%	100%
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	+2.3%	2% increase	2% increase
Level of satisfaction of MB Members with ECHA Secretariat's support to their governing role	High	High	High
(NEW) Proportion of work programme indicators for which the set targets were achieved	NA	98%	95%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	6 731 601	7 138 594	6 965 826
Human resources (FTE)	42	42	36

⁵⁵ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

⁵⁶ European Commission's Internal Audit Service (IAS), ECHA's Internal Audit Capability (IAC), Court of Auditors (CoA)

2.3 Resources

Finance, Human Resources, Corporate Services, communications and Information Communications Technology (ICT) functions are needed for an organisation with stable and reliable funding, services, competences and place of work.

2.3.1 Financial resources

Overview

This activity covers the general financial management of the Agency, financial programming and reporting. It also includes overseeing and ensuring the correctness of the budget implementing operations as well as accounting and treasury operations. Finance unit coordinates and provides advice on the planning, launching, reporting and publication of the Agency's procurement activities. In addition, Finance unit performs SME company size verification to ensure that only genuine SMEs benefit from reduced fees and charges under REACH/CLP and BPR regulations.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
SME status checks for REACH/CLP	570	330	400

Key objective

ECHA ensures correct, sound and efficient management of its financial resources comprising of fee income and EU subsidy awarded under three different EU budget lines and adjusts its expenditure over the year to the revenue effectively collected.

Main actions and outputs of 2018

- Prepare the Agency's budget and manage its implementation, including amendments and transfers, revenue collection and cash management, procurement and contracting, financial reporting including annual accounts.
- Continue regular exchange with Commission partner services, including reporting on actual budget implementation, communicating revenue and expenditure estimates for the future and discussing ways of handling any shortfall or surplus during the budget year.
- Monitor and report on reimbursements to Member States and prepare eventual reviews of the Management Board rules on this matter.
- Continue the streamlining and automation of ECHA financial processes, including implementation of the Financial Information Management System (FIMS), with emphasis on electronic processing of purchase invoices, tender publications and submissions and developing a new budgeting tool.
- Continue ensuring the correctness of the SME fee reductions claimed by registrants by performing eligibility checks.

Performance indicators	2016 actual	2017 estimate	2018 target
Commitment rate (of commitment appropriations at the end of the year).	98%	95%	95%
Payment rate (of payment appropriations at the end of the year).	86%	80%	80%

Carryover rate (% of committed funds carried over into the next year)	13%	<20%	<20%
Percentage of payments made within the legal/contractual deadlines	98.7%	≥95%	≥95%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	3 850 643	4 005 230	4 145 478
Human resources (FTE)	25	27	26

2.3.2 Human resources

Overview

Human Resources activity covers Agency's staff planning and reporting on an organisational basis, including implementation of ECHA's selection and recruitment plans and engagement of Seconded National Experts, trainees and interim staff. It also includes the development and implementation of Implementing Rules and policies, in line with the revised Staff Regulations and taking account of ECHA's specific circumstances.

Other activities include the management of personnel and payroll administration, in line with applicable rules and regulations; the management of staff welfare and wellbeing actions including matters related to individual wellbeing, (European) schooling matters and the integration of staff with Helsinki City; the management of performance appraisal, reclassification and related HR exercises to ensure that organisational objectives are met and that staff receive accurate feedback and recognition on their performance and the management of ECHA's learning and development function, including capacity-building actions identified under Strategic Objective No 3.

Key objective

ECHA has a sufficient number of skilled staff to ensure the implementation of the Work Programme and offers staff a well-functioning work environment.

Main actions and outputs of 2018

- Conduct the annual objective setting, performance appraisal and reclassification exercises
- Maintain good relations and dialogue with the Staff Committee, the European School of Helsinki and other key stakeholders
- Conduct the Job Screening Exercise as part of a wider inter-Agency benchmarking exercise initiated by the European Commission.
- Provide relevant learning and development activities to ensure continuous capacity-building of staff
- Review of ECHA's competency mapping framework
- Ensure availability of necessary workforce for the 2018 registration deadline activities

Performance indicators ⁵⁷	2016 actual	2017 estimate	2018 target
Percentage of Establishment Plan posts filled	98%	98%	98%
Turnover of TAs.	2%	< 5%	< 5%
Turnover of CAs (excluding short-term CAs).	7%	< 10%	< 10%

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	3 814 363	3 667 413	3 771 337
Human resources (FTE)	24	25	24

2.3.3 Corporate services

Overview

Corporate Services cover the management of ECHA's building and related facilities (including building and facilities maintenance and refurbishments; management of the conference centre and delivery of audio visual and virtual conferencing services; the provision of canteen and catering services; workspace allocation and waste management activities). The activity also covers coordination of ECHA's security, business continuity and crisis management activities and involves providing events/meetings logistical and secretarial support, the management of ECHA's travel management services and the coordination of postal and courier services and the purchase and maintenance of office supplies. It is responsible for the preparatory work to support the decision-making regarding the ECHA premises in view of the expiry of the current lease contract at the end of 2019.

Also covered by the Corporate Services are ECHA's external and internal communication activities that play a fundamental role in both the efficient management of the Agency and in the management of its corporate and visual identity. ECHA aims to communicate effectively with its external audiences, in 23 languages where appropriate, and works with the media in order to maintain an accurate and balanced media presence. The main communication vehicle remains the multilingual website, its ECHA Weekly e-news as well as the ECHA Newsletter, but other vehicles are also used to increase the outreach to new audiences – for example, social media, which are constantly seeing a significant uptake. Also various communications networks support ECHA in reaching out to relevant audiences. Effective internal communication (through intranet, staff events and briefings) remains key to ensuring that the staff has a sense of belonging and feels part of a common corporate endeavour.

Workload driver estimates	2016 actual	2017 estimate	2018 estimate
Number of meetings held at ECHA Conference Centre (including internal meetings)	1 580	1 600	1 650
Number of new publications produced	85	50	40
Number of pages translated into 22 languages	1 600	1 100	800

⁵⁷ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

Key objective

ECHA has secure and healthy office premises and adequate facilities for the staff and external visitors; and maintains effective internal and external communication.

Main actions and outputs of 2018

- Ensure the implementation of the contract for ECHA's future office building
- Provide high quality corporate services to staff and external meeting participants and visitors
- Implement the Events Logistics Management tool to further streamline the organisation of meetings and events
- Publish and promote information on all regulatory developments of importance to companies as well as the general public via relevant communications tools and platforms and monitor their impact on target audiences
- Develop further the dedicated website ('microsite') aimed for consumers and published in 2017.

Performance indicators ⁵⁸	2016 actual	2017 estimate	2018 target
Level of satisfaction of the Committees, Forum and MB members with the functioning of the conference centre	High	High	High
Level of accredited stakeholder satisfaction with the information they receive and their engagement with ECHA.	NA	High	High
Level of reader satisfaction with ECHA's written output, including language availability measured in terms of timeliness, content and usability	NA	High	High
Level of satisfaction of the staff with the corporate services	NA	High	High

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	3 249 273	3 080 627	3 142 701
Human resources (FTE)	20	21	20

⁵⁸ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

2.3.4 ICT

Overview

This activity manages and provides the IT services for the Agency and for the external users of ECHA's IT tools in Industry and in national authorities. It is a core activity on which all other activities depend, ensuring that the staff have the appropriate IT tools at their disposal, that the external users can rely on high availability of the IT tools, adequate performance and good users support whilst complying to IT security standards.

The activity ensures the procurement, delivery and management of all ECHA's IT applications.

All services are assessed for business continuity and security requirements, while designed and maintained according to the identified needs.

This activity also provides the integrated access management services for all ECHA's IT applications.

A key resource managed by this activity is the outsourcing contracts used for the delivery of services, requiring significant effort to procure, manage services and external providers.

With the increase in the number of contracted partners a growing area of attention is the complexity of managing multiple parties.

The support to the IT Governance of the Agency as well as the management of the ICT assets of the Agency is part of this activity.

Workload driver estimates⁵⁹	2016 actual	2017 estimate	2018 estimate
Number of IT related incidents	NA	5600	to be confirmed in 2017
Number of IT contracts to be managed in a year ⁶⁰	NA	111	100
Number of Agency-wide IT applications in operation	32	41	66

Key objective

The IT services of the Agency are operated at a high level of users' satisfaction, continuity and security.

Main actions and outputs of 2018

- Deliver the IT services for the registration 2018 deadline, including IT support for Business Continuity and ICT facilities for to the additional staffing.
- Deliver the IT services for MSCAs, DNAs, NEAs users
- Manage the transition to the new framework contract for infrastructure capacity services. Prepare by refactoring the networks design towards simplification and optimisation of the managed network services.
- Complete the implementation of the sourcing strategy regarding the combined outsourcing of software development and application management services

⁵⁹ New workload drivers were introduced in SPD2017-2019 and their values were not recorded in 2016 (NA)

⁶⁰ ECHA's own established IT Framework contracts and the major service contracts managed under HANSEL (Finnish Administration Procurement) including specific contracts implementing ECHA's own established IT Framework contracts and major service contracts managed under HANSEL (the specific contract amount to c.a. 100 per year)

- Continue the evolution towards leased IT facilities for the workplace, ultimately leading to a full transition from asset based to as a service delivered.

Performance indicators ⁶¹	2016 actual	2017 estimate	2018 target
Availability of mission-critical systems for externally used IT systems (i.e. uptime during service hours).	99.8%	98%	98%
Level of internal users satisfaction with the ICT services	High	High	High
(NEW) Average time to resolve an internal, ICT service related request	NA	<3days	<2days

Resources	2016 actual	2017 estimate	2018 estimate
Financial resources (costs, euros)	3 108 000	3 374 020	3 771 398
Human resources (FTE)	26	23	24

⁶¹ New indicators were introduced in SPD2017-2019 and their values for 2016 are not available (NA)

Annexes

Annex I: Resource allocation per Activity of the work Programme 2018

Annex II: Human and Financial Resources

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Table 2 – Revenue

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Annex III: Staff population and its evolution

Table 1 – Staff population and its evolution; Overview of all categories of staff

Table 2 – Multi -annual staff policy plan year

Annex IV:

A. Recruitment policy

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Annex VII: Evaluations 2018

Annex VIII: Risks 2018

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Annex XI: IT Resource

Annex XII: 2018 Registration deadline scenarios

Annex I: Resource allocation per Activity of the Work Programme 2018

Activity	Staff allocation in FTE (TA, CA) – 2017 final estimate	Staff allocation in FTE (TA, CA) – 2018 estimate	Draft Budget 2017	Budget estimate 2018
1.1. 1 Registration dossier preparation	49	50	12 330 283	12 503 085
1.1.2 Registration and dossier submission	42	45	9 564 452	11 454 871
1.1.3 Evaluation	106	106	17 874 662	19 095 180
1.1.4 Communication of risk management advice through the supply chain	16	17	3 036 807	2 911 108
1.2.1 Identifying needs for Regulatory Risk Management	16	17	3 143 386	3 163 176
1.2.2 Authorisation	31	26	5 544 310	4 657 389
1.2.3 Restrictions	17	24	3 454 427	4 251 330
1.2.4 Classification and Labelling	23	27	4 446 081	4 762 036
1.3 Biocides	59	64	10 358 000	11 899 055
1.4 PIC	7	8	1 183 000	1 096 320
1.5 Data management and dissemination	39	40	10 104 257	10 441 117
2.1.1 Committees	17	16	3 358 212	3 043 994
2.1.2 Forum	8	8	1 551 735	1 795 489
2.1.3 HelpNet and Security Officers Network	2	2	311 233	334 708
2.1.4 Board of Appeal	11	11	1 696 662	1 805 558
2.2 Management	42	36	7 138 594	6 965 826
2.3.1 Financial resources	27	26	4 005 230	4 145 478
2.3.2 Human resources	25	24	3 667 413	3 771 337
2.3.3 Corporate Services	21	20	3 080 627	3 142 701
2.3.4 ICT	23	24	3 374 020	3 771 398
Totals	581	591	109 223 390	115 011 156
1.6 Delegated tasks	3	3	600 000	1 600 000

Annex II: Human and Financial Resources

Table 1: Expenditure

ECHA

Expenditure	2017		2018	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1	69 298 606	69 298 606	74 397 206	74 397 206
Title 2	15 001 508	15 001 508	17 021 310	17 021 310
Titles 3-5	26 230 440	26 433 623	25 863 230	25 192 640
Total expenditure	110 530 554	110 733 737	117 281 746	116 611 156

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
Title 1 Staff Expenditure	65 766 995	69 298 606	74 397 206	7%	75 156 650	77 139 010
11 Salaries & allowances	60 757 809	63 661 316	68 983 900	8%	69 741 220	72 027 070
- of which establishment plan posts	54 222 409	55 894 347	60 569 808	8%	61 840 504	63 891 750
- of which external personnel	6 535 400	7 766 969	8 414 092	8%	7 900 716	8 135 320
12 Expenditure relating to Staff recruitment	501 286	542 266	582 656	7%	546 350	546 330
13 Mission expenses	41 014	60 000	65 000	8%	63 020	63 020
14 Socio-medical infrastructure	1 608 168	1 782 470	1 874 255	5%	1 930 360	1 930 580
15 Training	892 322	1 072 455	977 270	-9%	980 440	980 360
16 External Services	1 959 654	2 163 088	1 898 124	-12%	1 875 250	1 571 640
17 Receptions and events	6 742	17 011	16 001	-6%	20 010	20 010
Title 2				-		
Infrastructure and operating expenditure	14 686 304	15 001 508	17 021 310	13%	18 244 500	15 562 360
20 Rental of buildings and associated costs[1]	7 642 657	7 652 839	7 978 773	4%	8 538 540	7 878 140
21 Information and communication technology	6 319 556	6 752 999	7 585 699	12%	7 522 900	7 174 430

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
22 Movable property and associated costs	489 369	311 314	1 194 905	284%	1 597 540	244 250
23 Current administrative expenditure	225 765	279 856	249 802	-11%	573 390	253 280
24 Postage / Telecommunications	0	0	0	-	0	0
25 Meeting expenses	8 957	4 500	12 131	170%	12 130	12 260
26 Running costs in connection with operational activities	0	0	0	-	0	0
27 Information and publishing	0	0	0	-	0	0
28 Studies	0	0	0	-	0	0
Title 3					0	0
Operational expenditure	26 723 612	22 753 179	23 304 060	2%	20 737 620	21 423 270
30 REACH	25 169 009	21 020 734	19 547 060	-7%	17 801 620	18 441 270
3003 Registration, data sharing and dissemination	533 989	1 254 168	2 499 844	99%	950 000	1 000 000
3004 Evaluation	1 295 374	195 273	155 000	-21%	180 000	180 000
3005 Risk Management	435 522	650 905	643 000	-1%	875 000	1 020 000
3006 Classification and labelling	13 194	64 218	62 000	-3%	110 000	260 000
3007 Advice and assistance through guidance and helpdesk	161 401	250 900	264 250	5%	230 750	230 750
3008 Scientific IT tools	14 854 250	11 978 562	10 525 503	-12%	10 173 800	10 428 010
3009 Scientific and technical advice to EU institutions and bodies	103 371	259 000	350 000	35%	400 000	400 000
3011 Committees and Forum	2 146 960	1 423 500	1 157 700	-19%	1 289 000	1 239 000
3012 Board of Appeal	68 936	55 430	77 000	39%	77 000	77 000
3013 Communications including Translations	4 115 603	3 232 248	1 674 002	-48%	1 612 120	1 612 120
3014 International cooperation	0	0	40 000	-	80 000	165 000
3022 Management Board and management of the Agency	925 125	1 062 430	1 517 176	43%	1 200 950	1 206 390
3030 Missions	515 284	594 100	581 585	-2%	623 000	623 000
3031 External training	0	0	0	-	0	0
3090 Refunds REACH/CLP	0	0	0	-	0	0
31 MULTIANNUAL ACTIVITIES	212 927	832 445	1 477 000	77%	1 786 000	1 732 000
3111 Committees and Forum (Multiannual)	212 927	832 445	1 477 000	77%	1 786 000	1 732 000
38 INTERNATIONAL ACTIVITIES	1 164 794	300 000	680 000	127%	550 000	650 000

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
3801 Cooperation with international organisations for IT programmes	1 164 794	300 000	680 000	127%	550 000	650 000
39 EARMARKED OPERATIONS	176 882	600 000	1 600 000	167%	600 000	600 000
3901 IPA programme according to agreement 2009/214-524	0	0	0	-	0	0
3902 IPA programme according to agreement 2012/291-934	27 909	0	0	-	0	0
3903 IPA programme according to agreement 2015/361-049	148 973	0	0	-	0	0
3911 Delegated tasks	0	600 000	1 600 000	167%	600 000	600 000
Title 4					0	0
Operational expenditure	1 934 802	3 085 602	2 331 786	-24%	2 286 380	2 216 840
4000 Substances, products and technical equivalence	0	0	15 000	-	20 000	20 000
4003 Submissions, datasharing, dissemination	0	0	0	-	0	0
4007 Advice assistance through guidance and helpdesk	30 091	31 650	46 750	48%	38 750	38 750
4008 Scientific IT tools	1 361 881	2 230 176	1 162 201	-48%	1 309 680	1 205 590
4009 Scientific technical advice to EU institut and bodies	0	0	0	-	0	0
4011 Biocidal products Committee and the BPR Subgroup of the Forum	307 374	454 873	590 000	30%	620 600	651 600
4012 Board of Appeal	5 521	6 500	11 500	77%	11 500	11 500
4013 Communications including Translations	113 093	185 250	320 402	73%	102 030	102 030
4022 Management Board and management of the Agency	58 264	110 553	107 533	-3%	114 820	118 370
4030 Missions	58 577	66 600	78 400	18%	69 000	69 000
4031 External training	0	0	0	-	0	0
4901 Preparatory work BPR 13/3938 Norwegian	0	0	0	-	0	0
Title 5					0	0
Operational expenditure	363 916	391 659	227 384	-42%	241 710	237 600
5000 Studies and consultants	0	0	0	-	0	0
5007 Advice assistance through guidance and helpdesk	0	0	0	-	0	0
5008 Scientific IT tools	331 036	359 609	207 176	-42%	198 950	199 840

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
5011 Meetings with the DNAs and experts on PIC implem	0	6 300	0	-100%	6 300	6 300
5013 Communications including Translations	20 267	11 850	8 602	-27%	17 460	17 460
5030 Missions	12 613	13 900	11 606	-17%	19 000	14 000
5031 External training	0	0	0	-	0	0
TOTAL EXPENDITURE	109 475 628	110 530 554	117 281 746	6%	116 666 860	116 579 080

EXPENDITURE	Payment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
Title 1 Staff Expenditure	65 401 567	69 298 606	74 397 206	7%	75 156 650	77 139 010
11 Salaries & allowances	60 757 809	63 661 316	68 983 900	8%	69 741 220	72 027 070
- of which establishment plan posts	54 222 409	55 894 347	60 569 808	8%	61 840 504	63 891 750
- of which external personnel	6 535 400	7 766 969	8 414 092	8%	7 900 716	8 135 320
12 Expenditure relating to Staff recruitment	458 328	542 266	582 656	7%	546 350	546 330
13 Mission expenses	39 302	60 000	65 000	8%	63 020	63 020
14 Socio-medical infrastructure	1 533 145	1 782 470	1 874 255	5%	1 930 360	1 930 580
15 Training	805 959	1 072 455	977 270	-9%	980 440	980 360
16 External Services	1 800 369	2 163 088	1 898 124	-12%	1 875 250	1 571 640
17 Receptions and events	6 655	17 011	16 001	-6%	20 010	20 010
Title 2				-		
Infrastructure and operating expenditure	12 983 517	15 001 508	17 021 310	13%	18 244 500	15 562 360
20 Rental of buildings and associated costs[1]	7 277 135	7 652 839	7 978 773	4%	8 538 540	7 878 140
21 Information and communication technology	5 202 422	6 752 999	7 585 699	12%	7 522 900	7 174 430
22 Movable property and associated costs	303 269	311 314	1 194 905	284%	1 597 540	244 250
23 Current administrative expenditure	192 022	279 856	249 802	-11%	573 390	253 280
24 Postage / Telecommunications	0	0	0	-	0	0
25 Meeting expenses	8 668	4 500	12 131	170%	12 130	12 260
26 Running costs in connection with operational activities	0	0	0	-	0	0
27 Information and publishing	0	0	0	-	0	0

EXPENDITURE	Payment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
28 Studies	0	0	0	-	0	0
Title 3				-	0	0
Operational expenditure	15 858 446	22 956 362	22 633 470	-1%	20 628 620	21 272 270
30 REACH	15 075 341	21 020 734	19 547 060	-7%	17 801 620	18 441 270
3003 Registration, datasharing and dissemination	416 937	1 254 168	2 499 844	99%	950 000	1 000 000
3004 Evaluation	183 335	195 273	155 000	-21%	180 000	180 000
3005 Risk Management	256 544	650 905	643 000	-1%	875 000	1 020 000
3006 Classification and labelling	13 194	64 218	62 000	-3%	110 000	260 000
3007 Advice and assistance through guidance and helpdesk	161 401	250 900	264 250	5%	230 750	230 750
3008 Scientific IT tools	8 056 703	11 978 562	10 525 503	-12%	10 173 800	10 428 010
3009 Scientific and technical advice to EU institutions and bodies	78 176	259 000	350 000	35%	400 000	400 000
3011 Committees and Forum	1 444 924	1 423 500	1 157 700	-19%	1 289 000	1 239 000
3012 Board of Appeal	23 376	55 430	77 000	39%	77 000	77 000
3013 Communications including Translations	3 376 075	3 232 248	1 674 002	-48%	1 612 120	1 612 120
3014 International cooperation	0	0	40 000	-	80 000	165 000
3022 Management Board and management of the Agency	598 377	1 062 430	1 517 176	43%	1 200 950	1 206 390
3030 Missions	466 300	594 100	581 585	-2%	623 000	623 000
3031 External training	0	0	0	-	0	0
3090 Refunds REACH/CLP	0	0	0	-	0	0
31 MULTIANNUAL ACTIVITIES	12 950	250 816	875 030	249%	1 502 000	1 556 000
3111 Committees and Forum (Multiannual)	12 950	250 816	875 030	249%	1 502 000	1 556 000
38 INTERNATIONAL ACTIVITIES	644 759	1 084 812	611 380	-44%	725 000	675 000
3801 Cooperation with international organisations for IT programmes	644 759	1 084 812	611 380	-44%	725 000	675 000
39 EARMARKED OPERATIONS	125 396	600 000	1 600 000	167%	600 000	600 000
3901 IPA programme according to agreement 2009/214-524	0	0	0	-	0	0
3902 IPA programme according to agreement 2012/291-934	27 909	0	0	-	0	0
3903 IPA programme according to agreement 2015/361-049	97 487	0	0	-	0	0
3911 Delegated tasks	0	600 000	1 600 000	167%	600 000	600 000

EXPENDITURE	Payment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
Title 4						
Operational expenditure	1 934 802	3 085 602	2 331 786	-24%	2 286 380	2 216 840
4000 Substances, products and technical equivalence	0	0	15 000	-	20 000	20 000
4003 Submissions, datasharing, dissemination	0	0	0	-	0	0
4007 Advice assistance through guidance and helpdesk	30 091	31 650	46 750	48%	38 750	38 750
4008 Scientific IT tools	1 361 881	2 230 176	1 162 201	-48%	1 309 680	1 205 590
4009 Scientific technic advice to EU institut and bodies	0	0	0	-	0	0
4011 Biocidal products Committee and the BPR Subgroup of the Forum	307 374	454 873	590 000	30%	620 600	651 600
4012 Board of Appeal	5 521	6 500	11 500	77%	11 500	11 500
4013 Communications including Translations	113 093	185 250	320 402	73%	102 030	102 030
4022 Management Board and management of the Agency	58 264	110 553	107 533	-3%	114 820	118 370
4030 Missions	58 577	66 600	78 400	18%	69 000	69 000
4031 External training	0	0	0	-	0	0
4901 Preparatory work BPR 13/3938 Norwegian	0	0	0	-	0	0
Title 5						
Operational expenditure	363 916	391 659	227 384	-42%	241 710	237 600
5000 Studies and consultants	0	0	0	-	0	0
5007 Advice assistance through guidance and helpdesk	0	0	0	-	0	0
5008 Scientific IT tools	331 036	359 609	207 176	-42%	198 950	199 840
5011 Meetings with the DNAs and experts on PIC implem	0	6 300	0	-100%	6 300	6 300
5013 Communications including Translations	20 267	11 850	8 602	-27%	17 460	17 460
5030 Missions	12 613	13 900	11 606	-17%	19 000	14 000
5031 External training	0	0	0	-	0	0
TOTAL EXPENDITURE	96 542 247	110 733 737	116 611 156	5%	116 557 860	116 428 080

REACH/CLP

Expenditure	2017		2018	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1	61 870 223	61 870 223	66 014 722	66 014 722
Title 2	13 315 154	13 315 154	14 967 589	14 967 589
Title 3	22 753 179	22 956 362	23 304 060	22 633 470
Total expenditure	97 938 556	98 141 739	104 286 371	103 615 781

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
Title 1 Staff Expenditure	59 681 251	61 870 223	66 014 722	7%	65 541 970	67 082 960
11 Salaries & allowances	55 395 258	57 077 591	61 442 000	8%	61 074 000	62 911 020
- of which establishment plan posts	49 685 758	50 588 860	54 345 925	7%	54 603 458	56 246 383
- of which external personnel	5 709 500	6 488 731	7 096 075	9%	6 470 542	6 664 637
12 Expenditure relating to Staff recruitment	445 210	445 921	459 186	3%	416 910	416 900
13 Mission expenses	37 461	53 160	57 135	7%	54 750	54 750
14 Socio-medical infrastructure	1 470 637	1 579 264	1 647 468	4%	1 677 430	1 677 660
15 Training	819 745	959 955	859 441	-10%	851 910	851 880
16 External Services	1 506 737	1 739 074	1 535 226	-12%	1 449 340	1 153 120
17 Receptions and events	6 203	15 258	14 266	-7%	17 630	17 630
Title 2				-		
Infrastructure and operating expenditure	13 780 564	13 315 154	14 967 589	12%	15 860 610	13 529 830
20 Rental of buildings and associated costs[1]	7 191 430	6 775 343	7 006 875	3%	7 419 990	6 846 050
21 Information and communication technology	5 922 266	5 982 398	6 667 815	11%	6 537 040	6 234 280
22 Movable property and associated costs	444 837	291 260	1 050 319	261%	1 388 240	212 240
23 Current administrative expenditure	213 825	262 166	231 917	-12%	504 800	226 620
24 Postage / Telecommunications	0	0	0	-	0	0
25 Meeting expenses	8 207	3 987	10 663	167%	10 540	10 640
26 Running costs in connection with operational activities	0	0	0	-	0	0
27 Information and publishing	0	0	0	-	0	0

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
28 Studies	0	0	0	-	0	0
Title 3 Operational expenditure	26 723 612	22 753 179	23 304 060	2%	20 737 620	21 423 270
30 REACH	25 169 009	21 020 734	19 547 060	-7%	17 801 620	18 441 270
3003 Registration, datasharing and dissemination	533 989	1 254 168	2 499 844	99%	950 000	1 000 000
3004 Evaluation	1 295 374	195 273	155 000	-21%	180 000	180 000
3005 Risk Management	435 522	650 905	643 000	-1%	875 000	1 020 000
3006 Classification and labelling	13 194	64 218	62 000	-3%	110 000	260 000
3007 Advice and assistance through guidance and helpdesk	161 401	250 900	264 250	5%	230 750	230 750
3008 Scientific IT tools	14 854 250	11 978 562	10 525 503	-12%	10 173 800	10 428 010
3009 Scientific and technical advice to EU institutions and bodies	103 371	259 000	350 000	35%	400 000	400 000
3011 Committees and Forum	2 146 960	1 423 500	1 157 700	-19%	1 289 000	1 239 000
3012 Board of Appeal	68 936	55 430	77 000	39%	77 000	77 000
3013 Communications including Translations	4 115 603	3 232 248	1 674 002	-48%	1 612 120	1 612 120
3014 International cooperation	0	0	40 000	-	80 000	165 000
3022 Management Board and management of the Agency	925 125	1 062 430	1 517 176	43%	1 200 950	1 206 390
3030 Missions	515 284	594 100	581 585	-2%	623 000	623 000
3031 External training	0	0	0	-	0	0
3090 Refunds REACH/CLP	0	0	0	-	0	0
31 MULTIANNUAL ACTIVITIES	212 927	832 445	1 477 000	77%	1 786 000	1 732 000
3111 Committees and Forum (Multiannual)	212 927	832 445	1 477 000	77%	1 786 000	1 732 000
38 INTERNATIONAL ACTIVITIES	1 164 794	300 000	680 000	127%	550 000	650 000
3801 Cooperation with international organisations for IT programmes	1 164 794	300 000	680 000	127%	550 000	650 000
39 EARMARKED OPERATIONS	176 882	600 000	1 600 000	167%	600 000	600 000
3901 IPA programme according to agreement 2009/214-524	0	0	0	-	0	0
3902 IPA programme according to agreement 2012/291-934	27 909	0	0	-	0	0
3903 IPA programme according to agreement 2015/361-049	148 973	0	0	-	0	0
3911 Delegated tasks	0	600 000	1 600 000	167%	600 000	600 000

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
TOTAL EXPENDITURE	100 185 427	97 938 556	104 286 371	6%	102 140 200	102 036 060

EXPENDITURE	Payment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
Title 1 Staff Expenditure	59 315 823	61 870 223	66 014 722	7%	65 541 970	67 082 960
11 Salaries & allowances	55 395 258	57 077 591	61 442 000	8%	61 074 000	62 911 020
- of which establishment plan posts	49 685 758	50 588 860	54 345 925	7%	54 603 458	56 246 383
- of which external personnel	5 709 500	6 488 731	7 096 075	9%	6 470 542	6 664 637
12 Expenditure relating to Staff recruitment	402 252	445 921	459 186	3%	416 910	416 900
13 Mission expenses	35 749	53 160	57 135	7%	54 750	54 750
14 Socio-medical infrastructure	1 395 614	1 579 264	1 647 468	4%	1 677 430	1 677 660
15 Training	733 382	959 955	859 441	-10%	851 910	851 880
16 External Services	1 347 453	1 739 074	1 535 226	-12%	1 449 340	1 153 120
17 Receptions and events	6 116	15 258	14 266	-7%	17 630	17 630
Title 2				-		
Infrastructure and operating expenditure	12 077 777	13 315 154	14 967 589	12%	15 860 610	13 529 830
20 Rental of buildings and associated costs[1]	6 825 908	6 775 343	7 006 875	3%	7 419 990	6 846 050
21 Information and communication technology	4 805 132	5 982 398	6 667 815	11%	6 537 040	6 234 280
22 Movable property and associated costs	258 737	291 260	1 050 319	261%	1 388 240	212 240
23 Current administrative expenditure	180 082	262 166	231 917	-12%	504 800	226 620
24 Postage / Telecommunications	0	0	0	-	0	0
25 Meeting expenses	7 918	3 987	10 663	167%	10 540	10 640
26 Running costs in connection with operational activities	0	0	0	-	0	0
27 Information and publishing	0	0	0	-	0	0
28 Studies	0	0	0	-	0	0
Title 3						
Operational expenditure	15 858 446	22 956 362	22 633 470	-1%	20 628 620	21 272 270
30 REACH	15 075 341	21 020 734	19 547 060	-7%	17 801 620	18 441 270
3003 Registration, data sharing and dissemination	416 937	1 254 168	2 499 844	99%	950 000	1 000 000
3004 Evaluation	183 335	195 273	155 000	-21%	180 000	180 000

EXPENDITURE	Payment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
3005 Risk Management	256 544	650 905	643 000	-1%	875 000	1 020 000
3006 Classification and labelling	13 194	64 218	62 000	-3%	110 000	260 000
3007 Advice and assistance through guidance and helpdesk	161 401	250 900	264 250	5%	230 750	230 750
3008 Scientific IT tools	8 056 703	11 978 562	10 525 503	-12%	10 173 800	10 428 010
3009 Scientific and technical advice to EU institutions and bodies	78 176	259 000	350 000	35%	400 000	400 000
3011 Committees and Forum	1 444 924	1 423 500	1 157 700	-19%	1 289 000	1 239 000
3012 Board of Appeal	23 376	55 430	77 000	39%	77 000	77 000
3013 Communications including Translations	3 376 075	3 232 248	1 674 002	-48%	1 612 120	1 612 120
3014 International cooperation	0	0	40 000	-	80 000	165 000
3022 Management Board and management of the Agency	598 377	1 062 430	1 517 176	43%	1 200 950	1 206 390
3030 Missions	466 300	594 100	581 585	-2%	623 000	623 000
3031 External training	0	0	0	-	0	0
3090 Refunds REACH/CLP	0	0	0	-	0	0
31 MULTIANNUAL ACTIVITIES	12 950	250 816	875 030	249%	1 502 000	1 556 000
3111 Committees and Forum (Multiannual)	12 950	250 816	875 030	249%	1 502 000	1 556 000
38 INTERNATIONAL ACTIVITIES	644 759	1 084 812	611 380	-44%	725 000	675 000
3801 Cooperation with international organisations for IT programmes	644 759	1 084 812	611 380	-44%	725 000	675 000
39 EARMARKED OPERATIONS	125 396	600 000	1 600 000	167%	600 000	600 000
3901 IPA programme according to agreement 2009/214-524	0	0	0	-	0	0
3902 IPA programme according to agreement 2012/291-934	27 909	0	0	-	0	0
3903 IPA programme according to agreement 2015/361-049	97 487	0	0	-	0	0
3911 Delegated tasks	0	600 000	1 600 000	167%	600 000	600 000
TOTAL EXPENDITURE	87 252 046	98 141 739	103 615 781	6%	102 031 200	101 885 060

BIOCIDES

Expenditure	2017		2018	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1	6 814 920	6 814 920	7 751 434	7 751 434
Title 2	1 508 476	1 508 476	1 815 835	1 815 835
Title 4	3 085 602	3 085 602	2 331 786	2 331 786
Total expenditure	11 408 998	11 408 998	11 899 055	11 899 055

EXPENDITURE	Commitment and Payment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
Title 1 Staff Expenditure	5 513 118	6 814 920	7 751 434	14%	8 869 330	9 299 030
11 Salaries & allowances	4 863 887	6 067 125	6 971 900	15%	8 031 220	8 460 970
- of which establishment plan posts	4 078 987	4 818 887	5 688 883	18%	6 643 045	7 033 547
- of which external personnel	784 900	1 248 238	1 283 017	3%	1 388 175	1 427 423
12 Expenditure relating to Staff recruitment	46 712	88 436	108 470	23%	113 360	113 350
13 Mission expenses	3 085	6 120	6 955	14%	7 380	7 380
14 Socio-medical infrastructure	130 338	181 814	200 546	10%	225 880	225 880
15 Training	64 301	102 187	107 531	5%	114 950	114 910
16 External Services	404 258	367 485	354 297	-4%	374 160	374 160
17 Receptions and events	539	1 753	1 735	-1%	2 380	2 380
Title 2				-		
Infrastructure and operating expenditure	759 439	1 508 476	1 815 835	20%	2 128 950	1 815 150
20 Rental of buildings and associated costs[1]	376 025	784 724	859 196	9%	999 010	921 770
21 Information and communication technology	333 738	689 525	811 675	18%	880 360	839 570
22 Movable property and associated costs	38 660	17 941	127 856	613%	186 920	28 580
23 Current administrative expenditure	10 366	15 827	15 810	0%	61 240	23 790
24 Postage / Telecommunications	0	0	0	-	0	0
25 Meeting expenses	651	459	1 298	183%	1 420	1 440
26 Running costs in connection with operational activities	0	0	0	-	0	0
27 Information and publishing	0	0	0	-	0	0

EXPENDITURE	Commitment and Payment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
28 Studies	0	0	0	-	0	0
Title 4						
Operational expenditure	1 934 802	3 085 602	2 331 786	-24%	2 286 380	2 216 840
4000 Substances, products and technical equivalence	0	0	15 000	-	20 000	20 000
4003 Submissions, data sharing, dissemination	0	0	0	-	0	0
4007 Advice assistance through guidance and helpdesk	30 091	31 650	46 750	48%	38 750	38 750
4008 Scientific IT tools	1 361 881	2 230 176	1 162 201	-48%	1 309 680	1 205 590
4009 Scientific technic advice to EU institut and bodies	0	0	0	-	0	0
4011 Biocidal products Committee and the BPR Subgroup of the Forum	307 374	454 873	590 000	30%	620 600	651 600
4012 Board of Appeal	5 521	6 500	11 500	77%	11 500	11 500
4013 Communications including Translations	113 093	185 250	320 402	73%	102 030	102 030
4022 Management Board and management of the Agency	58 264	110 553	107 533	-3%	114 820	118 370
4030 Missions	58 577	66 600	78 400	18%	69 000	69 000
4031 External training	0	0	0	-	0	0
4901 Preparatory work BPR 13/3938 Norwegian	0	0	0	-	0	0
TOTAL EXPENDITURE	8 207 359	11 408 998	11 899 055	4%	13 284 660	13 331 020

PIC

Expenditure	2017		2018	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1	613 463	613 463	631 050	631 050
Title 2	177 878	177 878	237 886	237 886
Title 5	391 659	391 659	227 384	227 384
Total expenditure	1 183 000	1 183 000	1 096 320	1 096 320

EXPENDITURE	Commitment appropriations					
	2016	2017	2018	VAR 2018/2017	2019	2020
			Agency request			
Title 1 Staff Expenditure	572 626	613 463	631 050	3%	745 350	757 020
11 Salaries & allowances	498 665	516 600	570 000	10%	636 000	655 080
- of which establishment plan posts	457 664	486 600	535 000	10%	594 000	611 820
- of which external personnel	41 000	30 000	35 000	17%	42 000	43 260
12 Expenditure relating to Staff recruitment	9 363	7 909	15 000	90%	16 080	16 080
13 Mission expenses	469	720	910	26%	890	890
14 Socio-medical infrastructure	7 193	21 392	26 241	23%	27 050	27 040
15 Training	8 277	10 313	10 298	0%	13 580	13 570
16 External Services	48 659	56 529	8 601	-85%	51 750	44 360
17 Receptions and events	0	0	0	-	0	0
Title 2				-		
Infrastructure and operating expenditure	146 301	177 878	237 886	34%	254 940	217 380
20 Rental of buildings and associated costs[1]	75 202	92 772	112 702	21%	119 540	110 320
21 Information and communication technology	63 553	81 076	106 209	31%	105 500	100 580
22 Movable property and associated costs	5 872	2 113	16 730	692%	22 380	3 430
23 Current administrative expenditure	1 574	1 863	2 075	11%	7 350	2 870
24 Postage / Telecommunications	0	0	0	-	0	0
25 Meeting expenses	99	54	170	215%	170	180
26 Running costs in connection with operational activities	0	0	0	-	0	0
27 Information and publishing	0	0	0	-	0	0
28 Studies	0	0	0	-	0	0
Title 5				-		
Operational expenditure	363 916	391 659	227 384	-42%	241 710	237 600
5000 Studies and consultants	0	0	0	-	0	0
5007 Advice assistance through guidance and helpdesk	0	0	0	-	0	0
5008 Scientific IT tools	331 036	359 609	207 176	-42%	198 950	199 840
5011 Meetings with the DNAs and experts on PIC implem	0	6 300	0	-100%	6 300	6 300
5013 Communications including Translations	20 267	11 850	8 602	-27%	17 460	17 460
5030 Missions	12 613	13 900	11 606	-17%	19 000	14 000
5031 External training	0	0	0	-	0	0

EXPENDITURE	Commitment appropriations					
	2016	2017	2018 Agency request	VAR 2018/2017	2019	2020
TOTAL EXPENDITURE	1 082 842	1 183 000	1 096 320	-7%	1 242 000	1 212 000

Annex II: Table 2 – Revenue

ECHA

Revenues	2017	2018
	Revenues estimated by the agency	As requested by the agency
EU contribution	69 340 298	33 839 320
Other revenue	41 393 439	82 771 836
Total revenues	110 733 737	116 611 156

REVENUES	2016	2017	2018	VAR 2018 / 2017	2019	2020
	Executed Budget	Revenues estimated by the agency	As requested by the agency			
1 REVENUE FROM FEES AND CHARGES	49 828 533.26	39 152 289	80 440 128	105%	39 800 100	37 910 100
2. EU CONTRIBUTION	60 920 188	69 340 298	33 839 320	-51%	74 226 000	75 902 000
of which Administrative (Title 1 and Title 2)	49 624 164	52 864 605	26 509 693	-50%	59 401 638	60 367 909
of which Operational (Titles 3-5)	11 296 024	16 475 693	7 329 627	-56%	14 824 362	15 534 091
of which assigned revenues deriving from previous years' surpluses	441 492	3 021 261	5 239 696	73%	0	0
3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)	1 767 954	1 641 150	731 708	-55%	1 931 760	2 015 980
of which EFTA	1 639 917	1 609 043	653 624	-59%	1 735 472	1 777 158
of which Candidate Countries	0	0	0	-	0	0
4 OTHER CONTRIBUTIONS	900 000	600 000	1 600 000	167%	600 000	600 000
of which delegation agreement, ad hoc grants	900 000	600 000	1 600 000	167%	600 000	600 000
5 ADMINISTRATIVE OPERATIONS	543 830	0	0	-	0	0
6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT	0	0	0	-	0	0
7 CORRECTION OF BUDGETARY IMBALANCES	0	0	0	-	0	0
TOTAL REVENUES	113 960 505	110 733 737	116 611 156	5%	116 557 860	116 428 080

REACH / CLP

Revenues	2017	2018
	Revenues estimated by the agency	As requested by the agency
EU contribution	64 289 500	30 517 000
Other revenue	33 852 239	73 098 781
Total revenues	98 141 739	103 615 781

REVENUES	2016	2017	2018	VAR 2018 / 2017	2019	2020
	Executed Budget	Revenues estimated by the agency	As requested by the agency			
1 REVENUE FROM FEES AND CHARGES	42 216 388	31 664 289	70 889 170	124%	32 614 000	31 999 000
2. EU CONTRIBUTION	58 919 188	64 289 500	30 517 000	-53%	67 224 000	67 682 000
of which Administrative (Title 1 and Title 2)	48 210 364	49 251 525	23 850 973	-52%	53 632 683	53 550 882
of which Operational (Title 3)	10 708 824	15 037 975	6 666 027	-56%	13 591 317	14 131 118
of which assigned revenues deriving from previous years' surpluses		0	4 794 979	-	0	0
3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)	1 625 575	1 587 950	609 611	-62%	1 593 200	1 604 060
of which EFTA	1 625 575	1 587 950	609 611	-62%	1 593 200	1 604 060
of which Candidate Countries		0	0	-	0	0
4 OTHER CONTRIBUTIONS	900 000	600 000	1 600 000	167%	600 000	600 000
of which delegation agreement, ad hoc grants	900 000	600 000	1 600 000	167%	600 000	600 000
5 ADMINISTRATIVE OPERATIONS	517 204	0	0	-	0	0
6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT		0	0	-	0	0
7 CORRECTION OF BUDGETARY IMBALANCES		0	0	-	0	0
TOTAL REVENUES	104 178 355	98 141 739	103 615 781	6%	102 031 200	101 885 060

BIOCIDES

Revenues	2017	2018
	Revenues estimated by the agency	As requested by the agency
EU contribution	3 867 798	2 226 000
Other revenue	7 541 200	9 673 055
Total revenues	11 408 998	11 899 055

REVENUES	2016	2017	2018	VAR 2018 / 2017	2019	2020
	Executed Budget	Revenues estimated by the agency	As requested by the agency			
1 REVENUE FROM FEES AND CHARGES	7 612 146	7 488 000	9 550 958	28%	7 186 100	5 911 100
2. EU CONTRIBUTION	850 000	3 867 798	2 226 000	-42%	5 760 000	7 008 000
of which Administrative (Title 1 and Title 2)	649 621	2 821 739	1 789 784	-37%	4 768 665	5 842 627
of which Operational (Title 4)	200 379	1 046 059	436 216	-58%	991 335	1 165 373
of which assigned revenues deriving from previous years' surpluses	330 372	2 977 798	368 932	-88%	0	0
3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)	142 379	53 200	122 097	130%	338 560	411 920
of which EFTA	14 342	21 093	44 013	109%	142 272	173 098
of which Candidate Countries		0	0	-	0	0
4 OTHER CONTRIBUTIONS		0	0	-	0	0
of which delegation agreement, ad hoc grants		0	0	-	0	0
5 ADMINISTRATIVE OPERATIONS	13 588	0	0	-	0	0
6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT		0	0	-	0	0
7 CORRECTION OF BUDGETARY IMBALANCES		0	0	-	0	0
TOTAL REVENUES	8 618 112	11 408 998	11 899 055	4%	13 284 660	13 331 020

PIC

Revenues	2017	2018
	Revenues estimated by the agency	As requested by the agency
EU contribution	1 183 000	1 096 320
Other revenue	0	0
Total revenues	1 183 000	1 096 320

REVENUES	2016	2017	2018	VAR 2018 / 2017	2019	2020
	Executed Budget	Revenues estimated by the agency	As requested by the agency			
1 REVENUE FROM FEES AND CHARGES	0	0	0	-	0	0
2. EU CONTRIBUTION	1 151 000	1 183 000	1 096 320	-7%	1 242 000	1 212 000
of which Administrative (Title 1 and Title 2)	764 178	791 341	868 936	10%	1 000 290	974 400
of which Operational (Title 5)	386 822	391 659	227 384	-42%	241 710	237 600
of which assigned revenues deriving from previous years' surpluses	111 120	43 463	75 785	74%	0	0
3 THIRD COUNTRIES CONTRIBUTION (incl. EFTA and candidate countries)	0	0	0	-	0	0
of which EFTA	0	0	0	-	0	0
of which Candidate Countries		0	0	-	0	0
4 OTHER CONTRIBUTIONS		0	0	-	0	0
of which delegation agreement, ad hoc grants		0	0	-	0	0
5 ADMINISTRATIVE OPERATIONS	13 038	0	0	-	0	0
6 REVENUES FROM SERVICES RENDERED AGAINST PAYMENT		0	0	-	0	0
7 CORRECTION OF BUDGETARY IMBALANCES		0	0	-	0	0
TOTAL REVENUES	1 164 038	1 183 000	1 096 320	-7%	1 242 000	1 212 000

Annex II: Table 3 - Budget outturn and cancellation of appropriations**Calculation budget outturn***REACH / CLP*

Budget outturn	2014	2015	2016
Reserve from the previous years' surplus (+)	160 044 885	87 189 692	8 839 384
Revenue actually received (+)	27 817 012	24 825 943	95 338 971
Payments made (-)	-90 826 274	-93 301 724	-87 252 046
Carry-over of appropriations (-)	-10 333 258	-10 460 492	-13 339 281
Cancellation of appropriations carried over (+)	490 200	546 332	885 682
Adjustment for carry over of assigned revenue appropriations from previous year (+)		51 427	323 288
Exchange rate differences (+/-)	-2 873	-11 794	-1 018
Adjustment for negative balance from previous year (-)			
Total	87 189 692	8 839 384	4 794 980

The amount of € 1 686 496 remained uncommitted and is cancelled.

BIOCIDES

Budget outturn	2014	2015	2016
Revenue actually received (+)	7 728 121	11 536 716	8 618 112
Payments made (-)	-7 089 216	-6 653 783	-6 879 964
Carry-over of appropriations (-)	-543 110	-2 037 505	-1 449 970
Cancellation of appropriations carried over (+)	234 577	26 444	69 538
Adjustment for carry over of assigned revenue appropriations from previous year (+)		178 581	122 162
Exchange rate differences (+/-)		0	
Adjustment for negative balance from previous year (-)		0	
Total	330 372	3 050 453	479 879

The amount of € 233 815 remained uncommitted and is cancelled.

PIC

Budget outturn	2014	2015	2016
Revenue actually received (+)	1 297 391	1 222 925	1 164 039
Payments made (-)	-1 003 063	-1 015 317	-908 928
Carry-over of appropriations (-)	-192 017	-164 310	-185 558
Cancellation of appropriations carried over (+)	8 810	2 769	6 234
Adjustment for carry over of assigned revenue appropriations from previous year (+)		166	
Exchange rate differences (+/-)			

Budget outturn	2014	2015	2016
Adjustment for negative balance from previous year (-)			
Total	111 121	46 233	75 786

The amount of € 69 552 remained uncommitted and is cancelled.

Annex III. Staff population and its evolution

Table 1 – Overview of all categories of staff

Staff population		Staff population - posts actually filled in 31.12.2015*				Staff population in voted EU budget 2016				Staff population - posts actually filled in 31.12.2016*				Staff population in voted EU budget 2017				Staff population - posts actually filled in 31.12.2017*				Staff population in draft EU budget 2018*				Staff population envisaged in 2019				Staff population envisaged in 2020								
		REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	Delegated tasks	TOTAL	REACH/CLP	Biocides	PIC	Delegated tasks	TOTAL	REACH/CLP	Biocides	PIC	Delegated tasks	TOTAL	REACH/CLP	Biocides	PIC	Delegated tasks	TOTAL					
Officials	AD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-					
	AST	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-					
TA	AD	304	31	1	336	303	30	1	334	299	31	1	331	304	35	1		340	301	35	1		337	301	38	1		340	301	43	1		345	301	44	1		346
	AST	117	9	5	131	117	9	5	131	110	9	5	124	106	9	5		120	103	9	5		117	103	9	6		118	103	10	6		119	103	10	6		119
	AST/SC																																					
Total AD+AST		421	40	6	467	420	39	6	465	409	40	6	455	410	44	6		460	404	44	6		454	404	47	7		458	404	53	7		464	404	54	7		465
CA FG IV		14	4		18	20	4	1	25	17	7		24	19	6	1	2	28	19	7		2	28	20	7	1	2	30	19	10	1	2	32	19	10	1	2	32
CA FG III		53	6		59	64	8		72	58	5		63	65	7		1	73	62	6		1	69	66	6		1	73	62	6		1	69	62	6		1	69
CA FG II		23	0	1	24	18	2		20	25	1	1	27	18	2			20	31	2	1		34	24	2			26	18	2			20	18	2			20
CA FG I		2			2				0				0					0					0					0					0					0
TOTAL CAs in place		92	10	1	103					100	13	1	114						112	15	1	2	130															
Total CA (FTE)		85	9.08	1	95	102	14	1	117	89.5	10.5	0.9	101	102	15	1	3	121	100	14	0.9	2	117	110	15	1	3	129	99	18	1	3	121	99	18	1	3	121
SNE		7	1		8	13	2	0	15	8	1		9	13	1	0		14	7	1	0		8	5	2	0	0	7	13	2	0	0	15	13	2	0	0	15
Structural service providers**		40			40					22									15																			
Total		560	51	7	618	535	55	7	597	539	54	7	600	525	60	7	3	595	526	59	6.9	2	594	519	64	8	3	594	516	73	8	3	600	516	74	8	3	601
External staff for occasional replacement**		34	9	3	46					3	2	3	8						39																			

* 3 TAs under recruitment
* 3 CAs under recruitment

* 1 TA under recruitment
* 6 CAs under recruitment

* final number of posts will be determined by the budgetary authority

Table 2 – Multi-annual staff policy plan 2018-2020

Category and grade	Establishment plan in the voted EU budget 2016				Posts filled 31 December 2016*				Establishment plan in the voted EU budget 2017				Modifications in establishment plan 2017 in application of flexibility rule				Establishment plan 2018				Establishment plan 2019				Establishment plan 2020			
	TA				TA				TA				TA				TA				TA				TA			
	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL
AD 16	0		0	0	0	0	0	0	0	0	0	0				0			0	0			0	0			0	0
AD 15	1		0	1	1	0	0	1	1		0	1				0			0	1			1	1			0	1
AD 14	4		0	4	4	0	0	4	5		0	5				8			0	7			7	8			0	8
AD 13	15		0	15	7	0	0	7	15		0	15				16			0	16	16		0	16	17		0	17
AD 12	20	2	0	22	12	1	0	13	18	2	0	20				19	2	0	21	19	2	0	21	21	2	0	23	
AD 11	31	3	0	34	16	1	0	17	31	3	0	34				31	3	0	34	31	3	0	34	32	3	0	35	
AD 10	33	3	0	36	23	1	0	24	36	3	0	39				39	4	0	43	39	5	0	44	43	5	0	48	
AD 9	48	6	0	54	42	1	0	43	48	6	0	54	1			51	6	0	57	51	10	0	61	54	10	0	64	
AD 8	50	9	1	60	50	4	0	54	49	12	1	62	1			51	12	1	64	51	12	1	64	48	11	1	60	
AD 7	52	5	0	57	62	7	0	69	59	5	0	64	1			60	5	0	65	60	4	0	64	56	6	0	62	
AD 6	41	4	0	45	62	12	0	74	31	4	0	35				21	6	0	27	21	6	0	27	17	5	0	22	
AD 5	8		0	8	20	4	1	25	8		0	8				5		0	5	5	1	0	6	4	1	0	5	
Total AD	303	32	1	336	299	31	1	331	301	35	1	337	3			301	38	1	340	301	43	1	345	301	43	1	345	
AST 11	0		0	0	0	0	0	0	0		0	0				0		0	0			0	0			0	0	
AST 10	0		0	0	0	0	0	0	0		0	0				1		0	1	1		0	1	1		0	1	
AST 9	6		0	6	3	0	0	3	5		0	5	-1			4		0	4	4		0	4	4		0	4	
AST 8	9		0	9	2	0	0	2	7		0	7	-1			7		0	7	7		0	7	7	1	1	9	
AST 7	12	1	2	15	5	0	0	5	11	1	2	14	-1			11	1	2	14	11	1	2	14	12	1	1	14	
AST 6	16		0	16	10	0	1	11	15		0	15				18		0	18	18	1	0	19	21	1	0	22	
AST 5	31	3	0	34	20	2	1	23	31	3	0	34				31	3	0	34	31	3	0	34	25	3	1	29	
AST 4	12	2	0	14	27	2	0	29	19	2	1	22				17	3	2	22	17	4	2	23	21	3	2	26	
AST 3	19	1	3	23	30	5	3	38	13	3	2	18				13	2	2	17	13	1	2	16	11	1	1	13	
AST 2	7		0	7	11	0	0	11	5		0	5				1		0	1	1		0	1	1		0	1	
AST 1	5		0	5	2	0	0	2	3		0	3				0		0	0	0		0	0	0		0	0	
Total AST	117	7	5	129	110	9	5	124	109	9	5	123	-3			103	9	6	118	103	10	6	119	103	10	6	119	
AST/SC 6				0				0				0							0				0					0
AST/SC 5				0				0				0							0				0					0
AST/SC 4				0				0				0							0				0					0
AST/SC 3				0				0				0							0				0					0
AST/SC 2				0				0				0							0				0					0
AST/SC 1				0				0				0							0				0					0
TOTAL AD+AST	420	39	6	465	409	40	6	455	410	44	6	460				404	47	7	458	404	53	7	464	404	53	7	464	

Annex IV: A. Recruitment policy

Selection procedures

ECHA has a set of comprehensive staff selection and recruitment procedures in place covering all the key stages of the process in a clear and detailed manner. The aim of the selection and recruitment procedures is to recruit staff that best fit the job profile in a timely and transparent manner and to ensure that staff members are selected and appointed in accordance with the Staff Regulations and with due regard to the principles of professional qualification, transparency, equal access and non-discrimination. The selection procedure information is available on ECHA's website.

Employment Conditions

The employment conditions of staff members employed by ECHA are governed by the Staff Regulations of Officials (SR), the Conditions of Employment of Other Servants of the European Union (CEOS) and the Implementing Rules adopted by ECHA. These temporary agent (TA) and contract agent (CA) staff are referred to as statutory staff. While both TA and CA staff are financed from staff-related expenditure (Title 1), CA's are engaged by ECHA's Appointing Authority in positions that are not included in the Establishment Plan.

a. Officials

ECHA does not engage officials.

b. Temporary agents

All temporary agents employed by ECHA are temporary agents that fall under Article 2(f) and 2(a) of the Staff Regulations.

Temporary agent posts are classified according to the nature and responsibility of the duties, as follows:

- Administrator function group (AD) comprises eleven grades, from AD 5 to AD 15, corresponding to scientific, technical, administrative and legal duties;
- Assistant function group (AST) comprises eleven grades, from AST 1 to AST 11, corresponding to administrative, technical and clerical duties.

TAs are recruited by open calls for expressions of interest and may be selected for employment using either a selection procedure conducted by ECHA, the European Personnel Selection Office (EPSO) or a selection procedure organised through the Inter Agency Job Market. ECHA engages the services of an executive search consultancy to assist in the selection of candidates for management posts and certain high-level specialist posts involving supervisory/key coordination responsibilities. The consultancy assists in the screening of applicants and in assessing management capabilities, utilising modern selection methods.

ECHA adopts a systematic approach to selection planning, involving an identification of its staffing needs on a quarterly basis and the development and implementation of related staffing plans. TAs are appointed on 5-year contracts, which may be renewed for an additional 5 years, with the possibility of a second renewal for an indefinite period. In line with the necessity for staffing flexibility, ECHA also organises selection procedures for short-term assignments under the Temporary Agent contract, in accordance with the Article 8 of the Conditions of Employment of Other Servants of the European Union. In 2016, ECHA did not recruit secretaries at AST level and, for the period 2018-2020, ECHA does not intend to recruit any secretaries at AST level.

c. Contract agents

The Decision of ECHA's Management Board MB/07/2009 (D) 3, dated 26 February 2009, is the Implementing Rule that sets out the procedure governing the engagement and the use of contract agents at ECHA. Again, the SWP has decided to work on new Implementing Rules that will give effect to the changes brought by the new SR, taking account the specificities of the agencies. Once agreed by the SWP, ECHA is committed to adopt these IRs (subject to Commission agreement).

Contract agent positions are classified in four function groups corresponding to the nature and responsibilities involved:

- Function Group I: administrative and manual support service tasks
- Function Group II: clerical and secretarial tasks, office management and other equivalent tasks
- Function Group III: administrative, finance and other equivalent technical tasks, and
- Function Group IV: operational, scientific and equivalent technical tasks.

Contract Agents are appointed on 3-year contracts, which may be renewed for an additional 3 years, with the possibility of a second renewal for an indefinite period. For the 2018 registration deadline, ECHA is also planning on using specific short-term CA contracts.

d. Seconded national experts⁶²

ECHA engages seconded national experts (SNEs) for highly specialised positions requiring a high level of expertise. ECHA publishes a call for expressions of interest on its website and the procedure is conducted in a transparent manner. Typically, the length of secondment is for one year (renewable) however, ECHA has engaged experts for shorter periods.

⁶² SNEs are not employed by the Agency

e. Structural service providers⁶³

Structural service providers carry out specialised outsourced tasks, principally in the area of information technology. The tender procedures adopted follow the best practice procurement rules and the duration of contracts vary in accordance with the specific nature of the contract. ECHA is committed to ensuring that the number of structural service providers will be reduced in the coming years.

f. External staff for occasional replacement⁶⁴

External staff may be contracted by ECHA from a contractor (employment agency) to work at ECHA on a temporary basis, for a limited period of time, to cover absences, work peaks, specific projects, etc. ECHA is committed ensuring that the numbers of operational interims will be reduced in the coming years, except in 2018 when ECHA anticipates a peak in registrations and such external staff will be required to handle this exceptional peak-in-workload activity.

g. Traineeships

Traineeships are targeted at university graduates who are aiming for a career related to chemicals or activities in ECHA's stakeholder community. For the period 2018–2020, ECHA estimates the following intake of graduate trainees:

Year	2017	2018	2019	2020
Trainees	20	30	25	25

⁶³ Structural service providers are not employed by the agency

⁶⁴ External staff for occasional replacements is not employed by the agency

Annex IV: B. Appraisal of performance and reclassification/promotions

Table 1 - Reclassification of temporary staff/promotion of officials

Category and grade	Staff in activity at 1.01.2015		How many staff members were promoted / reclassified in 2016		Average number of years in grade of reclassified/promoted staff members in 2016
	officials	TA	officials	TA	TA
AD 16	0	0	0	N/A	N/A
AD 15	0	1	0	0	N/A
AD 14	0	3	0	0	N/A
AD 13	0	7	0	1	6.30
AD 12	0	14	0	1	6.09
AD 11	0	17	0	0	N/A
AD 10	0	30	0	4	5.92
AD 9	0	45	0	4	5.55
AD 8	0	51	0	8	4.21
AD 7	0	54	0	5	4.85
AD 6	0	84	0	16	3.86
AD 5	0	46	0	11	4.20
Total AD	0	350	0	50	4.48
AST 11	0	0	0	N/A	N/A
AST 10	0	0	0	N/A	N/A
AST 9	0	3	0	N/A	N/A
AST 8	0	1	0	N/A	N/A

AST 7	0	6	0	N/A	N/A
AST 6	0	10	0	N/A	N/A
AST 5	0	21	0	2	5.65
AST 4	0	24	0	1	3.87
AST 3	0	52	0	12	4.20
AST 2	0	14	0	3	4.50
AST 1	0	11	0	0	N/A
Total AST	0	142	0	18	4.39
Total	0	492	0	68	4.46

Table 2 - Reclassification of contract staff

Function Group	Grade	Staff in activity at 1.01.2015	How many staff members were reclassified in 2016	Average number of years in grade of reclassified staff members in 2016
CA IV	18	0	N/A	N/A
	17	0	0	N/A
	16	2	0	N/A
	15	1	0	N/A
	14	10	1	2.84

	13	7	2	2.86
CA III	12	0	0	N/A
	11	1	0	N/A
	10	13	0	N/A
	9	31	2	4.09
	8	13	5	3.12
CA II	7	0	0	N/A
	6	0	0	N/A
	5	12	1	5.47
	4	11	1	2.63
CA I	3	0	0	N/A
	2	2	0	N/A
	1	0	0	N/A
Total		103	12	3.37

The agency's policy on performance appraisal and promotion/reclassification – short description

Following the extensive work of the Inter-Agency Standing Working Group, ECHA's has adopted by analogy in 2015 a new policy with respect to performance appraisal articulated in the ECHA Decision (MB/74/2015) on performance appraisal of temporary agents and contracts agents dated 18 June 2015 (implementing Article 43 of the Staff Regulations) and Article 15(2) of the CEOS.

ECHA's policy with respect to promotion/reclassification is articulated in the ECHA Decision (MB/05/2016) on the policy and procedure for the reclassification of Temporary Agents dated 17 March 2016 (implementing Article 10 of the Staff Regulations and Article 10 of the CEOS) and in the

ECHA Decision (MB/06/2016) on the policy and procedure for the reclassification of Contract Agents dated 17 March 2016 (implementing Article 87(3) of the Staff Regulations and Article 10 of the CEOS).

As a guiding principle, ECHA's establishment plan evolution and the annual reclassification exercise is carried out in line with the multiplication rate for guiding the average career equivalence as provided for in Article 6 and Annex IB of the Staff Regulations, and on the basis of comparative merit and budgetary availability.

Annex IV. C. Mobility policy

Mobility within ECHA

ECHA revised its internal mobility policy in 2016, in collaboration with the Staff Committee, with the objective of further encouraging mobility within the organisation on a permanent and temporary basis. In 2016, eighteen (18) staff members availed of internal mobility opportunities within ECHA.

Mobility between Agencies (Inter-Agency Job Market)

ECHA signed the Inter-Agency Job Market agreement in January 2008 and is supportive of the Inter-Agency Job Market, in particular for posts that may be considered attractive for potential candidates in other Agencies. Following the adoption of the Implementing Rules for the TA 2 (f) that offer the possibility of the continuation of employment contracts between Agencies, ECHA did not publish any Inter Agency Mobility in 2016.

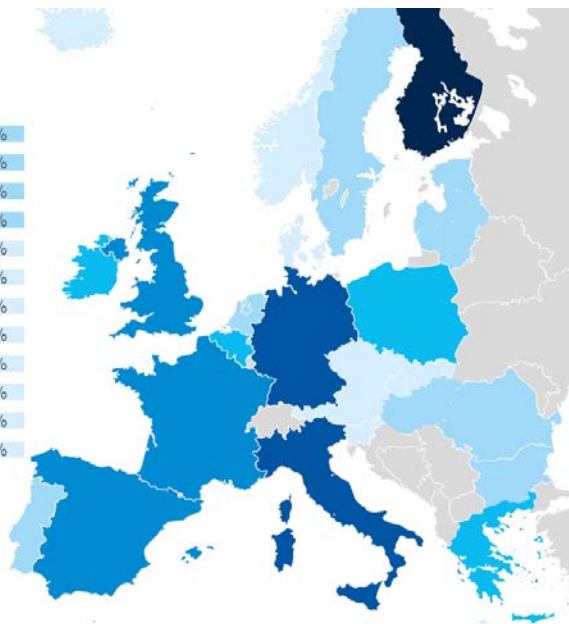
Mobility between the Agencies and the Institutions

ECHA encourages mobility between the Agencies and the European Institutions and welcomes candidates from such Agencies and Institutions.

Annex IV: D. Gender and geographical balance

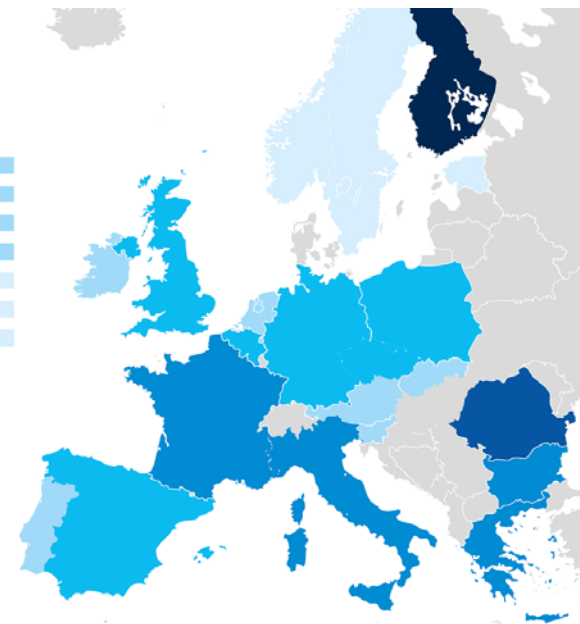
TA GEOGRAPHICAL BALANCE

Finnish	30.8%	Bulgarian	1.5%
Italian	7.9%	Estonian	1.5%
German	7.7%	Lithuanian	1.3%
Spanish	6.6%	Latvian	1.1%
British	6.2%	Slovenian	0.9%
French	5.1%	Slovakian	0.9%
Polish	4.6%	Czech	0.9%
Greek	4.4%	Danish	0.7%
Belgian	4.0%	Austrian	0.7%
Irish	2.9%	Maltese	0.7%
Romanian	2.0%	Iceland	0.2%
Portuguese	2.0%	Liechtenstein	0.2%
Hungarian	1.8%		
Dutch	1.5%		



CA GEOGRAPHICAL BALANCE

Finnish	31.5%	Slovakian	1.9%
Romanian	10.2%	Slovenian	1.9%
French	6.5%	Portuguese	1.9%
Bulgarian	6.5%	Irish	1.9%
Greek	6.5%	Swedish	0.9%
Italian	5.6%	Estonian	0.9%
German	3.7%	Norwegian	0.9%
British	3.7%		
Belgian	3.7%		
Spanish	2.8%		
Polish	2.8%		
Czech	2.8%		
Austrian	1.9%		
Dutch	1.9%		



TA GENDER BALANCE (ECHA)



CA GENDER BALANCE (ECHA)



Annex IV: E. Schooling

Legal Basis

The European Schooling Helsinki (ESH) opened in September 2008 to provide education for the children of ECHA staff, following the enactment of the ESH Act on 1 January 2008. The ESH is maintained by the State of Finland and it annually concludes an attainment contract with the Finnish National Board of Education. It is organised on the basis of the educational structure of the European Schools, providing education based on the syllabi of the European Schools. It is an Accredited European School and is administered and funded by the Finnish Government, which receives EU subsidies^[1], and own revenues generated through certain fees. The Act provides that the children of ECHA staff (Category I pupils) have an entitlement to enrolment at ESH. In 2009, an amendment to the Act on European Schooling Helsinki was adopted to facilitate admission of Category II (non-ECHA) pupils to the School. Category II pupils may apply for enrolment in the ESH since 2010 and, presently, approximately 41 % of the pupils are of category II.

Administration

The School is managed by a Director and an Administrative Board (consisting of a chair, a vice-chair and a maximum of 8 members), which is appointed for a term of 4 years. Although being the main stakeholder of the ESH, ECHA has only one vote on the Administrative Board.

The School has three language sections – Finnish, French and English – and education is divided into a 2-year nursery cycle (Years NI-N2); a 5-year primary cycle (Years P1-P5) and a 7-year secondary cycle (Years S1-S7). The student numbers for ECHA related children for the school year 2016-2017 are the following: nursery: 16, primary: 82 and secondary: 65. The total number of ECHA related children is therefore 163, and it is envisaged that this number remains relatively stable within the next years.

Accreditation

The ESH is linked to the European Schools system through an Accreditation and Cooperation Agreement, which was initially signed on 20 January 2009. Following an audit of ESH, conducted in December 2010, the Secretary General, representing the Board of Governors of the European Schools, signed an Additional Agreement to the Accreditation and Cooperation Agreement on 26 May 2011, recognising the European schooling provided by European Schooling Helsinki for secondary years 6 and 7 and the European Baccalaureate. The School has offered the European Baccalaureate for the first time in 2013.

^[1] Note: As of 01 July 2011, based on the EU Contribution Agreement entered into with the European Commission, Finland received financial contributions from the EU budget based on the number of Category I children enrolled in the ESH in the given year. This system was amended in 2013 with the consequence that for the school year 2016/2017, ECHA has to pay the subsidy out of its own budget, which amounts to €1.2 Million.

The ESH joined the network of Accredited European Schools in 2011. ECHA participates in the meetings of the network together with other EU Agencies in order to exchange best practices and to further strengthen the provision of European Schooling, which is essential for staff recruitment and retention.

Issues

The availability of a high quality of education in Helsinki is a critical attraction and retention factor for ECHA and, in this respect, the ESH is a key stakeholder for ECHA. There is a clear requirement for the School's budget – and, specifically, the subsidy from the Finnish state - to be maintained at a sufficient level to continue to ensure the provision of a high quality of education at the School. ECHA will, through its presence on the Administrative Board and interactions with other stakeholders, continue to represent the interests of ECHA staff on this issue.

ECHA co-chairs the Sub-Network of EU Agencies on Accredited European Schools (SNAES) within the Network of the Heads of Administration to ensure coordination and mutual support among Agencies on this important topic.

Annex V: Buildings

Current building(s)

	Name, location and type of building	Other Comment
<i>Information to be provided per building:</i>	Annankatu 18 (AK18) Lönrotinkatu 12 (LK) Bulevardi (BL)	
Surface area (in square metres) - Of which office space - Of which non-office space	24 809 m ² 15 823 m ² 8 986 m ²	
Annual rent (in EUR)	7 561 566 €	<i>While the actual rent payable 2017 is €6 060 294, the annual depreciation of the conference centre renovations is €1 501 272 per annum. The total annual rental cost of the building is, therefore, €7 561 566.</i>
Type and duration of rental contract	<i>Lease contract until 31.12.2019 (with a purchase option until 30.06.2019)</i>	
Host country grant or support	<i>No</i>	
Present value of the building	<i>building/A</i>	

Building projects in planning phase

As the current lease contract of ECHA's office building expires on 31 December 2019, a negotiated procedure took place in 2017 to identify its future building. The submission of the proposal on ECHA's future building to the Budgetary Authority has taken place at the beginning of Q4 2017 as planned. There may be a requirement in 2019 for some additional financing for the transition to ECHA's future building.

Building projects to be submitted to the European Parliament and the Council

The submission of a proposal on its future building to the Budgetary Authority took place in Q4 2017.

Annex VI: Privileges and immunities

The privileges and immunities of staff and the Agency are contained in the respective Protocol to the EU Treaty. Moreover, further effect is given by the Seat Agreement signed between Finland and ECHA on 28 June 2007.

Agency privileges	Privileges granted to staff	
	Protocol of privileges and immunities / diplomatic status	Education / day care
Inviolability	Immunity from jurisdiction regarding official capacity	Same access to day-care organised by municipalities as Finnish nationals
Facilitations for Communications	Exemption from registration requirements Duty free import of goods upon taking up services Reimbursement of VAT between 1 June 2007 and 31 May 2009 (no longer in place)	Access to Finnish school system

	<p>Right to free export when leaving the service</p> <p>Exemption from taxes on EU salaries</p> <p>Exemption from national car tax once every three years</p> <p>Executive Director and Directors join diplomatic status</p> <p>Temporary residence permits to family members who are not EU / EEA nationals</p> <p>Issuance of personal cards through the Foreign Ministry</p> <p>Issuance of Finnish identity numbers</p>	
Assistance and Cooperation in Security Matters		Access to European Schooling through the European Schooling Helsinki
Exemption from all duties and taxes		

Annex VII: Evaluations

In 2015 ECHA established its evaluations approach, after benchmarking with other agencies and analysing its current initiatives and projects. The aim of the approach is to build upon existing information and methods in order to ensure effective and efficient use of ECHA's resources. The ultimate goal is to improve ECHA's operations through better decision-making and learning from past decisions. The evaluations and the implementation of the findings should help ECHA in optimally investing in those activities, projects and programmes that help to achieve our corporate objectives.

The framework for ex-ante and ex-post post evaluations was agreed to be built upon the existing Prince2 methodology by strengthening the existing project/programme governance framework for ex-post and ex-ante evaluations. Thus, the Prince2 methodology was expanded to ensure that the 5 key evaluation criteria are covered and there is an emphasis on cost-benefit analysis.

The first multi-annual and annual rolling evaluation plan was drafted and a number of ex-ante and ex-post evaluations performed (details of those are reported to the Management Board Working Group on Audit and in the Consolidated Annual Activity Report of the Authorising Officer).

An Evaluation coordination function (ECF) was established to ensure the methodological quality and consistency when implementing the rolling plan and to coordinate the reporting obligations of the Authorising Officer. The ECF supported by ad-hoc working groups (WGs) on the individual evaluations was actively participating in performing or assisting the performance of the evaluations as planned in the rolling plan.

The Draft multi-annual rolling evaluation plan as presented to the Management Board Working Group on Audit on 20 June 2017 is below:

Year	Evaluation	Indicative scope	Who	Details
2017	Perform an ex post evaluation of ECHA Efficiency Programme	<ul style="list-style-type: none"> Evaluate the coverage of the 5 criteria including the benefits of the programme vs its cumulative cost 	ECF and WG	<ul style="list-style-type: none"> On-going evaluation, to be finalised by the end of June 2017
2017	In line with the renewed IT Governance, the new project vision template incorporating the ex-ante evaluation criteria will be applied	<ul style="list-style-type: none"> This will ensure that relevant projects budgeted at/above 1 million are subject to the ex-ante evaluation. 	ECF and Dir I	<ul style="list-style-type: none"> Template updated in Q2/2017, to become official as of Q3/2017; evaluations page created on ECHANet; support provided upon request; further communication foreseen for product/project managers

2017	Perform an ex ante evaluation of the outsourcing of the data centre	<ul style="list-style-type: none"> This will ensure that relevant projects budgeted at/above 1 million are subject to the ex-ante evaluation. 	ECF and Dir I	<ul style="list-style-type: none"> Ex-ante evaluation performed already in Q2/2017 (instead of 2018 as initially foreseen); results presented to the MBWG on audit on 20 June
2017/2018	Perform an ex-post evaluation of BPR related tools	<ul style="list-style-type: none"> Evaluate the coverage of the 5 criteria including the benefits of the programme vs its cumulative cost 	ECF and WG	<ul style="list-style-type: none"> Procurement for an external consultant to start in Q3/2017 and evaluation to be performed in the first half of 2018
2018/2019	Perform an ex-post evaluation of REACH- IT 3.0 & 3.1. and 3.2.	<ul style="list-style-type: none"> Evaluate the coverage of the 5 criteria with own resources or via outsourcing (roll-out in 2018) 	ECF and WG	<ul style="list-style-type: none"> Start the evaluation after the registration deadline of 31/05/18 to ensure it adds most value to decision-making. Procurement for an external consultant in 2018. Evaluation to be performed in 2019.
2018/2019	Perform an ex-post evaluation of Cloud Services	<ul style="list-style-type: none"> Evaluate the coverage of the 5 criteria including the benefits of the programme vs its cumulative cost 	ECF and WG	<ul style="list-style-type: none"> Planned for the end of 2018 or the first half of 2019

Annex VIII: Risks 2018

ECHA conducts an annual risk management exercise aligned to the planning cycle of the Work Programmes. The aim is to identify, assess and manage the potential events that could put the achievement of objectives defined in the Work Programme 2018 (WP 2018) at risk. As a result of this exercise a number of risks were identified, assessed and considered in the preparation of the WP 2018.

ECHA's management identified 21 risks, out of which 13 were proposed for risk assessment. As a result of the consolidated risk assessment, 7 corporate risks with high to medium likelihood and impact were proposed for the Corporate Risk Register 2018.

All identified risks were nevertheless taken into account when drafting the objectives of the WP 2018. The impact of the Brexit on ECHA's financial income and IT tools was also assessed, however as it is more relevant for WP 2019, it was not included in the Risk Register 2018.

For the 7 corporate risks in Risk Register 2018, risk responses have been chosen taking into account the existing controls and measures already taken. A response "Avoid" has been chosen for the risk with the highest potential likelihood and impact on the WP 2018, thus relevant WP objectives will be changed and presented only conditionally, subject to resource availability. The selected risk response for 3 of the risks is 'Reduce'. For these risks action plans are detailed in the table below, aiming to reduce either the risk likelihood or the impact on the WP 2018 implementation, should those risks occur. Risk response "Share" has been selected for 1 risk, due to the shared objectives with MSCA and the need to address the risk via joint efforts and actions. The risk response for 2 of the risks is "Accept", meaning that after the assessment of the existing controls, ECHA's management considers that the risk predominantly depends on external factors beyond the Agency's control.

The risks evolution and the effectiveness of the measures chosen will be closely monitored throughout the year.

More details on the risks and action plans are available in the table below:

ECHA CORPORATE RISK REGISTER 2018										
RISK IDENTIFICATION					RISK ASSESSMENT		RISK RESPONSE AND TREATMENT			
Activity affected	SPD Objective affected	Risk cause	Risk description	Risk consequence	Risk type	Risk level	Risk Response	Proposed Actions		
								Description	Owner	Deadline
1.3 Bicides	All Bicides processes	Lower than foreseen BPR applications for Union authorisation and active substances - linked to the difficulty to know accurately more than few months ahead the applications that will be made.	Insufficient fee income to balance the budget, resulting in the need to reduce significantly the non-mandatory expenditures. (Insufficient financial resources combined with rigidity to adjust the EU balancing subsidy). For 2018, the risk likelihood is high in view of the specific information provided by MSCAs in summer 2017 regarding the UA applications scheduled for this year.	Direct negative impact on the ability to deliver the work programme for operational BPR related activities.	1. EXTERNAL ENVIRONMENT	HIGH	Reduce	Request increased subsidy to Commission in order to balance the budget. In case this request is not rewarded prioritise key activities (i.e. Active Substances, Union authorisations, technical equivalence, IT product management, support to the Coordination Group, support to Article 75(1)(g) and Article 36 opinion forming). This could lead in particular to significant reduction in the development of guidance and other output. If the fee income is severely reduced and this reduction is not compensated by increased subsidy, this would even lead to the need to freeze key activities.	DI	continuous
2.3 Resources	All objectives affected / All output related to new initiatives	Absorbing new tasks (endocrine disruptors, POPs, poison centres, legislation finder etc) without relevant resources allocated to them (ECHA will not receive the additional resources needed for incorporation of new initiatives)	Risk of: i) not meeting the 2018 objectives/deprioritising goals as existing resources are spread thin across increased number of initiatives; ii) not being able to develop the one-stop notification portal for the notifications to the poison centres; iii) an increased administrative burden from the need to run the activities with existing resources and provide financial & HR reporting to the Commission on individual tasks	Deliveries will be delayed or not achieved and more pressure exerted to staff (either in the implementation of the new initiatives or in existing services and projects); Delays and slowdown in the provision on key financial/HR/IT services relevant for the operations of the Agency	1. EXTERNAL ENVIRONMENT	HIGH	Avoid	Objectives will be changed to avoid the risk. Scenario planning will be used in WP 2018 - the objectives related to the new activities will be presented only conditionally, e.g. in case there are resources available for those.	Dir B	continuous
1.3 Bicides	All Bicides processes	4 less posts approved for managing the Bicides processes for 2018	Lack of adequate resources to cope with the increased workload in all Bicides processes (especially in new processes, such as Union authorisations, where more time will be needed for proper process set-up)	Direct negative impact on output/quality	3. PEOPLE AND ORGANISATION	MEDIUM	Reduce	Prioritise key activities (i.e. Active Substances, Union authorisations, technical equivalence, IT product management, support to the Coordination Group, support to Article 75(1)(g) and Article 36 opinion forming). This could lead in particular to significant reduction in the development of guidance and other output.	DI	continuous
1.1 REACH dossier management and assessment	Manage successfully the registration deadline of 31 May 2018	Due to uncertainty of the estimations for incoming registrations and data sharing related processes (i.e. too high or too low number of disputes to be handled, too many companies registering or SMEs not registering due to high cost of registrations) and overall budgetary constraints	2 scenarios: i) Lower number of dossiers submitted/substances registered and thus lower income for ECHA; ii) Higher number of dossiers and thus insufficient resources to process them, the inquiries and data sharing disputes and implement the WP (i.e. late deployment of resources for DL 2018 and not enough time to increase the capacity and knowledge)	Scenario i) Negative impact on ECHA's WP implementation due to lower income, financial risk; ii) Negative impact of ECHA's WP implementation due to large redeployment of resources for DL management, iii) Delayed processing times causing challenges for the registrants to fulfil their registration obligations if no sufficient support can be given, not meeting the set REACH timelines; iv) possible market disruption affecting ECHA reputation, Commission and MS	1. EXTERNAL ENVIRONMENT	MEDIUM	Reduce	Scenario i) (too low number of dossiers): - recruitment strategy including decisions for recruiting additional interim staff based on monitoring of incoming dossiers. - identify tasks that can be anticipated if numbers are low for a while. - stop recruiting and potentially terminate contracts earlier than planned if numbers remain low Scenario ii) (too high number of dossiers): - Flexible redeployment from staff previously identified and trained that can be onboarded quickly if needed. - Contingency task force to identify tasks that can be minimised, dropped or postponed if numbers increase unexpectedly. Decisions to be made based on triggers that are continuously monitored.	CI	June
2.3 Resources	All objectives affected	Unknown industry intentions concerning REACH registrations and authorisations	Fee income does not materialise to the extent foreseen (Insufficient financial resources combined with rigidity to adjust the EU balancing subsidy)	Hampers the implementation of ECHA's Work Programme	1. EXTERNAL ENVIRONMENT	MEDIUM	Accept	i) Constant monitoring of the dossier pipeline and incoming payments vis-a-vis the budgeted income. Regular reporting to the senior management. ii) Involving the relevant Commission services in case of notable deviations.	Dir R	continuous
1.3 Bicides	Achievement of Review Programme target (i.e. 50 opinions per year)	Due to resource issues in the Member States	i) The Review programme targets may not be met in due time and/or quality; ii) The MSCAs may not be able to deliver the expected quantity of good quality evaluation reports	Direct negative impact on output. Future income of ECHA negatively impacted	1. EXTERNAL ENVIRONMENT	MEDIUM	Share	i) Involve the Commission in the review of the Programme ii) Further exchange solutions with the MSCAs on their resources needs and the potential efficiencies to be gained in their processes.	DI	continuous
1.1 REACH dossier management and assessment	ECHA identifies and addresses in an efficient manner, non-compliant registrations and prepares their IUCLID dossiers directly online " NOTE: variation from the 2017 Risk register.	Addressing groups and categories requires more time for scientific assessment; collaborative approach with MSCAs and registrants leads to high workload and delays; lack of resources and available expertise as other priorities may compete from the same expert resources.	Significantly lower than planned number of COH and TP (draft) decisions issued in 2018	Reputational risk: delays in getting the data necessary for identification of substances of concern	3. PEOPLE AND ORGANISATION	MEDIUM	Reduce	i) Internal specific monitoring of the work on categories and groups, including a forecast for formal dossier evaluation outputs; ii) Regular communication to the MB/G and MB regarding progress made in addressing groups and categories under dossier evaluation and regarding any risks of WP targets not being met for 2018 and, where relevant, providing a forecast of related outputs (COH/TP decisions and conclusions) in 2019-2020; iii) Identification of further efficiency improvements in the dossier evaluation processes and structures.	Dir E	continuous
1.1 REACH dossier management and assessment 2.3.4 ICT	"Provide cloud services to SMEs to enable them to manage their data and prepare their IUCLID dossiers directly online " NOTE: variation from the 2017 Risk register.	Due to later than expected release of the Cloud Services and providing a new type of complex service without prior experience,	Companies may be reluctant to switch for a new type of IUCLID delivery model	i) SMEs would not be able to benefit from the simplification planned in the Cloud Service during their preparation for the 2018 deadline; ii) Lack of return on investment that may jeopardise the strategy to switch all industry services to this type of delivery model	2. PLANNING PROCESSES AND SYSTEMS	MEDIUM	Accept	Further promote the service by keeping a constant positive information flow toward SME users, strengthened by the release of the ECHA Cloud for SMEs service in July that will allow to create registration dossiers for the REACH 2018 deadline, in a web browser.	Dir I	continuous

Annex IX: Procurement plan 2018

Contract subject	Estimated budget (€)	Budget line	Procurement channel	Foreseen launch	Foreseen signature
Services to support SID (Substance Identity) assessment and general SID activities	20 000	3003	FWC ECHA/2015/50.Lot 2	Q3	Q4
Scientific services addressing needs coming from operational work related to dossier evaluation	25 000	3004	FWC ECHA/2015/50 or low-value negotiated procedure	Q2/Q3	Q3/Q4
Services on validation of the final formats and tools with some real life cases (Poison centres)	20 000	3006	FWC ECHA 2015/50.Lot 1	Q3	Q4
Data management, text analytics and data screening services	250 000	3008	FWC ECHA/2017/10	Q1	Q1/Q2

Consulting services on Application for Authorisation	70 000	3005	FWC ECHA/2015/50/Lot 1	Q2	Q3
Consulting services to prepare Annex XV restrictions dossiers	100 000	3005	FWC ECHA/2015/50/Lot 1	Q2/Q3	Q3/Q4
Consulting services related to substitutions	30 000	3005	FWC ECHA/2016/130	Q2	Q3
Consulting services on SEA (socio-economic activities)	100 000	3005	FWC ECHA/2015/256 and FWC ECHA/2015/50/Lot 1	Q3	Q4
Consultings services on horizontal risk management activities	50 000	3005	FWC ECHA/2015/50/Lot 1	Q3	Q4
Consulting services for OSH (occupational health and safety) work	60 000	3005	FWC ECHA/2015/50/Lot 1	Q3	Q4

Several contracts for PROGRAMME Application Delivery Service Management & Release Management: application management and automation for IT applications	986 000	3008, 4008, 5008	FWC86, FWC103, FWC321, FWC333, FWC10, FWC09, DG DIGIT FWCs	Q4-2017-Q4-2018	Q1-Q4
Several contracts for PROGRAMME Application Delivery Service Management & Release Management: network services and outsourced managed services	896 000	3008, 4008, 5008	FWC86, FWC95N, FWC103, FWC321, FWC10, FWC09, FWC400	Q4-2017-Q4-2018	Q1-Q4
Several contracts for IT Service: SECURITY: SON meetings, security costs	155 010	3008, 4008, 5008	FWC for catering, FWC for travel services, FWC333, FWC09	Q2-Q3	Q3-Q4
Several contracts for PROGRAMME DATA MANAGEMENT: Dissemination, Data Integration Platform, Business Objects, Enterprise Data Modelling, Deficiencies and Concerns, Classlab and Master Data Management Platform, Reporting	1 631 000	3008, 4008	FWC86, FWC10	Q4-2017-Q2-2018	Q1-Q3

Several contracts for PROGRAMME ECM & ECHA Interacts: Dynamic Case and Records Management, Portal dashboard, ECHA Interact, Odyssey, Benefit realisation management, licences	2 450 000	3008, 4008, 5008	FWC86, FWC321, FWC103, FWC09, DG DIGIT FWCs	Q4-2017-Q4-2018	Q1-Q4
Several contracts for PROGRAMME ECM & ECHA Interacts: CIRCA-BC	118 503	3008, 4008, 5008	DG DIGIT MoU	Q4-2017-Q1-2018	Q1
Several contracts for Enterprise architecture: Studies for Ent. Architecture	98 000	3 008	DG DIGIT FWC, HANSEL	Q1-Q4	Q1-Q4
Several contracts for Programme IT Tools for Industry: Chesar, REACH-IT, IUCLID, ECHA CS, R4BP, ePIC, IDM, Poison Centres	1 747 000	3008, 4008, 5008	FWC103, FWC333, FWC09	Q4-2017-Q4-2018	Q1-Q4
Several contracts for IT Service: Testing: consultancy, Software as Service	831 000	3008, 4008	DG DIGIT, HANSEL	Q4-2017-Q3-2018	Q1-Q4
Several contracts for PROGRAMME ICT Helpdesk: IAM and interims	189 000	3008, 4008, 5008	DG DIGIT FWC, FWC for interims	Q4-2017-Q3-2018	Q1-Q4
Several contracts for PROGRAMME iTex Service Desk: ECHA Service desk, interim services and software	1 161 000	3008, 4008, 5008	FWC103, FWC333, FWC for interims, DG DIGIT FWC	Q4-2017-Q2-2018	Q1-Q3

Several contracts for PROGRAMME MIS: Remedy services, licences and maintenance	185 000	3008, 4008, 5008	DG DIGIT FWC	Q4-2017-Q2-2018	Q1-Q3
Several contracts for PROGRAMME ICT Procurement: interim services, programme management services, maintenance of software and hardware	1 094 000	3008, 4008, 5008	FWC86, FWC103, FWC333, DG DIGIT FWCs, FWC for interims	Q4-2017-Q4-2018	Q1-Q4
Several contracts for handover and takeover services	53 000	4008, 5008	FWC103, FWC95N, FWC09, FWC400	Q3-Q4	Q3-Q4
Framework contract on developing a pre-clinical/ clinical information database from the <i>Drugs@FDA</i> website for conducting toxicological correlation analyses for specific endpoints	500 000	3009	Open procedure	Q1-Q2	Q3-Q4
Scientific projects including Nano materials development of test methods	50 000	3009	FWC ECHA/2015/50/Lot 1 and low-value negotiated procedure	Q1/Q2	Q2/Q3
New framework contracts on Development of NAM (New Approach Method) approaches in a regulatory context and Data development for alternative methods	200 000	3009	Negotiated procedures with at least five candidates. FR 104/RAP 136(a)	Q1/Q2	Q2/Q3

Orders for printing and design services	36 000	3013	FWC ECHA/2016/30	Q1 - Q4	Q1-Q4
Services for Website development and maintenance	232 000	3013, 4013	FWC ECHA/2014/110	Q1	Q1
BIOCIDES dissemination website	78 500	4013	FWC 110. lot 1	Q1/Q2	Q2
Media and social media monitoring services	103 000	3013	FWC ECHA/2016/53	Q2	Q3
REACH 2018 deadline communications	20 000	3013	Negotiated procedure with at least three candidates. FR 104/RAP 137(1)	Q1	Q2
Refresh of ECHA Corporate and visual identity	130 000	3013	Negotiated procedures with at least five candidates. FR 104/RAP 136(a)	Q3	Q4
Project on capacity building	30 000	3014	Low-value negotiated procedure or FWC ECHA/2015/50/Lot 1	Q3	Q4
Restructuring of ECHA data curation project	30 000	3801	FWC ECHA/2016/71	Q3	Q3
Development and maintenance in 2016 of EChem Portal (the Global	200 000	3801	FWC ECHA/2014/86	Q3	Q4

Portal to Information on Chemical Substances)					
IUCLID Template Manager, provider agent, data extractor (ITEM)	200 000	3801	FWC ECHA/2011/103.Lot 3	Q1	Q1/Q2
General services for QSAR toolbox	250 000	3801	FWC ECHA/2013/109	Q2	Q3
Additional QSAR toolbox services, including progressive maintenance in 2018	150 000	3801	Amendment to FWC 109 (Article 114a(3) (d) FR)	Q4 2018	Q2 2019
Legal and court case, ad-hoc legal advice (several contracts)	350 000	3022	Exceptional negotiated procedure under Art 134.1.h RAP or low-value negotiated procedures	Q1-Q4	Q1-Q4
Advice on IPR	107 000	3022	FWC of JRC	Q1-Q4	Q1-Q4
Strategic policy stakeholder interaction (studies and events)	90 000	3022	Negotiated procedures with at least one/three/five candidates. FR 104	Q2/Q3	Q3/Q4

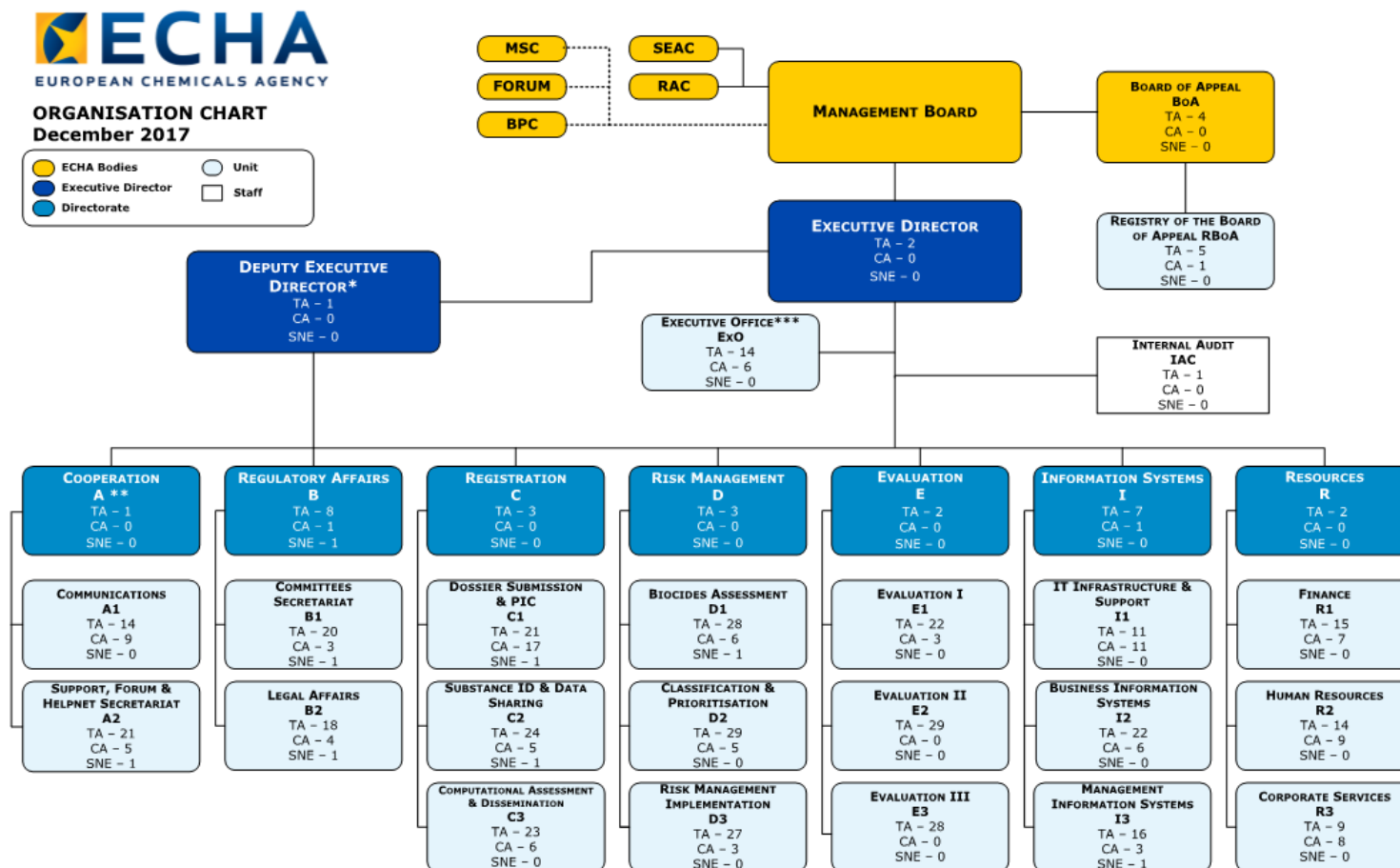
Certification ISO 9001: follow-up audit. Certification ISO 14001: follow-up audit , other quality related costs	17 000	3022, 4022	FWC ECHA/2013/483	Q1	Q2
Ex-post evaluation of the Portal Dashboard	25 000	3022, 4022	Negotiated procedure with at least three candidates. FR 104/RAP 137(1)	Q1	Q2
Ex-post evaluation of the R4BP IT-tool	25 000	4022	Negotiated procedure with at least three candidates. FR 104/RAP 137(1)	Q1	Q2
Streamlining of processes under efficiency programme (tools, assessments, analysis, audits, etc. based on assessed needs)	90 000	3022	HANSEL or negotiated procedures with at least five candidates. FR 104/RAP 136 (a)	Q2	Q3
FWC for IT services for IT solutions for industry under REACH	1 290 000 ⁶⁵	3008	Open procedure (FWC for 4 years, value 14 200 000 ⁶⁵)	Q1	Q3
Library expenditure (scientific databases, books, journals)	317 200	3022,04022	HANSEL, low-value and exceptional procedures	Q1-Q4	Q1-Q4
Operational missions	719 730	3030, 4030, 5030	Customer Specific Agreement for travel services – ECHA/2016/401 (HANSEL)	Q1-Q4	Q1-Q4

⁶⁵ Figure as determined by the Agency on 13 December 2017.

TOTAL SUM:	17 559 943 ⁶⁶		The Plan includes operational procurement of ECHA in 2018 ≥15000 €		
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⁶⁶ Figure confirmed after the update of 13 December 2017 – see previous footnote.

Annex X : Organisation chart 2018



* Exercising also the function of Director of Regulatory Affairs

** Exercising also the function of SME Ambassador

*** The Quality Manager forms part of the Executive Office

Annex XI : IT resources

IT tool	Main description	Activities served by tool	Main users
IUCLID	<p>Main tool for technical dossier preparation for Industry in REACH, CLP and BPR.</p> <p>Used as the central database of dossiers for the regulatory work of ECHA and for the work of national Competent Authorities in REACH, CLP and BPR.</p> <p>Tool for preparation of applications for authorisation.</p> <p>Tool for preparation of dossiers submitted by MSCAs e.g. in the substance evaluation process</p>	<p>1.1.1 Registration dossier preparation;</p> <p>1.1.2 Registration and dossier submission;</p> <p>1.1.3 Evaluation;</p> <p>1.2.1 Identifying needs for Regulatory Risk Management;</p> <p>1.2.2 Authorisation;</p> <p>1.2.3 Restrictions;</p> <p>1.2.4 Classification and Labelling;</p> <p>1.3 Biocides</p>	<p>Industry</p> <p>ECHA</p> <p>MSCAs</p>
ECHA Services SMEs	<p>Cloud for</p> <p>ECHA hosted company specific IUCLID instances accessible on the web and operated by ECHA</p>	<p>1.1.1 Registration dossier preparation;</p>	<p>Industry (SMEs)</p>
CHESAR	<p>Supports registrants to carry out their safety assessments in a structured manner, prepare their chemical safety reports (CSRs) and generate their exposure scenarios for communication in the supply chain.</p>	<p>1.1.1 Registration dossier preparation;</p> <p>1.1.4 Communication of risk management advice through the supply chain</p>	<p>Industry</p>

IT tool	Main description	Activities served by tool	Main users
QSAR Toolbox	<p>Software application intended to be used by OECD member states, chemical industry and other stakeholders in filling gaps in data needed for assessing the hazards of chemicals.</p> <p>Submission tool for REACH and CLP, as well as for automated processing of submissions in order to grant a registration decision, once technical completeness and other relevant rules are met.</p> <p>The tool for inquiry submission and processing.</p> <p>Invoicing tool for fee based submissions.</p> <p>It offers a secure communication inbox used for all communication with registrants, used also by non-submission regulatory processes (e.g. communication of evaluation decisions).</p> <p>Submission tool for the applications for authorisation.</p>	<p>1.1.1 Registration dossier preparation</p> <p>1.2.1 Prioritisation</p> <p>1.1.3 Evaluation</p> <p>7.1.1 Promotion of alternative methods</p>	<p>Industry</p> <p>Industry ECHA MSCAs</p>
REACH-IT		<p>1.1.1 Registration dossier preparation;</p> <p>1.1.2 Registration and dossier submission;</p> <p>1.2.2 Authorisation</p>	<p>Industry</p>
UFI generator for Poison Centre and Product Composition Editor	<p>Tools and formats to generate the standard notifications to national Poison Centres</p>	<p>Article 45 CLP: notification to Poison centres</p>	<p>National Appointed Bodies</p>

IT tool	Main description	Activities served by tool	Main users
Odyssey	<p>Guides the scientific decision making process in dossier evaluation and inquiry processing and ensures consistency & traceability.</p> <p>ECHA's website is the primary communication vehicle of the Agency.</p> <p>It is the fundamental source of information and guidance for :</p> <p>Companies seeking to comply with the legislation on chemicals.</p> <p>Public consultation in the different steps of the Authorisation process, on Restrictions, on CLP and on Biocides.</p> <p>Notifiers and DNAs on PIC and for companies wishing to appeal decisions.</p> <p>Procurement.</p>	<p>1.1.1 Registration dossier preparation;</p> <p>1.1.3 Evaluation</p>	<p>ECHA</p> <p>Industry</p> <p>Industry Associations</p> <p>Media</p> <p>Public</p> <p>MSCAs</p> <p>European Commission</p>
Website	<p>Job vacancies.</p>	<p>All ECHA's activities</p>	
Dynamic Case	<p>Case management tool to support the creation and processing of business cases at the same time providing a repository for the documents generated. It ensures traceability of the process steps also for auditing and other legal aspects (e.g. access to data, appeals).</p>	<p>1.1.2 Registration and dossier submission;</p> <p>1.1.3 Evaluation;</p> <p>1.2.1 Identifying needs for Regulatory Risk Management;</p> <p>1.2.2 Authorisation;</p> <p>1.2.3 Restrictions;</p>	<p>ECHA</p> <p>ECHA Committees members (in progress)</p>

IT tool	Main description	Activities served by tool	Main users
Secure BC	CIRCA- External collaboration tool used to exchange documents with MSCAs.	1.2.4 Classification and Labelling; 1.3 Biocides; 1.5 Data management and dissemination; 2.1.1 Committees; 2.1.2 Forum 2.1.4 Board of Appeal 2.2 Management 2.3.1 Financial resources 1.1.2 Registration and dossier submission; 1.1.3 Evaluation; 1.2.2 Authorisation; 1.2.3 Restrictions; 1.2.4 Classification and Labelling; 1.3 Biocides; 2.1.1 Committees; 2.1.2 Forum; 2.1.3 HelpNet and Security Officers Network;	ECHA ECHA Committees members ECHA MB MSCAs

IT tool	Main description	Activities served by tool	Main users
Reporting	Automated reporting is a key instrument to monitor, manage and inform about submissions, fee income and related data; the status of cases opened for evaluation: it is a crucial tool for the regular reports on evaluation foreseen in the regulations (e.g. Article 117 (2) report).	2.1.4 Board of Appeal; 2.2 Management 1.1.2 Registration and dossier submission; 1.1.3 Evaluation; 1.2.4 Classification and Labelling	ECHA
Business data analysis tools	ECHA develops algorithms and uses powerful dedicated data mining tools to screen the high volume of dossiers submitted and identify candidates for compliance checks according to the compliance checks strategy.	1.1.3 Evaluation; 1.2.1 Identifying needs for Regulatory Risk Management	ECHA MSCAs
Portal Dashboard for MSCAs/ NEAs	Portals for Competent Authorities and Enforcement Authorities under REACH and CLP to access integrated data on chemical substance (scientific data and regulatory data related to registration, risk management, substance evaluation).	1.2.1 Identifying needs for Regulatory Risk Management; 1.2.2 Authorisation; 1.2.3 Restrictions; 1.2.4 Classification and Labelling; 1.5 Data management and dissemination	MSCAs NEAs
Dissemination Portal		1.2.4 Classification and Labelling;	Public

IT tool	Main description	Activities served by tool	Main users
eChemPortal	<p>ECHA stores and integrates data on chemicals which represent one of the largest knowledge bases in the world on scientific and hazardous properties, experimental study data, safe use, risk management measures, classification and labelling. Complex and resource intensive IT support has been developed by ECHA to give facilitated access to the public to such knowledge base.</p> <p>ECHA Dissemination is the main source of data for the OECD public eChemPortal developed and operated by ECHA.</p>	1.5 Data management and dissemination	Industry ECHA MSCAs
R4BP	<p>Used by Industry for submitting applications for product authorisation (at national and EU level) under the Biocidal Products Regulation to ECHA and by ECHA/MSCAs for providing applicants with the related decisions. Used by Industry and ECHA as key IT support in the review programme. Invoicing tool. Platform for secure communication amongst parties. R4BP represents the implementation of the register for Biocidal products foreseen in the legislation.</p>	1.3 Biocides	
SPC Editor	<p>Tool for Industry and MSCAs to process the Summary of Product Characteristics (SPC) as foreseen in the BPR</p>	1.3 Biocides	Industry MSCAs

IT tool	Main description	Activities served by tool	Main users
ePIC	<p>Web application used by Industry for submitting PIC notifications to ECHA.</p> <p>Central IT tool for all the actors involved in PIC: Industry, ECHA, Designated National Authorities, Customs, European Commission.</p>	1.4 PIC	<p>Industry</p> <p>ECHA</p> <p>DNAs</p>
<p>MSCAs IUCLID central database for REACH&CLP;</p> <p>MSCAs IUCLID central database for Biocides</p>	<p>Two large central databases of scientific data in IUCLID format opening direct access and full IUCLID functionalities to MSCAs.</p>	1.5 Data management and dissemination	<p>MSCAs</p> <p>ECHA</p>
Data Integration Business Intelligence Platform	<p>The Data Integration Platform is the data management system to provide data integration and aggregation, business intelligence and reporting on business data;</p> <p>It provides integrated data to consuming systems, notably the Dissemination Portal, the Portal dashboard for MSCAs and Enforcement Authorities, Dynamic Case, and REACH-IT (web service).</p> <p>It enables the re-use of data without duplication, advanced searches, data intelligence; capabilities which make the data usable and meaningful for consumption.</p>	1.5 Data management and dissemination	ECHA

IT tool	Main description	Activities served by tool	Main users
Annex VI database	Tool for managing harmonised classification reference data	CLP	ECHA MSCAs
CRT	Tool for generating substance structure	1.1.2 Registration and dossier submission; 1.1.3 Evaluation;	ECHA
COMA	Contact Management tool used to manage lists of contacts (as Management Board or Committees members, experts listed by expertise, legal contacts, etc.), to search and sort data.	2.1.1 Committees; 2.1.2 Forum; 2.1.3 HelpNet and Security Officers Network; 2.2 Management	ECHA
ECM - Records Management system	System capable of storing and managing ECHA records according to ECHA filing plan, information security rules, retention rules, etc. making records immutable.	2.2 Management	ECHA
ECHANet	Intranet of ECHA – the Agency’s primary internal communication and collaboration tool.	2.2 Management	ECHA
ECM-Document Management System	Platform used by ECHA’s personnel to store and collaborate on documents applying the internal policies and procedures on management of documents and records	2.2 Management	ECHA

IT tool	Main description	Activities served by tool	Main users
	and on classification and handling of information.		
Mail registry	Supports the mail registry function	2.2 Management	ECHA
Declarations of Interest management tool	Tool used to declare, and search Declarations of Interests by all ECHA's personnel. Used in the Conflict of Interests checks in all processes.	2.2 Management	ECHA
Access to ABAC	Budget, Accounting and Asset management system provided by the European Commission.	2.3.1 Financial resources	ECHA
EasySign	Electronic workflow supporting some financial workflows.	2.3.1 Financial resources	ECHA
PMR, Time Tracking Tool, Budget Tool	Tools used in the planning and reporting tasks	2.2 Management	ECHA
Integrated Human Resource Management System (HRMS)	Supports the HR processes: Personnel and Payroll Administration, HR Financial management, Staff planning & reporting, Time management (and related time clocking devices), Recruitment, Performance & Career management, Training.	2.3.2 Human resources	ECHA
IMS	IT tool for Integrated Quality Management	2.2 Management	ECHA

IT tool	Main description	Activities served by tool		Main users
Mission management tool	Tool used to create mission orders and process mission claims and reimbursements.	2.3.2 resources;	Human	ECHA
		2.3.3 services	Corporate	ECHA
Event Logistics Management	Tool used to manage the logistic part of events	2.3.3 services	Corporate	ECHA Events participants
Webex	A platform for videoconferencing.	2.3.3 services	Corporate	ECHA All stakeholders
Integrated Access Management	IT service based on a bespoke IT solution to manage access to IT systems for internal and external users	All ECHA's activities		ECHA
Remedy Ticketing system and its customisation Helpex	IT service management tool in which the enquiries, service requests and incidents are stored for processing and a database for regular reporting on the service level of the ECHA Helpdesk and other ECHA services.	2.1.3 HelpNet	Corporate	ECHA National helpdesks
		2.3.3 services		
		2.3.4 ICT		
Application Delivery and Service Management Tool-chain	Bespoke tool suite used to support the build and deploy tasks in the application management of ECHA's IT tools	2.3.4 ICT		ECHA

Annex XII: 2018 Registration deadline scenarios

Baseline scenario

The last of the REACH registration deadline in 31 May 2018 will produce the largest amount of registrations. The current working estimation foresees 60 000 registrations submitted to ECHA in 2018 (covering 25 000 substances). This figure is derived from the estimations drawn up by the European Commission in 2006, which were based on extensive surveys performed for the impact assessment of REACH. ECHA modified the original Commission estimations to reflect a lower number of registrations for intermediates, in line with what we have observed in 2010 and 2013. Otherwise, the figures derived from that work proved to be a good forecast for the registration deadlines in 2010 and 2013.

Table 1 shows the detailed breakdown behind this estimation, as well as the forecasted fee income.

Table 1. 2018 registration assumptions and fee income

	Number of dossiers
Initial phase-in	
1-10 tonnes	32 570
10-100 tonnes	8 055
100-1000 tonnes	560
>1000 tonnes	470
Intermediates	10 323
All initial phase-in	51 978
Initial non phase-in	
1-10 tonnes	222
10-100 tonnes	50
100-1000 tonnes	61
>1000 tonnes	57
Intermediates	225
All initial non phase-in	615
Updates	
All updates	7 169
PPORDs	
All PPORDs	425
Total dossiers	
All submissions	60 187
Modelled Fee Income	
Total registration	68 513 973 €

Under registration activities, dossiers attracting fees are the registration dossiers and the PPORD notifications. As regards registration dossiers, they can be either initial dossiers that are submitted in any of the tonnage band (either for the 2018 deadline, or for substances registered in high volumes reflecting market dynamics and portfolio changes), and updates of existing dossiers to a higher tonnage band. In both cases, registrants may claim certain information confidential, which generates an additional fee. Forecasting of the registration fee income additionally requires the estimation of a number of parameters. Table 2 shows the values of those additional assumptions used for forecasting the registration fee in 2018.

Table 2. Assumptions used for fee 2018 income forecasting

SME	40%
1-10 t registrations with fee waiver	50%
Registrations within a joint submission	80%
Registration updates attracting a fee	10%
Average fee for registration updates	7 832
Initial registrations attracting a confidentiality claim fee	1.3%
Average confidentiality fee for initial registrations	2 263

The parameters used in Table 2 are briefly explained here below:

- SME: percentage of registrations submitted by micro, small or medium-sized companies.
- 1-10 t registration with a fee waiver: percentage of registrations where the fee is waived by the company under certain conditions (only for registrations in the range 1-10 tpa, with full information voluntarily included).
- Registrations within a joint submission: percentage of registrations for which the information is submitted jointly, by a lead registrant on behalf of the rest of companies registering the same substance.
- Registration updates attracting a fee: percentage of all registration updates which generate fee income (increase of tonnage band, new information claimed confidential or update from intermediate to REACH Article 10).

- Initial registrations attracting a confidentiality claim fee: percentage of initial registrations, which include a chargeable claim for confidentiality.

Alternative scenarios

There is a degree of uncertainty on the forecasted number of registrations for 2018 and the related fee income, since it is based on predictions of future behaviour. ECHA had a relatively good insight on the expected number of registrations for the first two deadlines in 2010 and 2013. Companies had submitted dossiers under previous legislation for substances placed on the market, therefore providing the opportunity to extrapolate such information. However, the previous regulation did not foresee data collection for the 1-10 tonne range. Additionally, ECHA has observed a steady flow of registrations for high volume substances -mainly coming from countries outside the European Union- which are low in number but with a significant impact on the fee income. These factors add to the uncertainty on the accuracy of the current estimation for 2018.

ECHA plans to mitigate these uncertainties by increasing its market intelligence throughout 2017:

- Using the leadership of the Directors' Contact Group (DCG) to activate chemical associations.
- Increasing the cooperation with Member States.
- Performing a large-scale survey to contact pre-registrants, together with a specific contract on market segmentation. Preliminary surveys conducted in 2015 and 2016 with major industry players and industry associations revealed that it was too early for industry to provide their real registration intentions for 2018. We intend to approach potential registrants in 2017 to refine the estimate.

Based on the current information, ECHA can draw three alternative scenarios to reflect the main areas of uncertainty and the potential impact to the number of registrations and the related fee income (Table 3).

These alternative scenarios reflect the variation of two single parameters:

- (i) Number of initial registrations affected by the 2018 deadline (1-10 and 10-100 tpa). The baseline estimation is modified by a range of $\pm 25\%$, yielding a lower scenario of 45 000 and a higher scenario of 75 000 registrations. A scenario with 45 000 registrations can be justified given the low response from companies to surveys so far. On the other hand, a scenario with 75 000 registrations is included to take stock of the uncertainties regarding registration of substances in the lowest tonnage (1-10 tpa), as explained earlier in this document.
- (ii) Proportion of registrations submitted by SME companies. The percentage of registrations submitted by SMEs is reduced to 30% to reflect a potential lower level compared to the baseline forecast of 40%.

These two parameters are selected because their uncertainty is high and, at the same time, their variation has a significant impact on the fee income. All the rest of assumptions presented in Table 2 are kept constant when building these alternative scenarios: it is considered that they

either have a lower potential impact on the fee income (e.g. confidentiality claims), or significant variations from the historical trend are not expected (e.g. number of high volume registrations).

Table 3 below shows the detailed breakdown of each of the alternative scenarios and the potential impact on the fee income in 2018.

Table 3. 2018 baseline scenario and alternative scenarios (differences highlighted in green)

2018	Baseline scenario 60 000 dossiers 40% SME	Alternative scenario 1 60 000 dossiers 30% SME	Alternative scenario 2 45 000 dossiers 40% SME (Lowest income)	Alternative scenario 3 75 000 dossiers 30% SME (Highest income)
Number of dossiers				
Initial phase-in				
1-10 tonnes	32 570	32 570	22 570	47 570
10-100 tonnes	8 055	8 055	3 055	8 055
100-1000 tonnes	560	560	560	560
>100 tonnes / R50-53				
>1000 tonnes	470	470	470	470
Intermediates	10 323	10 323	10 323	10 323
Intermediates 2013 deadline	0	0	0	0
Intermediates 2010 deadline				
All initial phase-in	51 978	51 978	36 978	66 978
Initial non phase-in				
1-10 tonnes	222	222	222	222
10-100 tonnes	50	50	50	50
100-1000 tonnes	61	61	61	61
>1000 tonnes	57	57	57	57
Intermediates	225	225	225	225
All initial non phase-in	615	615	615	615
Updates				
All updates	7 169	7 169	7 169	7 169
PPORDs				
All PPORDs	300	300	300	300
Total dossiers				
All submissions	60 062	60 062	45 062	75 062
Modelled Fee Income				
Total registration	68 464 423 €	73 955 582 €	49 318 972 €	82 673 534 €

These alternatives range from a low-income scenario (45 000 dossiers, 40% SME, 49 million euros), to a high-income scenario (75 000 dossiers, 30% SME, 83 million euros). Variations in the number of incoming registrations would not only influence the fee income, but would also have an impact on the workload. It is worth noting that the increase in workload would not be proportional to the increase in fee revenue. Indeed, while the tonnage band and the size of the company influences the fee income, the registration-related workload depends only on the total number of dossiers and it is largely independent from their size.

Our current estimations, revised in 2017 based on real data on time spent on manual verification at completeness check, indicate that we would require approximately 180 additional workforce to handle the peak in workload under the baseline scenario of 60 000 dossiers. This estimation would fluctuate between 150 and 200 additional workforce for the scenario of 45 000 and 75 000 dossiers, respectively.

The majority of the additional workforce will be covered through interim staff. However, there are certain tasks, such as invoicing, which can only be handled by statutory staff and therefore will require a number of short-term Contract Agents, and redeployment of current staff from other activities. Moreover, there is a limit on how many new staff can be accommodated into the organisation, which may also lead to the need to rely more than anticipated on the internal redeployment.

ECHA will use the information gathered through the market intelligence activities explained before to revisit the registration scenarios accordingly. However, feedback from the DCG and Member States is that companies are not willing to reveal their registration intentions, not even at the time of writing this one year ahead of the registration deadline. Therefore, estimates on the number of registrations will remain the biggest uncertainty in the Agency's preparations towards the deadline.